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Appendix A  
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ODA-FG-11-27-84 (CAS RN 112-90-3; Cis-9-Octadecenylamine). Putman, D.L. 1985. Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells. Study No. T2693.337010. Microbiological Associates Inc., Bethesda, MD, USA. ....	A-531
Genamin SH 301 (CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl). Müller, W. 1988. Genamin SH 301 – Study of the Mutagenic Potential in Strains of <i>Salmonella typhimurium</i> (Ames Test) and <i>Escheria coli</i> . Report No. 88.0293. Pharma Research Toxicology and Pathology, Frankfurt, Germany.....	A-534
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Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) Kirby, P.E. 1982. Evaluation of Test Article B0390-01 (MA#T1727) for Mutagenic Potential Employing the L5178Y TK <sup>+/-</sup> Mutagenesis Assay. Report No. T1727.701; for The Procter & Gamble Company, Cincinnati, OH, USA; from Microbiological Associates, Bethesda, MD, USA. ....	A-542
Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine) Coppinger, W.J. 1982. Unscheduled DNA Synthesis Assay in Primary Cultures of Rat Hepatocytes. Report No. YE-532, The Procter & Gamble Company, BTF – Miami Valley Laboratories, Cincinnati, OH, USA. ....	A-545

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Genamin S080 (20% in water + H <sub>3</sub> PO <sub>4</sub> ); Alkylamineethoxylate (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) Haworth, S.R. 1981. <i>Salmonella</i> /Mammalian-Microsome Mutagenesis Assay (Ames Test). Report No. 003-407-637-1; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA. ....	A-549
“TAMET” Benzoate (20% in water) (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) Haworth, S.R. 1981. <i>Salmonella</i> /Mammalian-Microsome Mutagenesis Assay (Ames Test). Report No. 003-468-677-1; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA. ....	A-552
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(POE) <sub>20</sub> Tallowamine (Varonic T-220) ( CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.) Coppinger, W.J. 1983. Unscheduled DNA Synthesis Assay in Primary Cultures of Rat Hepatocytes. Report No. M0021, The Procter & Gamble Company, BTF – Miami Valley Laboratories, Cincinnati, OH, USA. ....	A-565

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- Genamin LA 302 D (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine).  
Stammerger, I. 1999. Genamin LA 302 D. Mammalian Erythrocyte Micronucleus Test in Male and Female NMRI Mice. Report No. 99.0074. Hoechst Marion Roussel Deutschland GmbH, Drug Innovation & Approval, Department of Toxicology/Pathology, Frankfurt, Germany. .... A-568
- Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine,).  
Microbiological Associates, Inc. 1989. Oleylamine: Acute *in vivo* Cytogenetics Assay in Mice (Final Report) with cover letter dated 112789. EPA Doc. No. 40-8984323, Microfiche No. OTS0525407..... A-571
- Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine)  
Esher, H.J. 1982. In vivo Cytogenetics Study in Rats. Unpublished Report No. MRI-I65-PG-82-34; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G/Mason Research Institute, Worcester, MA, USA. .... A-574
- Tallow alkyl amine (CAS RN 61790-33-8).  
Fassio, F. 2000. Micronucleus Test in Rat Bone Marrow Cells Treated by Oral Route. APAG, Istituto di Recherche Biomediche, “Antoine Marxer” RBM S.p.A. .... A-577
- TallowAmine; Ethoxylate (15% TAMET solution with 5% H<sub>3</sub>PO<sub>4</sub> in water) (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Allen, J.A., R.J. Proudlock, K. McCaffrey. 1984. Micronucleus Test on E-2352.01 (ECM BTS 902/01) Tamet. Unpublished Report No. P+G 1114/84560; for Procter and Gamble N.V., Stroombeek-Bever, Belgium; from Huntingdon Research Centre plc, Huntingdon, England. .... A-579
- (POE)<sub>20</sub> Tallowamine (Varonic T-220) (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Esher, H.J. 1982. In vivo Cytogenetics Study in Rats. Unpublished Report No. MRI-182-PG-82-58; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G/Mason Research Institute, Worcester, MA, USA. .... A-582
- 5.8 TOXICITY TO REPRODUCTION**
- Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6].  
Smith, J.M. 1973. A Segment I Rat Fertility Study of Amine Fluoride 335/242. Project Number 72R-817. Bio/dynamics Inc., East Millstone, NJ, USA. .... A-585

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**5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY**

Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]. Smith, J.M. 1973. A Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 72R-820. Bio/dynamics Inc., East Millstone, NJ, USA. ....	A-592
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Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]. Smith, J.M. 1973. Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 73R-880. Bio/dynamics Inc., East Millstone, NJ, USA. ....	A-595
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Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]. Smith, J.M. 1973. Amine Fluoride 335/242 Segment II Rabbit Teratology Study. Project Number 72R-818. Bio/dynamics Inc., East Millstone, NJ, USA. ....	A-598
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Amine fluorides 335/242 [Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]. Smith, J.M. 1973. A Segment III Perinatal and Postnatal Study of Amine Fluoride 335/242 in Rats. Project Number 72R-819. Bio/dynamics Inc., East Millstone, NJ, USA. ....	A-601
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Oleylamine (9-Octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine). Mercieca, M.D. 1989. Teratology Study in Rats with Oleylamine. Study No. 3205.9. Springborn Laboratories Inc., Spencerville, OH, USA.  Mercieca, M.D. 1989. Range-Finding Teratology Study in Rats with Oleylamine. Study No. 3205.8. Springborn Laboratories Inc., Spencerville, OH, USA. ....	A-604
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Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine). Mercieca, M.D. 1989. Teratology Study in Rabbits with Oleylamine. Study No. 3205.11. Springborn Life Sciences, Inc., USA.  Mercieca, M.D. 1989. Range-Finding Teratology Study in Rabbits with Oleylamine. Study No. 3205.10. Springborn Life Sciences, Inc., USA. ....	A-608
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## 2.1 MELTING POINT

### Test Substance

Identity: 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: 1996  
Remarks:

### Results

Melting Point: 28.3° C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

Melting point was provided in a reliable reference text.  
The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a  
reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC  
Handbook of Chemistry and Physics, 76<sup>th</sup> edition.  
CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: June 3, 2002  
Order Number for Sorting: 30  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Armeen<sup>®</sup> DM12D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Melting Point: -20 to -15°C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was been adequately characterized in a product data bulletin from the manufacturer. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer.

### References

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

### Other Available Reports

### Other

Last Changed: June 6, 2002  
Order Number for Sorting: 122a  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1996  
Remarks:

### Results

Melting Point: 52.9° C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

Melting point was provided in a reliable reference text.  
The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a  
reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC  
Handbook of Chemistry and Physics, 76<sup>th</sup> edition.  
CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: June 3, 2002  
Order Number for Sorting: 41  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 67% octadecenylamine, 14% octadecylamine and 3%  
octadecadienylamine  
Remarks: Purity based on commercial product Armeen O<sup>®</sup> or  
Armeen OD<sup>®</sup>

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1983  
Remarks:

### Results

Melting Point: Approximately 70°F (21°C)  
Decomposition: NA  
Sublimation: NA  
Remarks:

### Conclusions

The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided by manufacturer's product information.

### References

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25.*]

### Other Available Reports

### Other

Last Changed: June 4, 2002  
Order Number for Sorting: 7  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: 9-Octadecenylamine, (Z)- (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Melting Point: 21°C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary.

### References

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS RN 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

### Other Available Reports

### Other

Last Changed: June 4, 2002  
Order Number for Sorting: 7a  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Octadecylamine, N,N-dimethyl- (CAS RN 124-28-7;  
1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: NA  
Remarks:

### Results

Melting Point: 22.9°  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was provided in a reliable reference text. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a reliable reference text.

### References

Merck & Co., Inc. Page 545 in: The Merck Index, 11<sup>th</sup> edition. Rahway, NJ, USA.

### Other Available Reports

### Other

Last Changed: May 31, 2002  
Order Number for Sorting: 34  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Dimethyl stearamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Melting Point: 68 - 73° F (19.6 – 22.4°C)  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Final Report on the Safety Assessment of Dimethyl Stearamine. 14(6), December 1995. Cosmetic Ingredient Review, 1997.

### Other Available Reports

### Other

Last Changed: June 3, 2002  
Order Number for Sorting: 38  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: NORAM SH (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: N/A  
Year: Not stated  
Remarks:

### Results

Melting Point: 52.9° C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

Melting point was provided in a reliable reference text.  
The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a  
reliable reference text.

### References

Weast, R.C. 1988. CRC Handbook of Chemistry and  
Physics, 69<sup>th</sup> edition, C-380.

### Other Available Reports

### Other

Last Changed: June 26, 2002  
Order Number for Sorting: 78d  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Armeen<sup>®</sup> T (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Melting Point: 34 to 40°C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was been adequately characterized in a product data bulletin from the manufacturer. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer.

### References

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

### Other Available Reports

### Other

Last Changed: July 26, 2002  
Order Number for Sorting: 205  
Remarks:

## 2.1 MELTING POINT

### Test Substance

Identity: Genamin TA 100, Genamin TA 100 D Armeen T  
(CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: DIN/ISO 3016  
GLP: NA  
Year: Not stated  
Remarks:

### Results

Melting Point: 25 – 30° C  
Decomposition: Not stated  
Sublimation: Not stated  
Remarks:

### Conclusions

The endpoint was from a reliable European ICCA IUCLID Data Set (2001) that cited a reliable report. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 1C  
Remarks: Reliable without restrictions; study according to national standards.

### References

Hoechst, A.G. 1996. EG-Sicherheitsdatenblatt Genamin TA 100. 02/08/1996.  
As referenced in European ICCA IUCLID Data Set (2001).  
Hoechst, A.G. 1997. EG-Sicherheitsdatenblatt Genamin TA 100 D. 17/01/97.  
As referenced in European ICCA IUCLID Data Set (2001).

### Other Available Reports

### Other

Last Changed: June 24, 2002  
Order Number for Sorting: 201a, 201b  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: 1996  
Remarks:

### Results

Boiling Point: 259° C  
Pressure: Not stated  
Pressure Unit: Not stated  
Decomposition: Not stated  
Remarks:

### Conclusions

Boiling point was provided in a reliable reference text.  
The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a  
reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC  
Handbook of Chemistry and Physics, 76<sup>th</sup> edition.  
CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: June 4, 2002  
Order Number for Sorting: 30  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1996  
Remarks:

### Results

Boiling Point: 346.8° C  
Pressure: Not stated  
Pressure Unit: Not stated  
Decomposition: Not stated  
Remarks:

### Conclusions

Boiling point was provided in a reliable reference text.  
The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a  
reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC  
Handbook of Chemistry and Physics, 76<sup>th</sup> edition.  
CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 41  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: Stearamine (CAS RN 124-30-1; Octadecylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Boiling Point: 348.8° C  
Pressure: 760 mm  
Pressure Unit: Not stated  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Final Report on the Safety Assessment of Lauramine and Stearamine. 1997. Cosmetic Ingredient Review.

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 69  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 67% octadecenylamine, 14% octadecylamine and 3%  
octadecadienylamine  
Remarks: Purity based on commercial product Armeen O<sup>®</sup> or  
Armeen OD<sup>®</sup>

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1983  
Remarks:

### Results

Boiling Point: 275 - 344°C  
Pressure: Not stated  
Pressure Unit: NA  
Decomposition: NA  
Remarks:

### Conclusions

The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided by  
manufacturer's product information.

### References

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [product chemistry data provided in *Armak*, 1982. *Physical Characteristics of Armeen Aliphatic Amines*. *Armak Product Data Bull.* 78(5)1-25.]

### Other Available Reports

### Other

Last Changed: July 15, 2002  
Order Number for Sorting: 7  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine))  
Purity: Not stated  
Remarks: Test substance referred to as Armeen OD and oleylamine in the article.

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Boiling Point: 335° C  
Pressure: Not stated  
Pressure Unit: Not stated  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary.

### References

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

### Other Available Reports

#### Other

Last Changed: July 16, 2002  
Order Number for Sorting: 7a  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: NORAM SH (CAS No. 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Boiling Point: 348° C  
Pressure: 1013 hPa  
Pressure Unit: hPa  
Decomposition: Yes  
Remarks:

### Conclusions

Boiling point was provided in a reliable text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Weast, R.C. 1988. CRC Handbook of Chemistry and Physics, 69<sup>th</sup> edition, C-380.

### Other Available Reports

### Other

Last Changed: June 4, 2002  
Order Number for Sorting: 78d  
Remarks:

## 2.2 BOILING POINT

### Test Substance

Identity: Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Boiling Point: 200-230°C  
Pressure: Not stated  
Pressure Unit: Not stated  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized by a reliable reference text. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint was provided in a reliable reference textbook.

### References

Gerhartz, W. (ed.). 1985. Ullmann's Encyclopedia of Industrial Chemistry, 5<sup>th</sup> Edition. BCH Verlagsgesellschaft mgH, Weinheim, Germany.

### Other Available Reports

### Other

Last Changed: July 25, 2002  
Order Number for Sorting: 202  
Remarks:

## 2.4 VAPOR PRESSURE

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Vapor Pressure: 0.000012 hPa  
Temperature: 20°C  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable European ICCA IUCLID Data Set (2001). (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Davis. 1942. Ind. Eng. Chem. 34:1414. Cited in European ICCA IUCLID Data Set (2001).

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 70  
Remarks:

## 2.4 VAPOR PRESSURE

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 67% octadecenylamine, 14% octadecylamine and 3%  
octadecadienylamine  
Remarks: Purity based on commercial product Armeen O<sup>®</sup> or  
Armeen OD<sup>®</sup>

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1983  
Remarks:

### Results

Vapor Pressure: Less than 1 mmHg (<1.3 hPa)  
Temperature: 20° C  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided by manufacturer's product information.

### References

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in Armak, 1982. Physical Characteristics of Armeen Aliphatic Amines. Armak Product Data Bull. 78(5)1-25.*]

### Other Available Reports

### Other

Last Changed: July 15, 2002  
Order Number for Sorting: 7  
Remarks:

## 2.4 VAPOR PRESSURE

### Test Substance

Identity: 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks: Test substance referred to as Armeen OD and oleylamine in the article.

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Vapor Pressure:  $1 \times 10^{-4}$  mm Hg (estimated) (0.00013 hPa)  
Temperature: 25° C  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary.

### References

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

### Other Available Reports

### Other

Last Changed: July 16, 2002  
Order Number for Sorting: 7a  
Remarks:

## 2.4 VAPOR PRESSURE

### Test Substance

Identity: Amines, hydrogenated tallow alkyl  
(CAS No. 61788-45-2)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Vapor Pressure: 0.000012 hPa  
Temperature: 20°C  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin based on a published study.

### References

Davis. 1942. Ind. Eng. Chem., 34, 1414 as cited in: BUA-Stoffdossier Kokosalkanamin und primaere gradzahlige Alkanamine (C8-C18) (01/18/91).

### Other Available Reports

#### Other

Last Changed: June 26, 2002  
Order Number for Sorting: 78a  
Remarks:

## 2.4 VAPOR PRESSURE

### Test Substance

Identity: Armeen<sup>®</sup> T (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Vapor Pressure: less than 1 mm Hg (<1.3 hPa)  
Temperature: 20°C  
Decomposition: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer.

### References

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

### Other Available Reports

### Other

Last Changed: June 6, 2002  
Order Number for Sorting: 205  
Remarks:

## 2.5 PARTITION COEFFICIENT

### Test Substance

Identity: Oleylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Methods of Leo, A., C. Hansch and D. Elkins. 1971. Partition coefficients and their uses. Chem. Rev. 71(6):525-616, and Lyman, W.J., W. F. Reehl and D. H. Rosenblatt. 1982. Handbook of Chemical Property Estimation Methods. Environmental behavior of organic compounds. Chapter 1: Octanol/water partition coefficient. New York: McGraw-Hill.  
GLP: NA  
Year: 1984  
Remarks: Used two estimation methods cited in reputable sources.

### Results

Log  $P_{ow}$ : 7.5 (estimate based on methods of Leo et al.)  
8.1 (estimate based on method of Lyman et al.)  
Temperature: Not stated  
Remarks: Values of 7.5 and 8.1 based on methods of Leo, A. et al. and Lyman, W. J. et al., respectively.

### Conclusions

The endpoint has been adequately characterized by two independent estimation methods. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in EPA review article.

### References

U.S. EPA. 1984. Assessment of Testing Needs: Oleylamine (9-Octadecenylamine). Support Document, Proposed Health Effects Test Rule, TSCA Section 4. U.S. EPA Document I.D. No. 40-8484001.

## **Other Available Reports**

### **Other**

Last Changed: July 16, 2002

Order Number for Sorting: 10

Remarks:

## 2.5 PARTITION COEFFICIENT

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 67% octadecenylamine, 14% octadecylamine and 3%  
octadecadienylamine  
Remarks: Purity based on commercial product Armeen O<sup>®</sup> or  
Armeen OD<sup>®</sup>

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1983  
Remarks:

### Results

Log P<sub>ow</sub>: 7.5 (estimated)  
Temperature: Not stated  
Remarks: Value estimated by the method of Leo et al. 1971.  
Chem. Rev. 71(6):525-615.

### Conclusions

The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided by manufacturer's product information.

### References

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [*product chemistry data provided in ArmaK, 1982. Physical Characteristics of Armeen Aliphatic Amines. ArmaK Product Data Bull. 78(5)1-25.*]

### Other Available Reports

### Other

Last Changed: July 15, 2002  
Order Number for Sorting: 7  
Remarks:

## 2.5 PARTITION COEFFICIENT

### Test Substance

Identity: Armeen OD (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks: Test substance also referred to as oleylamine in the  
article.

### Method

Method/Guideline followed: Modified OECD protocol, but no details were  
provided.  
GLP: Not stated  
Year: 1984  
Remarks:

### Results

Log  $P_{ow}$ : >3.11  
Temperature: Not stated  
Remarks: The author of the article indicated that the test  
chemical had migrated into the octanol phase and was  
highly lipophilic.

### Conclusions

The endpoint was adequately characterized. (American  
Chemistry Council Fatty Nitrogen Derivatives Panel,  
Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in  
a reliable laboratory report submitted as part of a  
TSCA test rule.

### References

Akzo Chemie America. 1984. Letter of submittal to  
US EPA, TSCA Test Rules Development Branch  
(TS-778). US EPA Document Title: Physical Property  
Laboratory Report with Cover Letter, Document ID  
No. 40-8484006.

### Other Available Reports

### Other

Last Changed: July 16, 2002  
Order Number for Sorting: 8  
Remarks:

## 2.5 PARTITION COEFFICIENT

### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: 1981  
Remarks: Two concentrations of the test substance in 4 mL octanol were partitioned in duplicate in 150 mL 1-octanol saturated deionized water. A stock solution of the test substance was prepared in chloroform.

### Results

Log  $P_{ow}$ : 3.15  
Temperature: 21°C  
Results:

Concentration of Test Substance (mg/L)	Time (Hours)	Log $P_{ow}$ (in duplicate)
125	8	2.4, 4.2
125	24	3.2, 3.1
250	24	4.0, 4.4

Remarks: The author concluded that there was an apparent concentration dependent partitioning of this test substance. The reported log  $P_{ow}$  was based on the lower concentration tested.

### Conclusions

The endpoint was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2C  
Remarks: Reliable with restrictions. Comparable to guideline study with acceptable restrictions.

### References

Wee, V.T. et al. 1982. Octanol/Water Partition Coefficient (PARC). Procter & Gamble ESD Laboratory. Unpublished report (No. E0390.0111).

## **Other Available Reports**

### **Other**

Last Changed: August 21, 2003

Order Number for Sorting: 331

Remarks:

## 2.5 PARTITION COEFFICIENT

### Test Substance

Identity: Armeen<sup>®</sup> T (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Log P<sub>ow</sub>: 7.5  
Temperature: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer.

### References

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

### Other Available Reports

#### Other

Last Changed: June 6, 2002  
Order Number for Sorting: 205  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: 1-Dodecanamine (CAS RN 124-22-1; Dodecylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: 1996  
Remarks:

### Results

Value: 2 g/l  
Solubility: Not stated  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks:

### Conclusions

Water solubility was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76<sup>th</sup> edition. CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: June 4, 2002  
Order Number for Sorting: 30  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1996  
Remarks:

### Results

Value: 1 g/l  
Solubility: 1 g/l  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks:

### Conclusions

Water solubility was provided in a reliable reference text. The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in a reliable reference text.

### References

Lide, D.R. and H.P.R. Frederikse. 1996. CRC Handbook of Chemistry and Physics, 76<sup>th</sup> edition. CRC Press, Inc.

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 41  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Value: qualitatively stated as “not soluble”  
Solubility: qualitatively stated as “not soluble”  
pH value and concentration: Not stated  
pKa value at 25°C: 10.6  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable European ICCA IUCLID Data Set (2001). (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Davis. 1942. Ind. Eng. Chem. 34:1414. Cited in European ICCA IUCLID Data Set (2001).

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 70  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Oleylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1984  
Remarks: Based on estimation method using log P values.

### Results

Value:  $0.5 \times 10^{-3}$  mg/l (estimate)  
 $0.7 \times 10^{-5}$  mg/l (estimate)  
Solubility: Not stated  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks: Estimates of solubility made by EPA for ODA using  
respective log P values of 7.5 and 8.1.

### Conclusions

The endpoint has been adequately characterized by an estimation method. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided in EPA review article.

### References

U.S. EPA. 1984. Assessment of Testing Needs: Oleylamine (9-Octadecenylamine). Support Document, Proposed Health Effects Test Rule, TSCA Section 4. U.S. EPA Document I.D. No. 40-8484001. [product chemistry data provided in: Armak company. 1978. Industrial Chemicals Division. Product data bulletin: Physical and chemical characteristics of ARMEEN<sup>®</sup> aliphatic amines. Bulletin 78-5. Box 1805, Chicago, IL, USA.]

## **Other Available Reports**

### **Other**

Last Changed: July 16, 2002

Order Number for Sorting: 10

Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 67% octadecenylamine, 14% octadecylamine and 3%  
octadecadienylamine  
Remarks: Purity based on commercial product Armeen O<sup>®</sup> or  
Armeen OD<sup>®</sup>

### Method

Method/Guideline followed: Not stated  
GLP: NA  
Year: 1983  
Remarks:

### Results

Value: Not stated  
Solubility: Insoluble  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks:

### Conclusions

The endpoint has been adequately characterized by a reputable source. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; information provided by manufacturer's product information.

### References

CRCS, Inc. 1983. Information Review: (Z)-9-Octadecenylamine. Prepared under EPA Contract No. 68-01-6650 for TSCA Interagency Testing Committee. [product chemistry data provided in *Armak*, 1982. *Physical Characteristics of Armeen Aliphatic Amines*. *Armak Product Data Bull.* 78(5)1-25.]

### Other Available Reports

### Other

Last Changed: July 15, 2002  
Order Number for Sorting: 7  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: 9-Octadecenylamine, (Z)- (CAS No. 112-90-3; Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks: Test substance referred to as Armeen OD and oleylamine in the article.

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Value: Not stated  
Solubility: Very insoluble  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks: Solubility was qualitatively characterized as very insoluble, but since it has hydrophilic and hydrophobic groups, it could readily form a stable dispersion in water.

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the results were provided in a reliable TSCA Section 4 Test Rule summary.

### References

Malshet, V.G. 1991. Risk Management Document for Oleylamine (CAS No. 112-90-3). In Memorandum from E. Bisinger, Akzo Chemical Co., Chicago, IL, USA. September 12, 1991.

### Other Available Reports

### Other

Last Changed: July 16, 2002  
Order Number for Sorting: 7a  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Dimethyl stearamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Value: qualitatively stated as “not soluble in water”  
Solubility: qualitatively stated as “not soluble in water”  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a reliable review article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; endpoint provided in a reliable review article.

### References

Final Report on the Safety Assessment of Dimethyl Stearamine. 14(6), December 1995. Cosmetic Ingredient Review, 1997. [Physical chemical properties obtained from: National Technical Information Service. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin No. 78-5, 1978. Report No. OTS0526854.

### Other Available Reports

### Other

Last Changed: July 18, 2002  
Order Number for Sorting: 38  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: 1981  
Remarks: A stock solution of the test substance was prepared in chloroform. A volume of this stock solution to provide 10 mg Adogen 343 was transferred to each of two 250-mL flask, the solvent was evaporated and 100 mL deionized water was added to each flask. The flasks were incubated at  $21\pm 2^\circ\text{C}$  for 14 days. The soluble fraction of the test substance was measured using an analytical method. The analytical methods were not provided in the report.

### Results

Solubility: 288  $\mu\text{g/L}$   
pH value and concentration: Not stated  
pK<sub>a</sub> value at 25°C: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; basic data provided; the analytical method was not provided.

### References

Wee, V. T. et al. 1982. Solubility of a Hydrophobic Solid in Water. Procter & Gamble ESD Laboratory. Unpublished report (No. E8039.0110).

### Other Available Reports

### Other

Last Changed: August 21, 2003  
Order Number for Sorting: 330  
Remarks:

## 2.6 WATER SOLUBILITY

### Test Substance

Identity: Armeen<sup>®</sup> T (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: Not stated  
GLP: Not stated  
Year: Not stated  
Remarks:

### Results

Value: Qualitatively described as “insoluble in water”.  
Solubility: Qualitatively described as “insoluble in water”.  
pH value and concentration: Not stated  
pKa value at 25°C: Not stated  
Remarks:

### Conclusions

The endpoint was adequately characterized in a product data article. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 2D  
Remarks: Reliable with restrictions; the endpoint was provided in a product data bulletin from the manufacturer.

### References

Armak Industries. 1978. Physical and Chemical Characteristics of Armeen Aliphatic Amines. Product Data Bulletin 78-5. Armak Industries, Chicago, IL, USA.

### Other Available Reports

### Other

Last Changed: June 6, 2002  
Order Number for Sorting: 205  
Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin 12R 100D (CAS RN 124-22-1; Dodecylamine)  
Purity: >99.9%  
Remarks:

#### Method

Method/Guideline followed: Essentially OECD Guideline 301D, Ready Biodegradability: Closed Bottle Test  
Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1988  
Contact Time: 28 Days  
Inoculum: Activated sludge, domestic, non-adapted, 1 drop/l test mixture  
Remarks: Test mixtures were incubated in completely filled closed bottles at  $20 \pm 1^\circ\text{C}$  for 28 days. The test was conducted in triplicate using the test substance (1.672 to 5.772 mg/l; ThOD[NO<sub>3</sub>]), a mineral medium (as prescribed by OECD 301) and activated sludge. The following controls were included: a control without the test substance but with the inoculum (the inoculum blank) and the positive control (sodium benzoate 5.19 mg/L ThOD) with inoculum. BOD/ThOD was determined electrometrically on day 0, 7, 14, 21 and 28. No abiotic control was included and no mention of experiment being performed in the dark so photodegradation cannot be ruled out.

#### Results

Degradation: 55% at 28 days  
Results: The guideline criteria for the test were met. Test substance is readily biodegradable.  
Kinetic:

Time (Days)	Test Substance (% BOD/ThOD)	Sodium Benzoate (% BOD/ThOD)
0	0	0
7	63	75
14	57	70
21	59	72
28	55	61

Breakdown Products: None stated  
Remarks: No abiotic control was included. Since in the report it

is not explicitly mentioned that the test was performed in the dark, photodegradation cannot be excluded. After degradation was >60% on day 7, it dropped again to slightly <60% from day 14 onwards. This may be explained by the fact that in the solution containing TS degradation stopped after day 7 whereas the inoculum blank still consumed some oxygen. However, as the criterion of >60% degradation within 28 days was met, TS can be considered readily biodegradable. Later measurements can be disregarded.

### **Conclusions**

The test substance was readily biodegradable based on > 60% degradation within 28 days. The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability:

2D

Remarks:

Reliable with restrictions; limited data available and photodegradation cannot be ruled out.

### **References**

Dr. Voelskow. 1994. Pruefung der leichten biologischen Abbaubarkeit von Genamin 12R 100D. [Ready Biodegradability Study with Genamin 12R 100D] Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

### **Other**

Last Changed:

September 13, 2002

Order Number for Sorting:

30e

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Dodecyldimethylamine, distilled (CAS RN 112-18-5; N,N-Dimethyl-1-dodecanamine)  
Purity: 98.7% tertiary amine  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline 301D, Ready Biodegradability, Closed Bottle Test.  
Test Type: Aerobic biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Activated sludge  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. The test compound and reference substance were added to the bottles using stock solutions of 1.0 g/l. The test substance stock solution was prepared by mixing the material in demineralized water at 50°C then acidified. Due to the use of the acidified stock, the pH in the closed bottle medium dropped to approximately 4. This medium was titrated to pH 7 with a 1N NaOH solution. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The test substance was degraded 67% at day 28 in the closed bottle test.  
Results: Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable.

**Kinetic:**

<b>Time (Days)</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	52	69
15	63	75
28	67	90

**Breakdown Products:**

Not stated

**Remarks:**

The validity of the test was demonstrated by oxygen consumption in the control bottles with reference substance, and an endogenous respiration of 0.3 mg/l. The oxygen depletion in the bottle without inoculum slightly exceeded the guideline recommendation. The pH of the medium at day 28 was 6.6.

**Conclusions**

The biodegradability of the test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality****Reliability:**

1A

**Remarks:**

Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of Armeen DM12D. Report No. CRL F91121. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports****Other****Last Changed:**

July 29, 2002

**Order Number for Sorting:**

122

**Remarks:**

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Farmin DM20 (CAS RN 112-18-5;  
*N,N*-Dimethyl-1-dodecanamine)  
Purity: Not stated.  
Remarks:

#### Method

Method/Guideline followed: Carbon dioxide (CO<sub>2</sub>) Evolution Test (Modified Sturm Test): OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC.

Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1996  
Contact Time: 29 Days  
Inoculum: Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK).  
Remarks: Preliminary study: A 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark.  
Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was tested using the CO<sub>2</sub> evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove CO<sub>2</sub> and connected to CO<sub>2</sub> traps (a series of Drechsel bottles with barium hydroxide) and incubated at 19.7 to 24.0°C. (Lowest temperature value falls outside the

minimum recommended for this assay, but it is not thought to be significant or to have affected the integrity of the test.) Ultimate biodegradability of the test substance was determined after 29 days. The residual barium hydroxide was determined at intervals by titration.

## Results

Degradation:

33% at 5 days; 72% after 29 days.

Results:

*Preliminary study:* The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.

*Definitive study:* The guideline criteria for the test were met. Mean cumulative CO<sub>2</sub> production by mixtures containing the test substance was equivalent to 10% of the theoretical value after three days and 63% (extrapolated) after 13 days. Test substance was considered to be readily biodegradable.

Kinetic:

Time (Days)	Sodium Benzoate (10 mg C/l)		Test Substance (Farmin DM20) (10 mg C/l)	
	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>
2	22.8	21	0	0
5	65.8	60	35.9	33
10	86.9	79	65.0	59
22	95.7	87	78.3	71
29	100.3	91	78.4	72

Breakdown Products:

None stated

Remarks:

## Conclusions

*Definitive study:* The test substance was readily biodegradable since CO<sub>2</sub> production was ≥60% of the theoretical value within ten days of the level achieving 10%. (Author of report)

The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jenkins, W.R. 1996. Farmin DM20: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS162/0292. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W.R. 1996. Farmin DM20: Assessment of Biotic/Abiotic degradability. Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS164/0313. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

Last Changed:

July 11, 2002

Order Number for Sorting:

124b (124c preliminary study)

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin LA 302 D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Approximately 100%  
Remarks:

#### Method

Method/Guideline followed: Methods correspond to 79/831/EWG (Part C), OECD – Guidelines for testing of Chemicals, Guideline 301F.

Test Type: Ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Dry substance from communal effluent water purification plants  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. BOD bottles were used as vessels and were incubated in a WTW-BOD device at  $20 \pm 1^\circ\text{C}$ . The content of the reaction medium followed the requirements for the cited EEC Directive. The inoculum was preconditioned for 5 days in the laboratory by stirring in a nutrient solution. The activity of the inoculum was tested using a reference substance, and a control was run with the inoculum and no addition of test substance. The biodegradability analysis occurred through the use of manometric calculation of oxygen-use. The test substance was measured directly into the BOD bottles. The averages of the parallel assays were as follows:  
Test concentration: 13 mg/l  
In relation to the theoretical BOD: 40 mg/l ( $\text{O}_2$ )  
In relation to the theoretical N-BOD: 44 mg/l ( $\text{O}_2$ )  
No analysis of COD was completed because of the limited solubility of the test substance.  
BOD per 1 g test substance:  $2.58 \times 10^3$  mg/g ( $\text{O}_2$ )  
The BOD per gram of test substance was ascertained by introduction of the probe directly into the BOD bottle. This method delivers only restricted accuracy of the ascertained value.  
The BOD could not be ascertained because of the limited solubility of the test substance.  
Theoretical BOD:  $3.16 \times 10^3$  mg/g ( $\text{O}_2$ )  
Theoretical N-BOD:  $3.45 \times 10^3$  mg/g ( $\text{O}_2$ )  
(N-BOD = BOD with nitrification: N-oxidation to

nitrate).

Dissolved oxygen content in the bottles was measured on days 7, 14, 21 and 28.

## Results

Degradation:

The biodegradation of the test substance was 67% at day 28.

Results:

The authors claim the test substance should be classified as readily biodegradable.

Kinetic:

Test Day	ThBOD (%)	ThN-BOD (%)
7	48	44
14	53	48
21	64	59
28	74	67

Breakdown Products:

None

Remarks:

## Conclusions

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

## References

Voelskow, H. 1992. Short Report on the Study of Ready Biodegradability of Genamin LA 302 D in the Respirometer Test. Report Number 92-0067-R1/R2. Hoechst AG, Germany.

## Other Available Reports

## Other

Last Changed:

June 7, 2002

Order Number for Sorting:

124f

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl)  
Purity: Approximately 100%  
Remarks:

#### Method

Method/Guideline followed: 84/449/EWG (Part C), OECD Guideline 301 D (“Closed Bottle Test”); COD determination followed the DIN-Norm 38 409 Part 3 and BOD determination followed the DIN Norm 38 409 Part 41.

Test Type: Ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Activated sludge from the communal wastewater purification plant in Frankfurt, Germany.  
Remarks: The test assessed the ready biodegradability of the test substance in the Closed Bottle Test. Inoculum was purification plant effluent, filtered over a folded filter. The inoculum was not acclimatized to the test substance or reference substance. COD determination of the stock solution = 45 mg/l (O<sub>2</sub>). COD determination per 1 gram of test substance = 2.25 mg/g (O<sub>2</sub>). In solutions of defined weight (not filtered), the results are calculated per gram of the measured values per liter of the stock solution. Test substance was added to the test assay in the amount of 132 ml/l, which in relation to the measured COD, equals a test concentration of 5.94 mg/l (O<sub>2</sub>). Incubation occurred at 20 ± 1°C. The content of the reaction medium conformed to the details of the cited EEC directive. The activity of the inoculum was checked by the use of a reference assay and a control was run using an assay without addition of test substance. Reaction vessels were BOD bottles with caps. They were filled to the rim without bubbles. The degradation analysis occurred by determining the decay of the dissolved oxygen content.

**Results**

Degradation: Degradation was less than or equal to 2% COD during the 28-day test.

Results: According to the criteria of this test, Genamin 14 R 302 D is not readily biodegradable. The oxygen consumption remained under 20% during the 28-day test.

Kinetics:

<b>Time (Days)</b>	<b>Consumption (% COD)</b>
7	0
14	2
21	0
28	0

Breakdown Products:

Not stated

Remarks:

The oxygen consumption of the reference substance reached >60% in less than 14 days after adaptation.

**Conclusions**

The test substance was not readily biodegradable.  
(Author of report)

The results of this study are dramatically inconsistent with results for other related chemicals (most being readily biodegradable). This study is not considered representative of the biodegradation of 1-Tetradecanamine, N,N-dimethyl. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2D

Remarks:

Although this is a guideline study, the results are scientifically unjustifiable.

**References**

Stuhlfauth, T. 1992. Short Report on the Study of the Ready Biodegradability of Genamin 14 R 302 D in the "Closed Bottle-Test". Report No. 92-0069-G1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports****Other**

Last Changed:

June 7, 2002

Order Number for Sorting:

260c

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen DM16D (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: 98.2%  
Remarks:

#### Method

Method/Guideline followed: Methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test. Also conformed with EEC Official Journal of the European Communities L251, Method C.6. Degradation-Biotic Degradation: Closed Bottle Test and ISO/TC 147/SC 5WG 4N152.

Test Type: Aerobic biodegradation in the Closed Bottle Test  
GLP: Yes  
Year: 1991  
Contact Time: 42 days  
Inoculum: Secondary activated sludge  
Remarks: The experiment measured the biodegradability of the test substance in the Closed Bottle Test. Prior to the start of the test, activated sludge was collected and preconditioned by aerating the sludge for a period of one week. The sludge was diluted to a concentration of 2 mg dry weight/l and used in the test. Solutions of the test substance were prepared at 2 mg/l. This was equivalent to a theoretical oxygen demand of 3.2 g O<sub>2</sub>/g test substance. A solution of sodium acetate was prepared at 6.7 mg/l and was used as a reference material. At test initiation, four experimental groups were made using duplicate 280-ml BOD bottles. Experimental groups were 1) mineral nutrient without test substance and without inoculum, 2) mineral nutrient solution without test substance but with inoculum, 3) mineral nutrient solution with test substance and with inoculum, and 4) mineral nutrient solution with sodium acetate and with inoculum. Ammonium chloride was omitted from the medium to prevent nitrification. Due to the omission, the pH of the medium decreased slightly. Dissolved oxygen concentrations were measured in each bottle on days 0, 5, 15, 28, and 42 using an oxygen electrode.

#### Results

Degradation: The test substance was degraded 59% at day 28 and

70% at day 42.

**Results:** Based on the degradation percentages, the test substance was considered readily biodegradable.

**Kinetics:**

<b>Day</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	47	69
15	53	75
28	59	90
42	70	--

**Breakdown Products:**  
**Remarks:**

Not stated.  
The validity of the test was demonstrated by the degradation of sodium acetate and an endogenous respiration of 0.3 mg/l.

**Conclusions**

The ready biodegradability of the test substance in the Closed Bottle Test was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

**Reliability:**  
**Remarks:**

1A  
Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DM16D. Project/Study No. CRL F91120; Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

**Last Changed:**  
**Order Number for Sorting:**  
**Remarks:**

July 9, 2002  
2a

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Farmin DM60 (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: Not stated.  
Remarks:

#### Method

Method/Guideline followed: OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC (Modified Sturm Test).

Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1996  
Contact Time: 29 Days  
Inoculum: Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK).

Remarks: Preliminary study: A 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark.

Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was tested using the CO<sub>2</sub> evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove CO<sub>2</sub> and connected to CO<sub>2</sub> traps (a series of Drechsel bottles with barium hydroxide) and incubated at 21.2 to 23.9°C. Ultimate biodegradability of the test substance was determined after 29 days. The residual

barium hydroxide was determined at intervals by titration.

## Results

Degradation:

107% after 29 days.

Results:

*Preliminary study:* The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.

*Definitive study:* The guideline criteria for the test were met. Mean cumulative CO<sub>2</sub> production by mixtures containing the test substance was equivalent to 60% of the theoretical value after eight days; a degradation plateau was not obtained by the end of the test. The highest degradation result (>100%) obtained from Farmin DM60 and the absence of a plateau after 29 days suggests that the initial estimate of its carbon content may have been slightly lower than the true value. The test substance was considered to be readily biodegradable.

Kinetic:

Time (Days)	Test Substance (Farmin DM60) (10 mg C/l)		Sodium Benzoate (10 mg C/l)	
	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>
2	0	0	22.3	20
4	17.9	16	57.5	52
8	66.2	60	81.8	74
18	100.5	91	92.5	84
29	117.8	107	98.2	89

Breakdown Products:

None stated

Remarks:

## Conclusions

The test substance was readily biodegradable since CO<sub>2</sub> production was ≥60% of the theoretical value within ten days of the level achieving 10%. (Author of report)

The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jenkins, W. R. 1996. Farmin DM60: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS176/0293. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W. R. 1996. Farmin DM60: Assessment of Biotic/Abiotic Degradability, Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS178/0316. Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

Last Changed:

July 11, 2002

Order Number for Sorting:

4b (4c preliminary study)

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Biodegradation measured as a function of oxygen consumption (BOD) in a respirometer, similar to that described in OECD Guideline 302C, Modified MITI Test.

Test Type: Aerobic biodegradation  
GLP: No  
Year: 1980  
Contact Time: 12 days  
Inoculum: Activated sludge from municipal sewage plant in Tokyo  
Remarks: To 3 liters of basal nutrient medium, 30 ppm of activated sludge was added along with test substance at 100 ppm. Biodegradation experiments were carried out with an oxygen consumption measuring apparatus at 25°C. Biodegradation was assessed as the ratio of the BOD measured to the theoretical BOD based upon the chemical structure of the test substance.

#### Results

Degradation: > 60% degradation by day 12  
Results: Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable.  
Kinetic:

Time (Days)	Test Substance (% BOD/ThOD)
5	~30
10	>50
12	>60

Breakdown Products: Not stated  
Remarks:

#### Conclusions

The biodegradability of Octadecylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2B

Remarks:

Reliable with restrictions; basic data given, comparable to guideline standards.

**References**

Yoshimura, K., S. Machida and F. Masuda.

Biodegradation of Long Chain Alkylamines. J. Am.

Oil Chem. Soc. 57:238-241.

**Other Available Reports**

**Other**

Last Changed:

July 17, 2002

Order Number for Sorting:

51

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin 18R 100D (CAS RN 124-30-1; Octadecylamine)  
Purity: >99% primary amines (of which >90% C18)  
Remarks:

#### Method

Method/Guideline followed: Essentially OECD Guideline 301F  
Test Type: Aerobic biodegradation  
GLP: No  
Year: 1992  
Contact Time: 28 Days  
Inoculum: Activated sludge, domestic, non-adapted, 30 mg/l dry matter  
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD. The test was conducted in duplicate using the test substance (126.5 –127.1 mg/l; 437 - 438 mg/l ThOD[NO<sub>3</sub>]), a mineral medium (as prescribed by OECD 301) and activated sludge. A control without the test substance but with the inoculum (the inoculum blank, 3 flasks) and the positive control of sodium benzoate (292 mg/L ThOD) and inoculum were included. Test mixtures were incubated at 20 ± 1°C for 28 days. BOD/ThOD was determined manometrically on day 7, 14, 21 and 28. No abiotic control was included and no mention of the experiment being performed in the dark so photodegradation cannot be ruled out. This review is based on abstract only so OECD guidelines cannot be verified.

#### Results

Degradation: 70% after 28 days  
Results: The guideline criteria for the test were met. Test substance is considered readily biodegradable.  
Kinetic:

Time (Days)	% Degradation (% ThOD(NO <sub>3</sub> ))	
	Test Substance	Sodium Benzoate
7	26 (28)*	83
14	50 (53)	89
21	65 (70)	87
28	70 (76)	86

\* Value in ( ) = %ThOD(NH<sub>3</sub>)

**Breakdown Products:** None stated  
**Remarks:** It could not be verified whether the criterion of >60% degradation within 10 days of start of degradation (10% degradation) was met because too few data points were available.

**Conclusions** The test substance was readily biodegradable based on > 60% degradation within 28 days. The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**  
**Reliability:** 2D  
Reliable with restrictions; report based on abstract only minimal data available; photodegradation cannot be ruled out.

**Remarks:**

**References** Dr. Voelskow. 1994. Pruefung der leichten biologischen Abbaubarkeit von Genamin 18R 100D. [Ready Biodegradability Study with Genamin 18R 100D] Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other**  
**Last Changed:** June 24, 2002  
**Order Number for Sorting:** 51a  
**Remarks:**

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Octadecenylamine, (Z)- (CAS No. 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Biodegradation measured as a function of oxygen consumption (BOD) in a respirometer, similar to that described in OECD Guideline 302C, Modified MITI Test.  
Test Type: Aerobic biodegradation  
GLP: No  
Year: 1980  
Contact Time: 12 days  
Inoculum: Activated sludge from municipal sewage plant in Tokyo  
Remarks: To 3 liters of basal nutrient medium, 30 ppm of activated sludge was added along with test substance at 100 ppm. Biodegradation experiments were carried out with an oxygen consumption measuring apparatus at 25°C. Biodegradation was assessed as the ratio of the BOD measured to the theoretical BOD based upon the chemical structure of the test substance.

#### Results

Degradation: > 60% degradation by day 12  
Results: Based on the percent biodegradation, the test substance was considered to be Readily Biodegradable.  
Kinetic:

Day	Test Substance (% BOD/ThOD)
5	~50
10	~60
12	>60

Breakdown Products: Not stated  
Remarks:

**Conclusions**

The biodegradability of Octadecenylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2B

Remarks:

Reliable with restrictions; basic data given, comparable to guideline standards

**References**

Yoshimura, K., S. Machida and F. Masuda.  
Biodegradation of Long Chain Alkylamines. J. Am. Oil Chem. Soc. 57:238-241.

**Other Available Reports**

**Other**

Last Changed:

July 17, 2002

Order Number for Sorting:

13

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen OD (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 98%  
Remarks:

#### Method

Method/Guideline followed: Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 42 days  
Inoculum: Secondary activated sludge  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15, 28 and 42. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The biodegradation of the test substance was 44% at day 28 and 72% at day 42.

Results: The authors claim the test substance should be classified as biodegradable.

Kinetic:

Day	% BOD/ThOD	
	Test Substance	Reference Substance
5	17	69
15	41	75
28	44	90
42	72	--

Breakdown Products:

Not stated

Remarks:

The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.9.

### Conclusions

The biodegradability of Octadecenylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

### References

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN OD. Report No. CRL F91123. Akzo Research Laboratories Arnhem, The Netherlands.

### Other Available Reports

#### Other

Last Changed:

July 17, 2002

Order Number for Sorting:

12

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: NORAM O (CAS No. 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 98%  
Remarks:

#### Method

Method/Guideline followed: ISO 9439, which is in agreement with OECD  
Guideline 301B

Test Type: Aerobic biodegradation  
GLP: Yes  
Year: 1992  
Contact Time: 41 days  
Inoculum: Activated sludge, domestic wastewater treatment plant  
Remarks: Duplicate test mixtures (in 3 L flasks) were incubated at constant temperature ( $20 - 25 \pm 1$  °C) for 41 days with continuous stirring. Test mixtures contained test substance (24.6 mg/L; ~110 mg ThCO<sub>2</sub>/1.5 l), volatile solvent (1,1-dichloro-1fluoroethane), emulsifying agent (Symperonic P94, 12.3 mg/L), mineral medium (as prescribed in OECD 301), and inoculum. Before the test, mixtures were aerated with CO<sub>2</sub>-free air overnight. Three barium hydroxide traps were connected to collect CO<sub>2</sub>. Controls included: 1) inoculum blank; 2) positive control (sodium benzoate (34.7 mg/l) and inoculum); 3) emulsifier control (emulsifier and inoculum); and 4) toxicity control (test substance, inoculum and sodium benzoate). For the test mixture, corrections were made for CO<sub>2</sub> in emulsifier control. The three traps were replaced and analyzed for CO<sub>2</sub> on days 0, 1, 4, 5, 8, 11, 14, 18, 22, 28, 33, 36, 40 and 41. No abiotic control was included. In the report it was not explicitly mentioned that the test was performed in the dark, but since an adaptation phase was observed, during which no degradation yielding CO<sub>2</sub> occurred, photodegradation was not expected to have occurred. In the method description, carbon content of sodium benzoate is said to be 58.3%, whereas in the table and further calculations it is said to be 57.7%. 58.3% is the correct value (calculated by reviewer); however, criterion of >60% within 14 days of ThOD is still met when the correct value is used.

**Results**

Degradation: 66% degradation by day 28  
 Results: Based on the percent biodegradation, the test substance was considered to be biodegradable, but not readily biodegradable under these test conditions. (Author of report)

Kinetic:

Day	Test Substance (% ThCO <sub>2</sub> )	Sodium Benzoate (% ThCO <sub>2</sub> )
4	-1	69
5	0	69
11	13	71
18	43	70
22	60	70
28	66	69

Breakdown Products: Not stated  
 Remarks: The emulsifying agent was not biodegradable and was no inhibitor. The test substance was biodegradable, though not readily biodegradable because the criterion of degradation, >60% with 10 day window after start of biodegradation phase (10%), was not met.

**Conclusions**

The biodegradability of Noram O was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A  
 Remarks: Reliable without restriction; guideline study.

**References**

Boutonnet, J.C. 1994. NORAM O Détermination de la biodégradabilité facile essai de dégagement de CO<sub>2</sub>. [NORAM O Determination of the Ready Biodegradability by the CO<sub>2</sub> evolution assay] Laboratoire accrédité par le Réseau. Study Report Elf Atochem/CAL 4658/93/A.

**Other Available Reports****Other**

Last Changed: August 14, 2002  
 Order Number for Sorting: 11a  
 Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin OL 100 D (CAS No. 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline 301F; OECD Guideline 302B/  
92/69/EWG (Teil C.4-D), EG Amtsblatt L 383 A.  
Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1992  
Contact Time: 28 days  
Inoculum: Activated sludge, industrial, non adapted  
Remarks: Duplicate test mixtures were incubated at constant  
temperature ( $20 \pm 1$  °C) for 28 days. Test mixtures  
contained test substance [177 mg/L (~604 m/l  
ThOD(NO<sub>3</sub>)) and 165 mg/L (~562 mg/l ThOD(NO<sub>3</sub>)],  
mineral medium (as prescribed by OECD 301), and  
inoculum. Controls included: 1) inoculum blank and  
2) positive control (diethylene glycol (ThOD 288 mg/l)  
and inoculum). BOD was determined manometrically  
on day 1, 5, 10, 15, 20 and 28.  
The report was stated to have followed the OECD  
guidelines, but limited information was provided so  
this cannot be fully verified. No abiotic control was  
included. Performance of the test was in compliance  
with OECD 301F, except for the inoculum, which was  
from an industrial wastewater plant and was applied in  
the test at a higher concentration than prescribed in the  
guideline. However, the concentration was  
comparable to the concentration prescribed in the  
Zahn-Wellens test for inherent biodegradability  
(OECD 302B). Adsorption could not be taken into  
account because the first measurement took place on  
day 1.

#### Results

Degradation: 69% degradation by day 28  
Results: Based on the percent biodegradation, the test substance  
was considered to be inherently biodegradable.

Kinetic:

Day	Test Substance (% ThOD(NO <sub>3</sub> ))	Diethylene Glycol (% ThOD(NO <sub>3</sub> ))
1	7 (7)	28
5	39 (42)	36
10	55 (59)	82
20	67 (72)	98
28	69 (74)	101

\* Value in () = % ThOD(NH<sub>3</sub>)

Breakdown Products:

Not stated

Remarks:

Adaptation phase – two to three days.

The test substance was evaluated in duplicate showing a large difference in results (41%) for the duplicates on day 28. According to OECD 301F, the test would thus be invalid; however, non-homogeneity of the sludge makes such a deviation unavoidable, which is acceptable in OECD 302B.

**Conclusions**

The biodegradability of Genamin OL 100 D was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2D

Remarks:

Reliable with restrictions; limited report and photodegradation cannot be ruled out.

**References**

Voelskov, H. 1994. Pruefung der biologischen Abbaubarkeit von Genamin OL 100 D. [Ready Biodegradability Study with Genamin OL 100D] Hoechst AG, Hoechst AG, Dr. Voelskov.

**Other Available Reports****Other**

Last Changed:

August 14, 2002

Order Number for Sorting:

11b

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Octadecylamine (CAS RN 124-28-7;  
1-Octadecanamine, N,N-dimethyl)  
Purity: Not Stated  
Remarks:

#### Method

Method/Guideline followed: Non-specific test method for measuring CO<sub>2</sub> evolution.  
Test Type: Aerobic biodegradability  
GLP: Not stated  
Year: 1985  
Contact Time: 40 days (screening test), 7 days (definitive test)  
Inoculum: Sludge  
Remarks: A screening level test (run for 40 days at 10 and 20 mg/l) and a definitive test (run for 7 days at 0.2 and 2.0 mg/l) were run. The reference provided basic data from the definitive CO<sub>2</sub> evolution test with <sup>14</sup>C-labelled test substance and the study report from the screening test using nonradiolabelled test substance. In the screening test, glucose was used as a reference material, while in the definitive test stearic acid was used as the reference material. Details provided for the screening test follow: Four, 4-liter Erlenmeyer flasks were prepared to contain the following: 1) Blank control, 2) Glucose control at 20 mg/l, 3) test substance at 10 mg/l and 4) test substance at 20 mg/l. All flasks received acclimated inoculum (20 ml containing  $6.3 \times 10^6$  organisms/ml) and were brought to volume (2000 ml) with mineral salts medium. Flasks were incubated at 20 to 23°C except on one day when the temperature dropped to 16°C due to inadvertent shut down of the furnace. The study director reported that this deviation did not affect the integrity of the study. The headspace of each flask was aerated with CO<sub>2</sub>-free air and any CO<sub>2</sub> evolved from the biodegradation of the test substance was collected in Ba(OH)<sub>2</sub> traps. Traps were periodically removed and the amount of CO<sub>2</sub> collected was determined titrimetrically. After CO<sub>2</sub> production ceased, solutions were acidified and aerated overnight. The amount of soluble organic carbon remaining in the flasks was also determined at the end of the test. The glucose control in the screening test produced a below normal percent TCO<sub>2</sub> over the test period of 43.1%. The Study Director indicated that this low value was

probably caused by a technician error in adding only 20 ml of 1000 ppm glucose stock solution instead of 40 ml. The study director indicated that this deviation did not affect the validity of the study. The screening study was extended to 40 days due to additional CO<sub>2</sub> production in the test flasks beyond the 25 day test period.

**Results**

Degradation:

In the screening test, the 10 and 20 mg/l treatments were degraded to 118 and 51%, respectively. In the definitive test, the 0.2 and 2.0 mg/l treatments were degraded to 91.1 and 79.4%, respectively.

Results:

In the definitive test, biodegradability was confirmed using radiolabeled techniques and realistic trace level concentrations (0.2 and 2.0 mg/l). The indigenous microflora in sludge rapidly and extensively mineralized the test substance. Greater than 80% of the amine was converted to <sup>14</sup>CO<sub>2</sub> with a half-life of 17 to 20 hours. The residual <sup>14</sup>C activity was associated with the biomass or dissolved in solution. The kinetics of mineralization and distribution of the radioactivity were similar to those of readily degradable stearic acid, demonstrating the biodegradable nature of the amine.

Kinetic:

Not provided for the definitive test

<b>Screening Study Kinetics</b>			
<b>Time (Days)</b>	<b>Test Substance 10 mg/l (% TCO<sub>2</sub>)</b>	<b>Test Substance 20 mg/l (% TCO<sub>2</sub>)</b>	<b>Glucose (% TCO<sub>2</sub>)</b>
6	7.1	-0.8	22.5
18	40.8	30.6	42.1
26	79.0	43.8	43.1
40	118.0	50.6	43.1

Breakdown Products:  
 Remarks:

Not stated

**Conclusions**

The biodegradable nature of Octadecylamine was adequately characterized in this study. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:  
 Remarks:

2B  
 Reliable with restrictions; basic data given, comparable

to guidelines/standards.

## References

Mooney, T.W. 1988. Letter from Proctor & Gamble Co. to U.S. EPA Regarding Request for Information on Tertiary Amines. The Proctor & Gamble Co. EPA Doc ID No. FYI-OTS-0794-1165. Also included in EPA document: Pence, W. H. 1985. CO<sub>2</sub> Production Test on B0793.01. Study Reference 85-0245-11, Hill Top Research, Inc., Cincinnati, OH, USA.

## Other Available Reports

### Other

Last Changed:	July 18, 2002
Order Number for Sorting:	35
Remarks:	

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Farmin DM80 (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated.  
Remarks:

#### Method

Method/Guideline followed: Carbon dioxide (CO<sub>2</sub>) Evolution Test: OECD Procedure 301B and Procedure C.4-C of the Annex to Directive 92/69/EEC (Modified Sturm Test).

Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1996  
Contact Time: 29 Days  
Inoculum: Activated sludge (30 mg solids/l from domestic sewage works at Oakley, Suffolk, UK).

Remarks: Preliminary study: The 5-day bacterial inhibition test was performed using the biochemical oxygen demand (BOD) method (OECD Guideline No 301D (Closed Bottle Test) and EC Procedure C.4-E of the Annex to Directive 92/69/EEC). The test was conducted using bacterial inoculum [sewage effluent (final effluent, 1 drop/l, trickling filter plant at Thorndon, Suffolk, UK)], the test substance (10 mg C/l), and a reference substance (sodium benzoate, 10 mg C/l). The test mixtures were prepared with or without the test substance and included the bacterial inoculum and reference substance. Solution vessels were incubated for 5 days at 20°C in the dark..  
Definitive study: The determination of the ultimate aerobic biodegradability of the test substance was made using the CO<sub>2</sub> evolution method. The test was conducted using activated sludge, the test substance (10 mg C/l), a reference substance (sodium benzoate, 10 mg C/l), and/or mineral salts medium. Specifically, the test included the following: 1) two test vessels containing the test material, activated sludge and mineral salts medium; 2) two control vessels containing activated sludge and mineral salts medium; and 3) one control containing activate sludge, mineral salts medium and sodium benzoate. Solution vessels were aerated with air treated to remove CO<sub>2</sub> and connected to CO<sub>2</sub> traps (a series of Drechsel bottles with barium hydroxide) and incubated at 21.2 to 23.9°C. Ultimate biodegradability of the test

substance was determined after 29 days. The residual barium hydroxide was determined at intervals by titration.

**Results**

Degradation:

49% after 29 days

Results:

*Preliminary study:* The guideline criteria for the test were met. The test substance did not significantly inhibit the degradation of the bacteria and the test substance showed no evidence of degradation.

*Definitive study:* The guideline criteria for the test were met. Mean cumulative CO<sub>2</sub> production by mixtures containing the test substance was equivalent to 10% of the theoretical value after five days and 49% after 29 days; a degradation plateau was not obtained by the end of the test. Test substance cannot be considered to be readily degradable, but because significant degradation occurred it can be considered to be inherently degradable.

Kinetic:

Time (Days)	Test Substance (Farmin DM80) (10 mg C/l)		Sodium Benzoate (10 mg C/l)	
	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>	CO <sub>2</sub> (mg)	%TCO <sub>2</sub>
2	0	0	22.3	20
5	10.9	10	67.6	61
15	40.1	37	90.1	82
29	53.3	49	98.2	89

Breakdown Products:

None stated

Remarks:

**Conclusions**

The test substance was not readily biodegradable, but because significant degradation occurred it can be considered to be inherently degradable. (Author of report)

The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jenkins, W. R.. 1996. Farmin DM80: Assessment of Ready Biodegradability – Modified Sturm Test. Report No. 96/KAS183/0317, Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

Jenkins, W. R.. 1996. Farmin DM80: Assessment of Biotic/Abiotic degradability. Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD). Report No. 96/KAS185/0318, Huntingdon Life Sciences Ltd., Eye, Suffolk, UK.

**Other**

Last Changed:

July 11, 2002

Order Number for Sorting:

38a (38b preliminary study)

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen CD (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 42 days  
Inoculum: Secondary activated sludge from the RWZI Nieuwgraaf in Duiven

Remarks: Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15, 28, and 42 dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.1 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The test substance was degraded 56% at day 28 and 74% at day 42.

Results: Based on the percent degradation,, close to 60%, the test substance was classified readily biodegradable. (Author of report)

Kinetic:

<b>Time (Days)</b>	<b>Armeen CD (%BOD/ThOD)</b>	<b>Sodium Acetate (%BOD/ThOD)</b>
5	42	69
15	42	75
28	56	90
42	74	--

Breakdown Products:

Remarks:

The validity of the test was demonstrated by 90% degradation of sodium acetate by day 28 and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.8.

**Conclusions**

The biodegradability of Amines, coco alkyl was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN CD. Report/Project No. CRL F91125. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed:

July 24, 2002

Order Number for Sorting:

88

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin CC 100 D (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: ≥96%  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline No. 301B: Ready Biodegradability, Modified Sturm Test (CO<sub>2</sub> Evolution)  
Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 29 days  
Inoculum: Activated sludge, domestic, non-adapted  
Remarks: Duplicate test mixtures were incubated in 5 L brown glass bottles at 22 ± 2 °C for 29 days. Test mixtures were 3 L and contained test substance (13 mg/l; ~ 10.1 mg C/l), filtrate of pre-conditioned activated sludge, and mineral medium as prescribed by Guideline. Before the test, mixtures were aerated with CO<sub>2</sub>-free air for 24 hours and aeration continued throughout test. Controls included: 1) inoculum blank; 2) positive control (sodium acetate (35 mg/l; ~10.2 mg C/l) with inoculum); and 3) toxicity control (test substance (13 mg/l), reference substance (35 mg/l) and inoculum). Released CO<sub>2</sub> was quantified by backtitration of residual Ba(OH)<sub>2</sub> with 0.05 N HCl on days 1, 3, 6, 8, 10, 13, 16, 20, 23 and 28.

#### Results

Degradation: The test substance was degraded 58% at day 28.  
Results: Based on the percent degradation, the test substance was classified as biodegradable, but not readily biodegradable as the criterion of >60% degradation within the 10 day window after start of degradation (10%) was not met.

Kinetic:

<b>Time (Days)</b>	<b>Genamin CC 100 D (%ThCO<sub>2</sub>)*</b>	<b>Genamin CC 100 D + Sodium Acetate (%ThCO<sub>2</sub>)</b>	<b>Sodium Acetate (%ThCO<sub>2</sub>)</b>
1	0	0	0
3	3	14	22
6	18	33	51
10	35	52	69
20	47	64	77
28	58	75	82
29**	61	80	85

\* Mean of two replicates calculated by reviewer.

\*\* After acidification with HCl.

Breakdown Products:

Not stated

Remarks:

The applied cell density was  $18 \times 10^5$  CFU/l, which is below the advised density in the guideline  $1 \times 10^7$  to  $1 \times 10^8$  cells/l; however, the results for the positive control indicate that the applied density provided a good test system.

**Conclusions**

The biodegradability of test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

1996. Genamin CC 100 D Ready Biodegradability, Modified Sturm Test. Hoechst, AG, Dr. U. Noack-Laboratorium.

**Other Available Reports****Other**

Last Changed:

August 14, 2002

Order Number for Sorting:

88b

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen CD, Distilled coco primary amine  
(CAS RN 61788-46-3; Amines, coco alkyl).  
Purity: 99%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: Closed Bottle Biodegradability (CO<sub>2</sub> test)  
GLP: Not stated  
Year: 1979  
Contact Time: 28 days  
Inoculum: Raw settled sewage (Duffel sewage treatment plant, Tricking filter, Belgium).  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 2.5-L flasks containing 2 L of test suspension. One bottle was prepared for each of the following treatments: 1) test substance at 10 mg/L, and 2) reference substance (dextrose) at 10 mg/L. Due to the low solubility of the test substance, no stock solution was made; the test substance was added directly to the test bottles (as is). Degradation was monitored on days 3, 8, 13, 16, 20, 24 and 28, and was expressed as percent theoretical carbon dioxide (% TCO<sub>2</sub>).

#### Results

Degradation: The biodegradation of the test substance was 91.1% as TCO<sub>2</sub> at day 28. The test substance was shown to be readily biodegradable at 10 mg/L, in spite of low water solubility.

Results:

Time (Days)	Test Substance (% TCO <sub>2</sub> )	Dextrose (% TCO <sub>2</sub> )
3	7.5	56.0
8	12.2	82.2
13	39.9	90.3
16	49.4	91.3
20	63.4	93.7
24	74.0	95.0
28	91.1	95.0

Kinetic:

Breakdown Products: Not stated

Remarks: The validity of the test was demonstrated by the 95% degradation of dextrose to TCO<sub>2</sub>.

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1B  
Remarks: Reliable without restrictions; comparable to guideline study

**References** De Henau, H. and N.T. de Oude. 1979. CO<sub>2</sub> Production on Distilled Coco Primary Amine. Procter & Gamble European Technical Center, Brussels. Unpublished report (No. 7823.01.01, ETS No. 41).

**Other Available Reports**

**Other**

Last Changed: September 18, 2003  
Order Number for Sorting: 325  
Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Cocodimethylamine, distilled (CAS RN 61788-93-0;  
Amines, coco alkyldimethyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Methods corresponded to OECD Guideline 301D:  
Ready biodegradability, Closed Bottle Test, and EEC  
Official Journal of the European Communities L251,  
1984, Part C, Method C.6. Degradation-biotic  
degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1991  
Contact Time: 28 days  
Inoculum: Secondary activated sludge  
Remarks: The test assessed the biodegradability of the test  
substance in the Closed Bottle Test. The test was  
performed in 280-ml BOD bottles. Duplicate bottles  
were prepared for each of the following treatments:  
1) control blank without inoculum, 2) control with  
inoculum, 3) test material at 2 mg/l, and 4) reference  
substance (sodium acetate) at 6.7 mg/l). All solutions  
were prepared in mineral nutrient solution. Inoculum  
was preconditioned in the laboratory by aerating the  
activated sludge for one week, then diluting to a  
concentration of 2 mg dry weight/l in the BOD bottles.  
Dissolved oxygen concentrations in the BOD bottles  
were measured on days 0, 5, 15 and 28.  
Biodegradation was calculated as the ratio of the  
biochemical oxygen demand to the theoretical oxygen  
demand (ThOD) based upon the chemical structure of  
the test substance. The ThOD of the test substance  
was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The biodegradation of the test substance was 81% at  
day 28.  
Results: The authors claim the test substance should be  
classified as readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	45	73
15	61	87
28	81	90

Breakdown Products:

Not stated

Remarks:

The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at day 28 was 6.8.

### Conclusions

The biodegradability of cocodimethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

### References

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN M2C. Report No. CRL F91068. Akzo Research Laboratories Arnhem, The Netherlands.

### Other Available Reports

### Other

Last Changed:

July 25, 2002

Order Number for Sorting:

127

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Cocodimethylamine, distilled (CAS RN 61788-93-0;  
Amines, coco alkyldimethyl)  
Purity: 99.5%  
Remarks:

#### Method

Method/Guideline followed: Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1991  
Contact Time: 28 days  
Inoculum: Secondary activated sludge  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15 and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The biodegradation of the test substance was 69% at day 28.

Results: The authors claim the test substance should be classified as readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	38	73
15	55	87
28	69	90

Breakdown Products:

Not stated

Remarks:

The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at day 28 was 6.8.

### Conclusions

The biodegradability of cocodimethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

### References

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMCD. Report No. CRL F91069. Akzo Research Laboratories Arnhem, The Netherlands.

### Other Available Reports

### Other

Last Changed:

July 25, 2002

Order Number for Sorting:

128

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Dicocomethylamine (CAS RN 61788-62-3; Amines, dicoco alkylmethyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Methods corresponded to OECD Guideline 301D: Ready biodegradability, Closed Bottle Test, and EEC Official Journal of the European Communities L251, 1984, Part C, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Secondary activated sludge  
Remarks: The test assessed the biodegradability of the test substance in the Closed Bottle Test. The test was performed in 280-ml BOD bottles. Duplicate bottles were prepared for each of the following treatments: 1) control blank without inoculum, 2) control with inoculum, 3) test material at 2 mg/l, and 4) reference substance (sodium acetate) at 6.7 mg/l). All solutions were prepared in mineral nutrient solution. Inoculum was preconditioned in the laboratory by aerating the activated sludge for one week, then diluting to a concentration of 2 mg dry weight/l in the BOD bottles. Dissolved oxygen concentrations in the BOD bottles were measured on days 0, 5, 15 and 28. Biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand (ThOD) based upon the chemical structure of the test substance. The ThOD of the test substance was 3.3 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The biodegradation of the test substance was 82% at day 28.  
Results: The authors claim the test substance should be classified as readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	15	69
15	67	75
28	82	90

Breakdown Products:

Not stated

Remarks:

The validity of the test was demonstrated by the oxygen consumption in the control bottle with sodium acetate and an endogenous respiration of 0.3 mg/l. The pH of the medium at day 28 was 6.7.

**Conclusions**

The biodegradability of dicocomethylamine was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN M2C. Report No. CRL F91122. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed:

July 24, 2002

Order Number for Sorting:

126

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Ethomeen C/12 (CAS RN 61791-31-9; Ethanol, 2,2'-iminobis-, N-coco alkyl derivs.)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test. Modifications to the method were described in Blok et al. (1985).

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1989  
Contact Time: 42 days  
Inoculum: Activated sludge.  
Remarks: Two tests were run, the first test used inoculum originating from a municipal sewage treatment plant, while the second test used a composite inoculum originating from several industrial wastewater treatment plants. The sludge was preconditioned by aerating a sludge suspension (s.s) of 1 g s.s./l in dilution water for a period of three days. Sludge was diluted to a concentration of 3 mg s.s./l for use in the test. The test substance was poorly water soluble, and emulsions were made in stock solutions using Genapol PF-40 and nonylphenol ethoxylate. The emulsifiers are non-toxic to bacteria and not biodegradable under test conditions. Each biodegradation test was set-up using three replicates of each of the following treatment groups: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution with sodium acetate as a biodegradable reference material, 3) mineral nutrient solution with emulsifier, and 4) mineral nutrient solution with test substance at 1.0 mg/l (for the domestic sludge test) or at 2.4 mg/l (for the industrial sludge test). On days 0, 14, 28, and 42, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the COD (x 100) of the test substance.

#### Results

Degradation: Domestic sludge test:  
The test substance was degraded by 61% by day 28

and 62% by day 42.

Industrial sludge test:

The test substance was degraded by 61% by day 28 and 60% by day 42.

Results:

The test substance may be regarded as readily biodegradable.

Kinetic:

<b>Biodegradation with Industrial Sludge</b>		
<b>Time (Week)</b>	<b>Test Substance (% BOD/COD)</b>	<b>Sodium Acetate (% BOD/COD)</b>
2	44	81
4	61	83
6	60	85

<b>Biodegradation with Domestic Sludge</b>		
<b>Time (Week)</b>	<b>Test Substance (% BOD/COD)</b>	<b>Sodium Acetate (% BOD/COD)</b>
2	24	81
4	61	83
6	62	85

Breakdown Products:

Not stated

Remarks:

The tests were considered valid due to the reference compound sodium acetate being degraded to >80% by day 13.

**Conclusions**

The biodegradability of Ethomeen C/12 has been adequately characterized by this study. In addition, biodegradation was demonstrated for municipal and industrial activated sludge sources. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Balk, F. and E.E. Hantink-de Rooij. 1989. Biodegradability of ETHOMEEN C/12. Study/Report No. F89012. Akzo Corporate Research.

**Other Available Reports**

**Other**

Last Changed:

July 26, 2002

Order Number for Sorting:

108

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Ethomeen HT/12  
(CAS RN 61791-31-9; Mono tallow amine 2-ethoxy).  
Purity: 91.6%  
Remarks:

#### Method

Method/Guideline followed: EEC Directive 79/831 Annex V (Method ENV/283/80 Rev 3 modified Sturm test)  
Test Type: CO<sub>2</sub> production  
GLP: Not stated  
Year: 1981  
Contact Time: 42 days  
Inoculum: Activated sludge; not preacclimated.  
Remarks: A stock solution of the test substance was prepared with benzoic acid and distilled water with which two test vessels were spiked at 10 mg/L and one test vessel was spiked at 20 mg/L. Additionally, a solvent control (7.8 mg benzoic acid/L) and reference solutions (dextrose, 10 and 20 mg/L) were prepared. Each 2-L treatment solution was inoculated with non-acclimated activated sludge from Tienen sewage treatment plant and incubated in 2.5 L brown glass flasks. Biodegradation of the test substance was monitored initially for 28 days, then for an additional 14 days to allow CO<sub>2</sub> production to plateau.

#### Results

Degradation: At 10 mg/L, the test substance showed degradation of up to 85% (TCO<sub>2</sub>) after 28 days by inoculum with no preacclimation. At 20 mg/L, biodegradation was somewhat lower (65.1% TCO<sub>2</sub>) possibly indicating microbial toxicity at this concentration.

## Results:

<b>Material</b>	<b>Concentration (mg a.i./L)</b>	<b>Final % TCO<sub>2</sub></b>
Solvent Control	7.8	85.3 <sup>a</sup>
Reference Substance	10	88.3 <sup>a</sup>
	20	84.3 <sup>a</sup>
Test Substance	10	91.3 <sup>b</sup>
		81.9 <sup>b</sup>
	20	79.8 <sup>b</sup>

<sup>a</sup> Degradation plateaued on Day 28.<sup>b</sup> Degradation plateaued on Day 35.

## Kinetic:

## Breakdown Products:

Not stated

## Remarks:

The validity of the test was demonstrated by the ready biodegradation of the reference substance (84-88% within 28 days at both concentrations).

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

## Reliability:

1A

## Remarks:

Reliable without restriction; guideline study.

**References**

Remijnse, H., H. De Henau and N.T. de Oude. 1981.  
CO<sub>2</sub>P (CO<sub>2</sub> Production – Biodegradability test).  
Study/Report No. E8013.01.01, ETS No. 67. Procter  
& Gamble European Technical Center, Brussels.

**Other Available Reports****Other**

## Last Changed:

September 18, 2003

## Order Number for Sorting:

329

## Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: OEAS Removability Test  
GLP: Not stated  
Year: 1981  
Contact Time: 7 Days  
Inoculum: Tricking filter effluent, Duffel sewage treatment plant.  
Remarks: Three parallel OECD confirmatory test units were inoculated with trickling filter effluent. When the total suspended solids (TSS) reached 1.3 mg/l, unit B was dosed with 2 mg/l of active test substance and unit C was dosed with 100 mg/l of another formulation (equivalent to 1 mg/l active test substance). Unit A was run as a blank in order to allow analytical recovery studies. After a 3-day acclimation period, the test was continued for 11 days with (A) blank; (B) 5 mg/l active test substance; (C) 100 mg/l of another formulation (equivalent to 1 mg/l active test substance).

Influent and effluent were analyzed for COD and for the test substance response. Suspended solids (SS) and pH were analyzed. Standard additions of the test substance (10 and 100 µg/l) were made to blank effluents (Unit A) to assess analytical recovery.

#### Results

Average % recovery: >95%

Results:

	Unit B	Unit C
COD removal (%)	83.12 (n=7)	83.16 (n=7)
PH	7.2 (n=7)	7.5 (n=7)
SS (g/l)	2.1 (n=6)	1.7 (n=6)
Influent (µg/l)	6085 (n=9)	958 (n=9)
Effluent (µg/l)	91 (n=9)	26.7 (n=9)
Test Substance removal (%)	98.5 (n=9)	97.1 (n=9)

Kinetic:

Breakdown Products:

Remarks:

None stated

This compound was highly removable in this OECD confirmatory test (>95%), whether spiked at 5 mg/l (as

Unit B) or as comparable formulation (equivalent to 1 mg/l, Unit C). Average analytical recovery was 90.6% (n=8, std. dev. = 11.7).

**Conclusions**

The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2D

Remarks:

Reliable with restrictions; summary information provided.

**References**

De Henau, H. and H.T. de Oude. 1981. OEAS – Removability testing. Procter & Gamble ETC P&RS Laboratory. Unpublished report (No. E8013.01-05, ETS No. 67).

**Other**

Last Changed:

September 18, 2003

Order Number for Sorting:

347

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: River Water Die Away test  
GLP: Not stated  
Year: 1981  
Contact Time: 30 days  
Inoculum: River water of Zenne (Tubize).  
Remarks: The rate and extent of primary biodegradation of the test material was determined by primary analytical response using the TAPDATE method. A stock solution was made in benzoic acid (1.0/0.39 by weight). Four 5-l treatment flasks of river water were spiked at either 100 µg/l or 500 µg/l. The final test suspension volume was 4 l. One flask of each treatment concentration was incubated at 10°C and 20°C. All flasks were stirred twice daily for 10 minutes to ensure aerobic conditions. Samples were collected frequently throughout the 30-day (maximum) incubation period and analyzed for either the C<sub>16</sub> or C<sub>18</sub> homologue of the test material. Results were calculated as percent degradation during the test and plotted by computer in the best non-linear regression curve.

#### Results

Degradation: Both homologues of the test substance showed rapid and complete biodegradation under all 4 test conditions. Generally, ~90% degradation was observed within approximately 4 days. However, the degradation rate was notably lower in the 500 µg/l treatment flask incubated at 10°C, yielding >90% degradation by approximately day 8. Oxygen saturation was confirmed in all test solution by regular dissolved oxygen readings.

Results:

Test Conditions <sup>1</sup>		C <sub>16</sub> Homologue			C <sub>18</sub> Homologue		
Spiking Concentration (mg/l)	Temp. (°C)	a	B	c	a	b	c
100	10	90.72	1.08	0.32	89.68	1.30	0.91
100	20	91.95	1.10	0.00	93.62	0.77	0.36
<b>500</b>	<b>10</b>	<b>98.11</b>	<b>0.61</b>	<b>0.53</b>	<b>100</b>	<b>0.42</b>	<b>0.91</b>
500	20	96.94	1.14	0.01	96.02	1.60	0.68

a = extent of degradation (maximum %)

b = rate constant (time -1)

c = log time prior to degradation

<sup>1</sup> **bold** = effect of cold temperature was perceivable at higher concentration.

Kinetic:

Breakdown Products:

Not stated

Remarks:

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2D

Remarks:

Reliable with restrictions; summary information  
provided.

**References**

De Henau, H. and H.T. de Oude. 1981. RWDA test  
on ETHOMEEN HT/12. Procter & Gamble ETC  
P&RS Laboratory. Unpublished report (No.  
E8013.01.06, ETS No. 67)

**Other Available Reports****Other**

Last Changed:

September 18, 2003

Order Number for Sorting:

348

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen HTD (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: 99.2%  
Remarks:

#### Method

Method/Guideline followed: Methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Secondary activated sludge from the RWZI Nieuwgraaf in Duiven.

Remarks: Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15 and 28, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: 75% at Day 28 in the Closed Bottle Test.  
Results: Based on the percent degradation, the test substance was classified readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Armeen HTD (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	34	73
15	58	87
28	75	92

Breakdown Products:

Not stated

Remarks:

The validity of the test was demonstrated by complete mineralization of sodium acetate and an endogenous respiration of 0.6 mg/l. The pH of the medium at Day 28 was 6.9.

**Conclusions**

The biodegradability of Armeen HTD was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN HTD. Report/Project No. CRL F91050. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed:

July 23, 2002

Order Number for Sorting:

78

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: NORAM SH (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: 97%  
Remarks:

#### Method

Method/Guideline followed: ISO DIS 9439 which is in agreement with OECD  
Guideline No. 301B: Ready Biodegradability  
Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 48 days  
Inoculum: Domestic sewage  
Remarks: Duplicate test mixtures (in 3 liter flasks) were  
incubated at constant temperature ( $20 - 25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ )  
for 48 days with continuous stirring. Test mixture  
contained: test substance (50 mg/l, ~40 mg  $\text{ThCO}_2$ /l);  
volatile solvent (1,1-dichloro-1-fluoroethane);  
emulsifying agent (Symperonic P103, 25 mg/L);  
mineral medium (as prescribed in OECD 301);  
inoculum from domestic wastewater treatment plant  
( $1 \times 10^6$  bacteria/l). Flasks were aerated before the test  
with  $\text{CO}_2$ -free air. Three barium hydroxide  
(0.0125 M) traps were connected to collect  $\text{CO}_2$ . The  
following controls were included: inoculum blank,  
positive control [sodium benzoate (10.4 g/l) with  
inoculum], emulsifier control (emulsifying agent with  
inoculum), and toxicity control (test substance and  
sodium benzoate with inoculum). The three traps were  
replaced and analyzed for  $\text{CO}_2$  on day 0, 1, 4, 6, 8, 11,  
15, 19, 22, 25, 28, 33, 40, 47 and 48. Corrections were  
made for  $\text{CO}_2$  in emulsifier control. Only results up to  
day 28 are provided in this summary.  
No abiotic control was included.

#### Results

Degradation: 64% at Day 28  
Results: Based on the percent degradation, the test substance  
was classified biodegradable but not readily  
biodegradable because the criterion of degradation  
>60% within 10 day window after start of  
biodegradation phase (10%) was not met.

**Kinetic:**

<b>Time (Days)</b>	<b>NORAM SH (% degradation)</b>	<b>Sodium Benzoate (% degradation)</b>
0	0	0
4	11	52
15	50	66
22	60	67
28	64	66

**Breakdown Products:**

Not stated

**Remarks:**

The emulsifying agent was not biodegraded and was not inhibited. Report did not state that test was performed in the dark, but since an adaptation phase is observed during which no degradation yielding CO<sub>2</sub> occurs, photodegradation is not expected to have occurred. In the method description, carbon content of sodium benzoate is said to be 58.3%, whereas in the table and further calculations it is said to be 57.7%. A reviewer calculated the correct value to be 58.3%; however, criterion of >60% within 28 days of ThOD is still met when the correct value is used.

**Conclusions**

The biodegradability of NORAM SH was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality****Reliability:**

1A

**Remarks:**

Reliable without restriction; guideline study.

**References**

Boutonnet, J.C. 1994. NORAM SH Détermination de la biodégradabilité facile, essai de dégagement de CO<sub>2</sub>. [Determination of the ready biodegradability, CO<sub>2</sub> evolution assay] Report No. 4656/92/A. ELF Atochem.

**Other Available Reports****Other****Last Changed:**

August 13, 2002

**Order Number for Sorting:**

78e

**Remarks:**

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Tallowdimethylamine, distilled (hydrogenated tallow-alkyl) [CAS RN 61788-95-2; Amines, (hydrogenated tallow alkyl) dimethyl]  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability  
GLP: Yes  
Year: 1991  
Contact Time: 42 days  
Inoculum: Secondary activated sludge from the RWZI Nieuwgraaf in Duiven  
Remarks: Secondary activated sludge was collected and preconditioned in the laboratory by aerating the material for a period of one week. Sludge was diluted to a concentration of 2 mg dry weight/l. Treatment groups included: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test material (2.0 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate (reference substance at 6.7 mg/l) and with inoculum. The test was carried out in 280-ml BOD bottles with two replicate bottles per experimental group. On days 0, 5, 15, 28, and 42, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD (ThOD) based on the formula of the chemical. The ThOD of the test substance was 3.2 g O<sub>2</sub>/g test substance.

#### Results

Degradation: The degradation of the test substance was 58% at day 28 and 66% at day 42.  
Results: Based on the percent biodegradation, the test substance was considered to be readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Armeen M2C (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	27	69
15	47	75
28	58	90
42	66	--

Breakdown Products:

Remarks:

Not stated

Validity of the test was demonstrated by the oxygen consumption in the sodium acetate reference treatment and by an endogenous respiration of 0.3 mg/l. The oxygen depletion in the bottle without inoculation exceeded the values laid down in the guideline slightly. The pH of the medium on day 28 was 7.0.

**Conclusions**

The biodegradability of amines, (hydrogenated tallow alkyl) dimethyl was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

Remarks:

1A

Reliable without restriction; guideline study.

**References**

van Ginkel, C.G. and C.A. Stroo. 1992. Biodegradability of ARMEEN DMHTD. Study/Report No. CRL F91119, Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports****Other**

Last Changed:

Order Number for Sorting:

Remarks:

July 25, 2002

105

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin SH 200 [CAS RN 61789-79-5; Amines, bis(hydrogenated tallow alkyl)]  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Guideline 92/69/EWG (Part C.4-D), EG Official Gazette L 383 A and the OECD Guideline 301 F (“Respirometric Method”)  
Test Type: Ready biodegradability  
GLP: Yes  
Year: 1995  
Contact Time: 28 days  
Inoculum: Activated sludge from Communal Purification Plant in Frankfurt am Main, Sindlingen  
Remarks: The test assessed the ready biodegradability of the test substance using the Respirometric Method. Centrifuged sediment from activated sludge was washed, re-centrifuged, re-suspended and used as the inoculum. Pretreatment included seven days aeration under stirring. Because of the minimal solubility of the test substance, no stock solution was prepared. Instead, the BOD was determined by weight. BOD [Direct weighing-in =  $3.08 \times 10^3$  mg/g (O<sub>2</sub>)]. 32.5 mg/l of the test substance was placed in each of three BOD bottles. The BOD of the test substance was 100 mg O<sub>2</sub>/l in each bottle. Incubation occurred at  $22 \pm 1^\circ\text{C}$ . The composition of the reaction medium complied with the cited EEC directive. The activity of the inoculum was checked by using a reference assay and the control was an assay without test substance. Reaction vessels were BOD bottles and they were incubated in a WTW BOD Machine. The biodegradability analysis was achieved by manometric calculation of the oxygen demand.

#### Results

Degradation: The biodegradability of the test substance reached 16% after 28 days.  
Results: The oxygen demand of the reference substance reached > 60% in less than 10 days after adaptation. In the assays containing test substance the adaptation phase in which the demand reached 10%, was 20 days. The rate of oxygen demand reached a value in the range

of 10 to 30%.

Kinetic:

<b>Time (Days)</b>	<b>% O<sub>2</sub></b>
3	2
10	5
17	7
21	12
28	16

Breakdown Products:  
Remarks:

Not stated

### Conclusions

Genamin SH 200 is not readily, but very slowly or partially biodegradable. (Author of report)  
Due to inconsistency with related chemicals it is considered possible that solubility of the test substance was inadequate for biodegradation. Similar studies frequently employ surfactants to suspend the test material and greater degradation is observed. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:  
Remarks:

1A  
Reliable without restriction; guideline study.

### References

Voelskow, H. and K. Demming. 1996. Study on the Ready Biodegradability of Genamin SH 200. Study Number 95-0060-45. Hoechst AG.

### Other Available Reports

#### Other

Last Changed:  
Order Number for Sorting:  
Remarks:

June 7, 2002  
131c

### 3.5 BIODEGRADATION

#### Test Substance

Identity: NORAM M2SH (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: AFNOR NF T 90-306 in compliance with Method C5 of the European Commission of Communities 84/449/CEE (Modified Sturm Assay)

Test Type: Aerobic biodegradation  
GLP: Not stated  
Year: 1991  
Contact Time: 28 and 40 Days  
Inoculum: Secondary effluent of the residential waste water treatment facility of Versailles (final concentration of bacteria in the test medium was  $4 \times 10^6$  bacteria/ml)

Remarks: The determination of the ultimate aerobic biodegradability of the test substance was made using the CO<sub>2</sub> evolution method. The test was conducted using the test substance, a reference substance (sodium acetate), or a mixture of the two (to study possible inhibitory effects). Since the test substance was insoluble in water, it was tested as an emulsion in Symperonic 94 and Symperonic P103. Specifically, the test included the following: 1) duplicate blanks consisting of medium only; 2) duplicate samples of the test substance (19.8 mg/l organic carbon); 3) the positive control, Na Acetate (19.9 mg/l organic carbon); 4) the test substance and Na Acetate, which served as the inhibition control (19.8 and 19.9 mg/l organic carbon, respectively); and 5) one flask containing Symperonic 94 and Symperonic P103 (5.8 mg/l each), which served as the emulsion control. Solutions were freshly prepared in glass flasks connected to CO<sub>2</sub> traps and incubated at 30 to 35°C. Ultimate biodegradability of the test substance was determined after 28 and 40 days. The following deviation from the method was noted: The method assumes the test substance is water soluble. The emulsions were made according to the method described in the guideline. This deviation was believed not to affect the verification of the aerobic biodegradation of the test substance. CO<sub>2</sub> was quantified from trapping solutions by titration with

HCl (0.05 M) after making the solution alkaline. The traps contained 0.05 M Ba(OH)<sub>2</sub> to react with the evolved CO<sub>2</sub> to form BaCO<sub>3</sub> precipitate in the traps. The amount of CO<sub>2</sub> trapped was determined by the amount of Ba(OH)<sub>2</sub> remaining. Following 28 days, after replacement of the traps, the solutions were acidified to decompose the carbonates and bicarbonates; and aeration continued for 24 hours to collect all CO<sub>2</sub> in the last trap. Total evolved CO<sub>2</sub> in the test material, positive control, inhibition control, and emulsion control samples was calculated by the difference in the test and appropriate controls.

### Results

Degradation:  
Results:

75% at 28 days; 85% at 40 days

The guideline criteria for the test were met. The test substance did not inhibit the bacteria with > 25% degradation in the inhibition control at 28 days (89% actual). The degradation of the positive control, Na Acetate, was > 50% at 28 days (100% actual). The difference at the 28<sup>th</sup> day in the % degradation in the emulsion control was < 30%. The emulsion control showed that the emulsion did not affect the CO<sub>2</sub> evolution of the test substance.

Kinetic:

Time (Days)	Test Substance (% BOD/ThOD)	Sodium Acetate (% BOD/ThOD)
2	1	39
7	38	77
12	56	94
26	74	103
33	78	104
43	85	102

Breakdown Products:  
Remarks:

None stated

### Conclusions

The test substance was readily biodegradable based on > 60% degradation in 28 days. (Author of report)  
The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:  
Remarks:

1A  
Reliable without restriction; guideline study.

## References

Boutonnet, M. 1991. Evaluation en milieu aqueux de la biodegradabilite aerobie “ultime” du Noram M2SH DNS; Methode par analyse du dioxyde de carbone degage.. [Evaluation of the aqueous aerobic ultimate biodegradability of Noram M2SH DNS using the CO<sub>2</sub> evolution method] in Report No. 34028. Atochem D.R.D.I.

## Other

Last Changed:

July 25, 2002

Order Number for Sorting:

103b

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen M2HT (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 97.3%  
Remarks:

#### Method

Method/Guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Closed Bottle Test.

Test Type: Aerobic Ready Biodegradability

GLP: No, but the document incorporated many GLP characteristics

Year: 1987

Contact Time: 42 days

Inoculum: Activated sludge

Remarks: The closed bottle test was carried out in 280-ml glass BOD bottles. Inoculum originated from an activated sludge municipal wastewater treatment plant. The sludge was preconditioned by aerating a sludge suspension (s.s) of 1 g s.s./l in dilution water for one week in order to reduce high residual respiration rates. The density of the inoculum in the test was 3 mg s.s./l. The dilution water was the medium as prescribed by the test guideline without ammonia. Because the test substance was not soluble in water, the test substance was emulsified with a nonbiodegradable emulsifier (Genapol PF40) and nonylphenol ethoxylate (10E05PO) and a stock solution was made. Stock solution was added to a mineral nutrient solution to achieve a test substance concentration of 1.6 mg/l. Due to the preparation method, the concentration might have been up to 10% less than 1.6 mg/l.) Additional test groups included sodium acetate as a reference substance in addition to the test substance with emulsifier and a blank, which contained mineral nutrient solution without test chemical. Each experimental group was run in triplicate BOD bottles, and dissolved oxygen measurements were carried out on days 0, 14, 28, and 42. To determine biodegradation, the measured COD was used for the calculations to determine biodegradation (BOD/COD). COD was determined according to the Kelkenberg method. The COD of the test suspension was 4.76 mg O<sub>2</sub>/l.

**Results**

Degradation: Biodegradation of the test substance reached 86% after 14 days and 102% after 28 days.

Results: The test substance was shown to be readily biodegradable.

Kinetic:

<b>Time (Days)</b>	<b>Armeen M2HT (% BOD/COD)</b>
14	86
28	102
42	99

Breakdown Products: Not stated

Remarks: The emulsifier was shown to be non-biodegradable and no toxicity was seen as evidenced by biodegradation of sodium acetate. The extremely high biodegradation values may be explained by an overestimation of the concentration of Armeen M2HT in the test suspension. (Author of report)

**Conclusions**

The biodegradability of Armeen M2HT was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A

Remarks: Reliable without restriction; guideline study.

**References**

Balk, F. and E.E. Hantink-De Rooij. 1987. Biodegradability of a Number of Nitrogen Derivatives (MU-30, Akzo Chemie). Unpublished Report, Project No. T 86-6-1. Akzo, Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed: July 25, 2002

Order Number for Sorting: 98

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methyl amine).  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: Biodegradability (CO<sub>2</sub> Production test)  
GLP: Not stated  
Year: 1981  
Contact Time: 53 days  
Inoculum: 1% by volume supernatant of homogenized activated sludge (generated from control SCAS units of a non-acclimated semi-continuous activated sludge system).  
Remarks: The melted test substance was added by weight directly to heated test medium in 4-L test flasks and mechanically mixed. The 2-L test solutions were allowed to cool prior to the addition of the inoculum ( $1.4 \times 10^6$  cfu/mL) at test initiation. The evolution of carbon dioxide (CO<sub>2</sub>) was monitored through Day 52 for two test concentrations (10 and 20 mg/L, based on nominal additions of active ingredient of the test substance), a reference solution (20 mg dextrose/L) and a negative control. The flasks were incubated at 21-23°C for the duration of the study. Each treatment was analyzed for soluble organic carbon (SOC), while only the 1000-mg/L stock reference solution was analyzed for total organic carbon (TOC = 0.395 mg/mg).

#### Results

Degradation: The test was continued beyond the initial 25 days because the cumulative TCO<sub>2</sub> increased by >5% between days 21 and 25. CO<sub>2</sub> evolution was monitored weekly thereafter until production leveled off. The test substance was shown to be only moderately biodegradable at 10 or 20 mg/L (51.0% and 34.8%, respectively) by day 30. The test substance degraded an additional 13±0.5% by day 53.

Results:

<b>Material</b>	<b>Concentration (mg a.i./L)</b>	<b>Final % TCO<sub>2</sub><sup>a</sup></b>	<b>Final SOC (mg C/mg a.i.)<sup>a</sup></b>
(-) Control	--	--	1.1
Reference Substance	--	81.1	1.7
Test Substance	10	63.5	2.6
	20	48.3	1.9

<sup>a</sup> Day 55.

Kinetic:

Breakdown Products:  
Remarks:

Not stated  
The validity of the test was demonstrated by the ready biodegradation of the reference substance, with a calculated asymptotic TCO<sub>2</sub> of 82.2% and biodegradation rate of 0.12 d<sup>-1</sup>.

### Conclusions

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:  
Remarks:

2D  
Reliable with restrictions; summary information provided.

### References

Marks, K.M., N. Yeager and P.J. Marks. 1982. CO<sub>2</sub> Production Test on B0390.01 Non-Acclimated Study. Unpublished report for Procter & Gamble Company, Cincinnati, OH, USA by Weston.

### Other Available Reports

### Other

Last Changed:  
Order Number for Sorting:  
Remarks:

June 11, 2003  
326

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methyl amine).  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: CO<sub>2</sub> production  
GLP: Not stated  
Year: 1981  
Contact Time: 55 days  
Inoculum: 1% by volume supernatant of homogenized activated sludge (generated from control SCAS units of a non-acclimated semi-continuous activated sludge system).  
Remarks: The melted test substance was added by weight directly to heated test medium in 4-L test flasks and mechanically mixed. The 2-L test solutions were allowed to cool prior to the addition of the inoculum ( $5.8 \times 10^6$  cfu/mL) at test initiation. The evolution of carbon dioxide (CO<sub>2</sub>) was monitored through Day 52 for the following treatments in duplicate: two test concentrations (10 and 20 mg/L, based on nominal additions of active ingredient of the test substance), a reference solution (20 mg dextrose/L) and a negative control. The flasks were incubated at 22-24°C (16°C for 2 hr. during a power shutdown) for the duration of the study. Each treatment was analyzed for soluble organic carbon (SOC), while only the 1000-mg/L stock reference solution was analyzed for total organic carbon (TOC=0.410 mg/mg).

#### Results

Degradation: The test was continued beyond the initial 25 days because the cumulative TCO<sub>2</sub> increased by >5% between days 21 and 25. CO<sub>2</sub> evolution was monitored weekly thereafter until production leveled off (by day 55). The test substance was shown to be moderately biodegradable at 10 and 20 mg/L (averaging 57.4% and 58.4%, respectively, after 29 days). Additional degradation occurred to day 55.

Results:

Material	Concentration (mg a.i./L)	Final % TCO <sub>2</sub> <sup>a</sup>	Final SOC (mg C/mg a.i.) <sup>a</sup>
(-) Control	--	--	1.6
			<1
Reference Substance	--	104.0	1.0
		101.2	1.4
Test Substance	10	81.7	2.8
		75.2	1.0
	20	73.3	1.8
		72.6	1.3

<sup>a</sup> Day 55.

Kinetic:

Breakdown Products:  
 Remarks:

Not stated  
 The validity of the test was demonstrated by the ready biodegradation of the reference substance, with a calculated asymptotic TCO<sub>2</sub> of 101.4% (geometric mean of replicates) and biodegradation rate of 0.15 d<sup>-1</sup>.

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:  
 Remarks:

1B  
 Reliable without restrictions; comparable to guideline study

**References**

Marks, K.M., D. Therry and P.J. Marks. 1982. CO<sub>2</sub> Production Test on B0390.01 – Combination Study. Unpublished report for Procter & Gamble Company, Cincinnati, OH, USA by Weston.

**Other Available Reports**

**Other**

Last Changed:  
 Order Number for Sorting:  
 Remarks:

September 18, 2003  
 327

### 3.5 BIODEGRADATION

#### Test Substance

Identity: DTMA (CAS RN 61788-63-4; Dihydrogenated tallow methylamine).  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: SCAS pre-acclimation of inoculum.  
Test Type: Biodegradability (CO<sub>2</sub> test)  
GLP: Not Stated  
Year: 1981  
Contact Time: 37 days  
Inoculum: 1% by volume supernatant of homogenized activated sludge (generated from SCAS units of an 8-day acclimated semi-continuous activated sludge system).  
Remarks: The melted test substance was added by weight directly to heated test medium in 4-L test flasks and mechanically mixed. The 2-L test solutions (10 mg/L, based on nominal additions of active ingredient of the test substance) were allowed to cool prior to the addition of the inoculum (14x10<sup>6</sup> cfu/mL) at test initiation. Carbon dioxide (CO<sub>2</sub>) evolution was monitored through Day 37 to investigate further degradation.

#### Results

Degradation: The test substance was shown to be rapidly biodegradable (71.9%) after an initial 10-day lag.

Results:

Time (Days)	Test Substance (% TCO <sub>2</sub> )
3	0
6	0
10	7.6
15	27.2
21	44.9
24	68.5
28	70.47
34	71.9
37	71.9

Kinetic:

Breakdown Products: Not stated

Remarks:

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1B

Remarks:

Reliable without restriction; comparable to guideline  
study.

**References**

De Henau, H., N.T. de Oude and T.M. McCarthy.  
1980. CO<sub>2</sub> Production on Di(hydrogenated)tallow  
methylamine. Procter & Gamble European Technical  
Center, Brussels. Unpublished report (No.  
E7820.01.01, ETS No. 39).

**Other Available Reports**

**Other**

Last Changed:

September 18, 2003

Order Number for Sorting:

328

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methyl amine).  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Test Type: Semi-continuous activated sludge removal  
GLP: Not stated  
Year: 1982  
Contact Time: 7 Days  
Inoculum: Activated sludge, Lower Salford Treatment Plant; Lower Salford, PA.  
Remarks: Units of activated sludge were acclimated to laboratory conditions for nine days in semi-continuous activated sludge (SCAS) units, pooled, then redistributed among four units. Two units were dosed with influent feed consisting of a 20-mg/l test mixture, based on nominal addition of active ingredient, while the other two served as controls (influent feed contained no test substance). During preparation, the test mixture became slightly turbid and the test material tended to cling to glassware surfaces. The test units were incubated at  $23 \pm 1^\circ\text{C}$  for 7 days, during which the test substance concentration into and out of units was monitored. Four influent feed samples (two containing 20 mg/l nominal active ingredient and two controls) were collected on days 1 and 7. A 100-ml sample of effluent was collected daily from each test unit (n=28). All samples were preserved with 1% formalin and another sponsor-provided preservative for subsequent analysis by sponsor.

The removability of the test substance in SCAS units was assessed using an analytical method, identified as DBAS, which measured removal of a parent compound relative to the average influent concentration at initiation and termination. A second estimate of removal was based on organic carbon measurements in effluent (this measurement was considered to be less accurate).

## Results

Average % Removal:

Based on DBAS: 91.2% (82.6-99.8%)

Based on SOC: 99.6% (98.6-100.5%)

Results:

Time (Days)	Average % Recovery (DBAS)
1	85.2
2	90.8
3	89.7
4	92.4
5	95.4
6	97.3
7	90.9

Kinetic:

Breakdown Products:

None stated

Remarks:

The total organic carbon (TOC) was not within the prescribed 15% of theoretical TOC (1.10 mg TOC/mg active; 0.83 mg theoretical TOC/mg active) because the low solubility made it impractical to obtain a representative sample. Percent removal (DBAS) was based on an average measured influent concentration of 8.3 mg/l (Day 1=7.7 mg/l; Day 7=8.9 mg/l).

## Conclusions

The endpoint was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability:

2C

Remarks:

Reliable with restrictions; Analytical procedure is not defined in the report.

## References

Marks, K. H. and P. J. Marks. 1982. Determination of Ultimate Removability of B0390.01 Using the Semi-Continuous Activated Sludge Test. Unpublished report prepared for The Procter & Gamble Company, Cincinnati, OH, by Roy F. Weston, West Chester, PA.

## Other

Last Changed:

September 18, 2003

Order Number for Sorting:

346

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin TA 100 D (CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: 99%  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline 301B, Ready Biodegradability: Modified Sturm Test (CO<sub>2</sub> Evolution)  
Test Type: Aerobic biodegradation  
GLP: Yes  
Year: 1992  
Contact Time: 28 Days  
Inoculum: Activated sludge, domestic, from a municipal wastewater treatment plant, non-adapted, 1800 CFU/ml  
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the CO<sub>2</sub> evolution. The test was conducted in duplicate in brown glass bottles using the test substance (13 mg/l), a mineral medium (as described in guidelines) and activated sludge. The test temperatures were 22 ± 2°C. The following controls were also included: 1) a control without the test substance but with the inoculum (the inoculum blank, 3 flasks); 2) the positive control, sodium acetate (35 mg/l), and inoculum; and 3) a toxicity control. Released CO<sub>2</sub> was quantified by back-titration of residual Ba(OH)<sub>2</sub> with 0.05N HCl. On day 28, HCl was added to release all formed CO<sub>2</sub>. Test mixtures were aerated with CO<sub>2</sub>-free air for 24-hours prior to test and for the duration of the test.

#### Results

Degradation: 56% after 28 days  
Results: The guideline criteria for the test were met. Test substance is biodegradable, but not readily biodegradable.

Kinetic:

Time (Days)	Degradation (% ThCO <sub>2</sub> )		
	Test Substance	Sodium Acetate	Test Substance + Sodium Acetate
1	0	0	0
8	27	63	44
16	50	74	54
23	55	81	60
28	56	82	61
28*	61	85	65

\* After acidification with HCl.

Breakdown Products:

None stated

Remarks:

**Conclusions**

The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Reliable without restriction, guideline study.

Remarks:

**References**

Noack, M. 1996. Genamin TA 100 D Ready  
Biodegradability, Modified Sturm Test. Hoechst AG,  
Dr. U. Noack-Laboratorium

**Other**

Last Changed:

August 9, 2002

Order Number for Sorting:

211a

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Armeen TD (CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline 301D, Ready Biodegradability:  
Closed Bottle Test  
Test Type: Aerobic biodegradation  
GLP: Yes  
Year: 1992  
Contact Time: 42 Days  
Inoculum: Activated sludge, domestic, 2 mg/l dry matter  
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD in 280 ml bottles. The test was conducted in duplicate in 280 ml BPD bottles using the test substance (2 mg/l), a mineral medium (probably as prescribed by guidelines though without ammonium chloride) and activated sludge. The following controls were included: 1) a control without the test substance but with the inoculum (the inoculum blank); 2) the positive control, sodium acetate (6.7 mg/l), and inoculum; and 3) a blank without test substance or inoculum. O<sub>2</sub> consumed was measured electrochemically. The sludge was aerated for one week prior to the test. The pH on day 28 was 6.9.

#### Results

Degradation: >51% after 28 days  
Results: The guideline criteria for the test were met. The test material is biodegradable, but not readily biodegradable.

**Kinetic:**

<b>Time (Days)</b>	<b>Degradation (% BOD/ThOD(NH<sub>3</sub>))</b>	
	<b>Test Substance</b>	<b>Sodium Acetate</b>
5	47 (44)*	69
15	41 (38)	75
28	55 (51)	90
42	72 (67)	Not reported

\* Value in () = %BOD/ThOD(NO<sub>3</sub>), calculated by reviewer

**Breakdown Products:**

None stated

**Remarks:**

Based on the information provided in the article, could not check if OECD guidelines were followed, although stated that they were followed. The test temperatures were not mentioned. Not stated whether an abiotic control was included. Not stated whether test was performed in the dark so photodegradation cannot be ruled out.

**Conclusions**

The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality****Reliability:**

2D

Reliable with restrictions; photodegradation cannot be ruled out.

**Remarks:****References**

van Ginkel, C.G. and C.A. Stroo. 1992.  
Biodegradability of Armeen TD. Akzo Chemicals Internationals BV, Akzo Research Laboratories Arnhem.

**Other****Last Changed:**

August 9, 2002

**Order Number for Sorting:**

211b

**Remarks:**

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Tallow alkyl amine (CAS RN 61790-33-8)  
Purity: 99 - 100%  
Remarks:

#### Method

Method/Guideline followed: OECD Guideline 301F  
OECD Guideline 302B  
Test Type: Aerobic biodegradation  
GLP: No  
Year: 1981  
Contact Time: 42 Days  
Inoculum: Activated sludge, industrial waste water treatment plant, non-adapted, 470 mg/l dry matter  
Remarks: The determination of the ultimate aerobic biodegradability of the test substance was tested by measuring the BOD. The test was conducted in duplicate using the test substance [226 mg/l (~774 mg/l ThOD(NO<sub>3</sub>)) and 177 mg/l (~606 mg/l ThOD(NO<sub>3</sub>))], a mineral medium (probably as described in guideline) and activated sludge. The following controls were included: 1) a control without the test substance but with the inoculum (the inoculum blank); 2) the positive control, diethylene glycol (ThOD 288 mg/l) and inoculum were included. O<sub>2</sub> consumed was measured manometrically. Temperature during the 28 day test was 20 ± 1°C.

#### Results

Degradation: 73% after 28 days  
Results: The guideline criteria for the test were met. Test substance is inherently biodegradable.  
Kinetic:

Time (Days)	Degradation (% BOD/ThOD(NO <sub>3</sub> ))	
	Test Substance	Sodium Acetate
1	6 (6)*	28
5	38 (41)	36
10	57 (61)	82
15	71 (77)	101
20	66 (71)	98
28	73 (79)	101

\* Value in () = % ThOD(NH<sub>3</sub>).

Breakdown Products: None stated  
Remarks:

**Conclusions** The endpoint was adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**  
Reliability: 2D  
Remarks: Reliable with restrictions; photodegradation cannot be ruled out.  
Limited report based on archived data (1988). Cannot check if OECD guidelines were followed. Not stated whether test was performed in the dark so photodegradation cannot be ruled out. No abiotic control was included. Performance of the test is in compliance with OECD 301F, except for the inoculum, which comes from an industrial wastewater plant and is applied in the test at a concentration prescribed in the Zahn-Wellens test for inherent biodegradability (OECD 302B). The test has therefore been considered as a test on inherent biodegradability. Since the first measurement was not taken until day 1, adsorption could not be evaluated; however, adsorption could not have been substantial as the % elimination on day 1 was 6%. The test substance was tested in duplicate showing a large difference of extreme (38%) for the duplicates on day 28. According to OECD 301F, the test would therefore be invalid; however, it is acceptable for a test on inherent biodegradability.

**References** Voelskow. 1994. Pruefung der biologischen Abbaubarkeit von Genamin TA 100 D. [Ready Biodegradability Study with Genamin TA 100 D] Hoechst AG.

**Other**  
Last Changed: August 9, 2002  
Order Number for Sorting: 211c  
Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin TAP 100 (CAS RN 61791-55-7; Amines, N-tallow alkyltrimethylenedi-)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: 88/302/EWG (Part C); OECD Guidelines for testing of chemicals, Guideline 302 B.  
Test Type: Inherent biodegradability  
GLP: Not stated  
Year: 1990  
Contact Time: 28 days  
Inoculum: Activated sludge from the Hoechst purification plant  
Remarks: The test assessed the inherent biodegradability of the test substance using the Zahn-Wellens-Test. The inoculum was centrifuged activated sludge containing  $\approx$  480 mg/l dry weight. Test substance was added in the amount of 704 ml of stock solution to 2 L. The calculated start concentration was 200 mg C/l (DOC). The actual start concentration was 208 mg/l DOC.

#### Results

Degradation: The results do not allow a prediction on the ready biodegradability of the test substance.  
Results: Adsorption in activated sludge after three hours was 87%. DOC elimination in three hours was approximately 90%.  
Kinetics: Not stated  
Breakdown Products: Not stated  
Remarks: As a result of the high adsorption, no prediction on the biodegradation is possible. Expected elimination in industrial purification plants in approximately 90% due to the high adsorption. DOC degradation is not assignable.

#### Conclusions

Remarks: The results do not allow a prediction on the ready biodegradability of the test substance. (Author of report)  
Adsorption significantly affected the conduct and interpretation of this test. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Voelskow, H. 1990. Study of the Biodegradability in the Zahn-Wellens-Test. Report Number 90-0093-W-1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed:

June 7, 2002

Order Number for Sorting:

282

Remarks:

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Tallowbis (2-hydroxyethyl) amine  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: 98%

Remarks:

#### Method

Method/Guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 301D: Ready Biodegradability, Closed Bottle Test, and EEC, Official Journal of the European Communities, L251, Method C.6. Degradation-biotic degradation: Closed Bottle Test.

Test Type: Aerobic ready biodegradability

GLP: Yes

Year: 1990

Contact Time: 35 days

Inoculum: Activated sludge

Remarks: The closed bottle test was carried out in 280-ml glass BOD bottles. Activated sludge was preconditioned by aerating a suspension of the material for one week in order to reduce high residual respiration rates. The density of the inoculum in the test was 2 mg dry weight/l. The test substance was soluble at the test concentration, and an aqueous stock solution was prepared at 1.0 g/l. The biodegradation test was set-up using two replicates of each of the following treatment groups: 1) mineral solution without test material and without inoculum, 2) mineral nutrient solution without test material but with inoculum, 3) mineral nutrient solution with test substance (2 mg/l) and with inoculum, and 4) mineral nutrient solution with sodium acetate at 6.7 mg/l as a biodegradable reference material. On days 0, 5, 15, 28, and 35, dissolved oxygen concentrations were measured in each bottle. Biodegradation was calculated as the ratio of the BOD to the theoretical BOD of the test substance ( $\times 100$ ).

#### Results

Degradation: The percent biodegradation of the test substance was 52% at day 28 and 62% at day 35.

Results: The results indicate that the test substance should be classified as readily biodegradable. The plot of the biodegradation curve indicated that following a lag

phase of approximately 15 days, biodegradation of the test substance proceeded rapidly.

Kinetic:

<b>Time (Days)</b>	<b>Test Substance (% BOD/ThOD)</b>	<b>Sodium Acetate (% BOD/ThOD)</b>
5	0	79
15	0	83
28	52	88
35	62	--

Breakdown Products:  
Remarks:

Not stated  
The validity of the test was demonstrated by oxygen consumption in the bottles containing sodium acetate and an endogenous respiration of 0.4 mg/l. The pH of the medium was 6.8 on day 28.

### Conclusions

The biodegradability of Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs. was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:  
Remarks:

1A  
Reliable without restriction; guideline study.

### References

van Ginkel, C.G. 1990. Biodegradability of ETHOMEEN T/12. Report/Study No. CRL F90192. Akzo Research Laboratories Arnhem, The Netherlands.

### Other Available Reports

### Other

Last Changed:  
Order Number for Sorting:  
Remarks:

July 27, 2002  
111

### 3.5 BIODEGRADATION

#### Test Substance

Identity: Genamin SO 302 D (CAS RN 61788-91-8;  
Amines, dimethylsoya alkyl)  
Purity: Approximately 100%  
Remarks: The report included the CAS RN as 61788-93-0, which corresponds to the FND Amines category supporting chemical, Amines, dimethyl coco alkyl; however, based on the product name and chemical name it was ascertained that the correct CAS RN was 61788-91-8.

#### Method

Method/Guideline followed: OECD Guideline 301 F; EEC 84/449  
Test Type: Ready biodegradability  
GLP: Yes  
Year: 1992  
Contact Time: 28 days  
Inoculum: Activated sludge from the purification plant FfM-Sindlingen (communal).  
Remarks: The test assessed the ready biodegradability of the substance using the Closed Bottle Test. The BOD per gram of test substance equaled  $3.06 \times 10^3$  mg/g (O<sub>2</sub>), and was measured by directly placing the probe in the BOD bottle. This method delivers a restricted accuracy of the determined value. The DOC could not be measured because of the limited solubility of the test substance. Inoculum was added to the test vessels in the amount of 7 mg/l dry weight after being aerated and stirred in nutrient salt solution. The inoculum was not acclimatized to the test substance or the reference substance in the laboratory. An average of 11 mg/l of the test substance was added directly to the vessels. In relation to the theoretical COD = 35 mg/l (O<sub>2</sub>). In relation to the theoretical N-biological oxygen demand = 37 mg/l (O<sub>2</sub>). Incubation occurred at  $20 \pm 1^\circ\text{C}$ . The composition of the reaction medium corresponded to the requirements of the cited EEC Directive. The activity of the inoculum was evaluated by using a reference assay and a control with no addition of test substance. Reaction vessels were BOD Bottles incubated in WTW BOD machine. The degradation analysis occurred by manometric determination of the oxygen demand.  
Theoretical COD:  $3.19 \times 10^3$  mg/g (O<sub>2</sub>)  
Theoretical N-Biological Oxygen Demand:  $3.41 \times 10^3$  mg/g (O<sub>2</sub>).

## Results

Degradation: The oxygen demand in assays containing the reference substance reached oxygen consumption of > 60% in less than 10 days after adaptation. Length of adaptation phase (consumption < 10%): 5 days

Results: Genamin SO 302 D is readily biodegradable. (Author of report)

Kinetic:

Time (days)	Consumption - ThCOD (%)	Consumption – N-BOD (%)
7	33	31
14	47	44
21	59	55
28	98	91

Breakdown Products:

Not stated

Remarks:

The author stated the following: The evaluation barrier of 60% was exceeded. The “10 day window” (degradation within 10 days after adaptation) is not useful in the preceding case since the test substance is a blend of different chain lengths. These need different adaptation times. The adaptation times overlap and are not individually distinguishable. The control showed no sign of toxicity in the test concentration.

## Conclusions

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

## References

Voelskow, H. 1992. Short Report on the Study of the Ready Biodegradability of Genamin SO 302 D in the Respirometer Test. Report Number 92-0068-R1. Hoechst Aktiengesellschaft, Frankfurt, Germany.

## Other Available Reports

### Other

Last Changed:

June 7, 2002

Order Number for Sorting:

104a

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Sododecyloxypropylaminopropylamine  
(CAS RN 68479-04-9; 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched)

Purity: NA

Remarks:

##### Method

Method/guideline followed: Test methods were based on ASTM Standard 4729-80, Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians, and EPA-660/3-75-009, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.

Type: Static-renewal, renewal daily

GLP: Yes

Year: 1993

Species/Strain/Supplier: Fathead minnow (*Pimephales promelas*)/NA/FBS, Florida

Analytical Monitoring: NA

Exposure Period: 96 hours

Statistical Methods: LC<sub>50</sub> values calculated using a computer program that performs probit, moving average, and binomial methods.

Remarks: The test measured the acute toxicity of the test substance to fathead minnows. The test was conducted in 400-ml polypropylene cups filled with 300 ml of test solution. Ten fish were used in each of four replicate containers (40 fish per test concentration). Test solutions were renewed every 24 hours. The dilution water used in testing was spring water diluted with deionized water. Test concentrations were prepared by adding aliquots of an aqueous stock solution to moderately-hard spring water. Dissolved oxygen, pH, temperature and conductivity were measured daily in all test levels. A photoperiod of 16 hours light/8 hours dark was provided during testing. Alkalinity was measured initially in the control and all test concentrations. Dissolved oxygen ranged from 6.6 to 9.2 mg/l, pH ranged from 7.6 to 8.1, temperature remained steady at 21°C. Conductivity and alkalinity was not provided in the reviewed report. Test chambers were monitored for mortalities daily. Death was defined as the absence of movement.

## Results

Nominal concentrations (mg/l): 0 (control), 0.04, 0.07, 0.15, 0.3, 0.6, and 1.0 mg/l.  
Measured concentrations (mg/l): NA  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.16 mg/l (95% confidence limit of 0.139 to 0.186 mg/l)  
Remarks: Additional endpoints measured were:  
48-hour LC<sub>50</sub> = 0.172 mg/l (0.148 – 0.199 mg/l)  
96-hour NOEC = 0.07 mg/l

## Conclusions

Remarks: The 96-hour acute toxicity of fathead minnows to 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 1D  
Remarks: Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

## References

MacGregor, R., III. 1993. Alkyl Amine DA-16, Evaluation of the Static Renewal Acute Toxicity to *Ceriodaphnia dubia* and *Pimephales promelas*. Final Report No. ATR-30-93-034, Halliburton NUS Environmental Corporation, Houston, Texas, USA. EPA Document No. 88-930000335.

## Other Available Reports

### Other

Last Changed: July 27, 2002  
Order number for sorting: 118a  
Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin 12 R 100 D (CAS RN 124-22-1;  
Dodecylamine)  
Purity: >99.9%  
Remarks:

##### Method

Method/guideline followed: OECD Guideline 203, Fish, Acute Toxicity Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Supplier: Hoechst AG  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Dilution water was reconstituted water according to ISO/DIN 7346/1 with the following chemistry parameters: pH = 7.9 to 8.2; O<sub>2</sub> = 100%. The vehicle was ethanol. The study consisted of four separate tests performed within a period of one month under the same conditions and with comparable results. The four tests included:  
test 1: 0 (untreated), 0 (vehicle), 2.5, 3.5 mg/l  
test 2: 0 (untreated), 1.0, 1.8 mg/l  
test 3: 0 (untreated), 0.5, 0.71 mg/l  
test 4: 0 (untreated), 0.25, 0.35 mg/l  
Each test was run with 16-liter glass vessels containing 10 liters of test medium with 10 fish/treatment. The fish, measuring 26 – 34mm, were fed twice daily in the pretreatment but were unfed during the test. Throughout the test, the test temperature was 21 to 22°C, dissolved oxygen ≥ 69%, pH = 7.4 to 8.3 and the photoperiod was 12 at ~700 lux. The fish were evaluated for mortality and symptoms of toxicity.

##### Results

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle), 0.25, 0.35, 0.5, 0.71, 1.0, 1.8, 2.5, and 3.5 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.42 mg/l  
Remarks: At concentrations ≥0.5 mg/l, symptoms and 100%

mortality occurred. Fish exposed to 0.25 and 0.35 mg/l showed some symptoms but no mortality. Symptoms observed in these groups included swimming at the water surface with the nose up and decreased activity. Fish in the 0.5 to 2.5 mg/l groups exhibited the following symptoms: fish at the bottom or at surface, upside-down position, swimming with the nose up, decreased activity, irregular or increased respiration, open gill, dark discoloration, decreased fright reaction, turning and darting around with flight behavior. Additional endpoints included:

LC<sub>0</sub> = 0.35 mg/l

LC<sub>100</sub> = 0.5 mg/l

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

Remarks:

1D

Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Markert, Dipl.-Ing. and R. Jung. 1988. Genamin 12R 100D Pruefung der akuten Toxizitaet am Fisch Zebrabaerbling (*Brachydanio rerio*) ueber 96. [Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours.] Stunden 88.0256/87.1503. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

### Other Available Reports

#### Other

Last Changed:

June 24, 2002

Order number for sorting:

30b

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: FARMIN DM20 (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Approximately 97%.  
Remarks:

##### Method

Method/guideline followed: Not stated.  
Type: Static  
GLP: No  
Year: 1996  
Species/Strain/Supplier: Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon.  
Analytical Monitoring: Not stated.  
Exposure Period: 96 hours  
Statistical Methods: Non-linear interpolation between two concentrations, which bracket the 50% effect level.  
Remarks: The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. Groups of five fish were exposed to the test substance; mean wet-weight of the fish was 2.3 g and mean length was 5.8 cm. The test was conducted at 13.0 – 13.9 °C in treated tap water with the hardness of 216 to 244 mg/l as CaCO<sub>3</sub> and the pH in the range of 7.8 – 8.5. The test media were gently aerated during the test.

##### Results

Nominal concentrations (mg/l): 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.57 mg/l  
Remarks: At concentrations ≥1.0 mg/l, there was 100% mortality by 24 hours of exposure. At 0.32 mg/l, all fish exhibited treatment-related effects, including darkened pigmentation and immobility. At 100 mg/l, the test media was hazy; lower concentrations were clear and colorless.  
NOEC = 0.1 mg/l  
96-hour LC<sub>0</sub> = 0.32 mg/l  
96-hour LC<sub>100</sub> = 1.0 mg/l

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2A

Remarks:

Reliable with restrictions; acceptable, well documented  
study report which meets basic scientific principles.

**References**

Jenkins, C. A. 1996. FARMIN DM20: Acute Toxicity  
to Rainbow Trout. Report No. 96/KAS163/0891.  
Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.  
Including cover letter from High Point Chemical to  
U.S. E.P.A. concerning reference report.  
January 22, 1999.

**Other Available Reports**

**Other**

Last Changed:

June 12, 2002

Order number for sorting:

124a

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: FARMIN DM40 (CAS RN 112-75-4;  
1-Tetradecanamine, N,N-dimethyl)  
Purity: Approximately 97%.  
Remarks:

##### Method

Method/guideline followed: Not stated.  
Type: Static  
GLP: No  
Year: 1996  
Species/Strain/Supplier: Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon.  
Analytical Monitoring: Not stated.  
Exposure Period: 96 hours  
Statistical Methods: Non-linear interpolation between two concentrations, which bracket the 50% effect level.  
Remarks: The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 2.3 g and mean length was 5.7 cm. The test was conducted at 13.0 to 14 °C in treated tap water with a hardness of 234 to 252 mg/l as CaCO<sub>3</sub> and the pH in the range of 7.8 to 8.3. The media were gently aerated during the test. Water hardness slightly exceeded 250 mg/l recommended for this test but it was not thought to have affected the integrity of the test.

##### Results

Nominal concentrations (mg/l): 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.18 mg/l  
Remarks: At concentrations ≥3.2 mg/l, all fish were adversely affected exhibiting hyperventilation, darkened pigmentation and/or loss of coordination. At concentrations ≥1.0 mg/l there was 100% mortality after 24 hours exposure and at 0.32 mg/l there was 100% mortality after 48 hours. At 32 and 100 mg/l, the test media were hazy dispersions; other concentrations were clear and colorless.

NOEC < 0.1 mg/l  
96-hour LC<sub>0</sub> = 0.1 mg/l  
96-hour LC<sub>100</sub> = 0.32 mg/l

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2A

Remarks:

Reliable with restrictions; acceptable, well-  
documented study report which meets basic scientific  
principles.

**References**

Jenkins, C. A. 1996. FARMIN DM40: Acute Toxicity  
to Rainbow Trout. Report No. 96/KAS177/0230.  
Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.  
Including cover letter from High Point Chemical to  
U.S. E.P.A. concerning reference report.  
January 22, 1999.

**Other Available Reports**

**Other**

Last Changed:

June 12, 2002

Order number for sorting:

255

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin MY 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl)  
Purity: approximately 99%  
Remarks:

##### Method

Method/guideline followed: OECD 203; 84/449/EWG C.1.; UBA VV May 1984  
Type: Static  
GLP: Not stated  
Year: 1988  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period.

##### Results

Nominal concentrations (mg/l): 0 (control), 0.1 and 1 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> >0.1 and < 1.0 mg/l  
Remarks: Symptoms and 100% mortality occurred at 1 mg/l. At 0.1 mg/l symptoms, but no mortality occurred.  
Additional endpoints included:  
48-hour LC<sub>50</sub> >0.1 and < 1.0 mg/l;  
LC<sub>0</sub> = 0.1 mg/l after 48 and 96 hours,  
LC<sub>100</sub> = 1 mg/l; after 48 and 96 hours.

##### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with minimal details provided.

##### References

Jung, R. 1988. Short Report: Acute Fish Toxicity. Report Number 88.0057. Pharma Forschung Toxikologie, Germany.

## **Other Available Reports**

### **Other**

Last Changed: June 7, 2002

Order number for sorting: 259

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl)  
Purity: approximately 99%  
Remarks:

##### Method

Method/guideline followed: OECD 203; 84/449/EWG C.1.; UBA May 1984  
Type: Static  
GLP: Not stated  
Year: 1988  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Tween 80 was used as the solvent in the test chambers. The control group was exposed to Tween 80 at 0.1 ml/l.

##### Results

Nominal concentrations (mg/l): 0, 0.01, 0.1 and 1 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element value: LC<sub>50</sub>  
Statistical Results: The 48-hour LC<sub>50</sub> >0.01 mg/l and <0.1 mg/l  
The 96-hour LC<sub>50</sub> >0.01 mg/l and <0.1 mg/l  
Remarks: At 0.1 and 1 mg/l, symptoms and mortality occurred (100% each). At 0.01 mg/l, symptoms but no mortality occurred. LC<sub>0</sub> = 0.01 mg/l, after 48 and 96 hours; LC<sub>100</sub> = 0.1 mg/l after 48 and 96 hours.  
Additional endpoints included:  
LC<sub>0</sub> = 0.01 mg/l after 48 and 96 hours  
LC<sub>100</sub> = 0.1 mg/l after 48 and 96 hours

##### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with minimal details provided.

## References

Jung, R. 1988. Short report: Acute Fish Toxicity – Zebra Fish, 96 Hours, Static. Report Number 88.0115. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

## Other Available Reports

### Other

Last Changed:

June 7, 2002

Order number for sorting:

260g

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin 14 R 302 D (CAS RN 112-75-4; 1-Tetradecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

##### Method

Method/guideline followed: OECD Guideline 203  
Type: Static renewal  
GLP: Yes  
Year: 1992  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Not stated/Zoo-Stumpe, Hildesheim  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: "Methoden der Wasseruntersuchungen" Bd. II (1982), VEB Gustav Fischer Verlag, Jena.  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. Animals were kept in a temperature range of 20 – 23°C in diffused light ( $\approx 5.5 \mu\text{mol}/\text{m}^2$ , natural day periodic). The test water was changed weekly. The tap water was prepared by activated charcoal filtration followed by aeration in a light resistant container over at least 24 hours. Feeding occurred six times per week. Food amount consisted of 2% of the fish weight. Test vessels were 15-liter tanks covered with glass plates. Ten zebra fish were placed in each of nine vessels. A parallel control was run with dilution water without addition of test substance. A test with a reference substance was not performed. The test substance was tested in the following concentrations: 0; 0.032; 0.058; 0.10; 0.18 and 0.32 mg/l. Since 100% mortality was not achieved with these concentrations, the test substance was also tested at 0.58 and 1.0 mg/l. An additional parallel control group was tested with these two additional concentrations. The test substance was treated with ultrasound for 30 minutes at 40°C until emulsification. Mortality and behavior of the fish, as well as water pH, temperature and oxygen saturation were logged after 24, 48, 72 and 96 hours.

##### Results

Nominal concentrations (mg/l): 0; 0.032; 0.058; 0.10; 0.18; 0.32; 0.58 and 1 mg/l  
Measured concentrations (mg/l): Not determined

Unit: mg/l  
 Element Value: 96-hour LC<sub>50</sub>  
 Statistical Results: 96-hour LC<sub>50</sub> = 0.35mg/l  
 Remarks: At concentrations of 1.0 and 0.58 mg/l 100% mortality occurred at 24 hours. At 0.32 mg/l 20% mortality occurred at 72 and 96 hours. At 0.18 mg/l symptoms, but no mortality were observed. Oxygen saturation ranged from 65 – 99%; pH values ranged from 7.61 – 8.31 and temperature ranged from 20 – 23°C.  
 Other endpoints included:  
 96-hour LC<sub>0</sub> = 0.18 mg/l  
 96-hour LC<sub>100</sub> = 0.58 mg/l

Time (hours)	LC <sub>50</sub> (mg/l)	95% confidence limit
24	0.43	0.39 to 0.47
48	0.43	0.39 to 0.47
72	0.35	0.29 to 0.41
96	0.35	0.29 to 0.41

### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 1D  
 Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Bauer, S. and U. Noack. 1992. Acute Toxicity Test on Fish (Zebra Fish) of Genamin 14 R 302 D. Project Number 920703HK. Study no. FAZ29691. Dr. U. Noack-Laboratories for Applied Biology, Hildesheim, Germany.

### Other Available Reports

### Other

Last Changed: June 7, 2002  
 Order number for sorting: 260h  
 Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: FARMIN DM60 (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: Approximately 97%.  
Remarks:

##### Method

Method/guideline followed: Not stated.  
Type: Static  
GLP: No  
Year: 1996  
Species/Strain/Supplier: Rainbow trout (*Oncorhynchus mykiss*)/ Fish Network Ltd., Devon.  
Analytical Monitoring: Not stated.  
Exposure Period: 96 hours  
Statistical Methods: Non-linear interpolation between two concentrations, which bracket the 50% effect level.  
Remarks: The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 2.3 g and mean length was 5.8 cm. The test was conducted at 13.2 to 14 °C in treated tap water with a hardness of 234 to 250 mg/l as CaCO<sub>3</sub> and the pH in the range of 7.9 to 8.3.

##### Results

Nominal concentrations (mg/l): 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.18 mg/l  
Remarks: At concentrations ≥3.2 mg/l, all fish were adversely affected exhibiting hyperventilation, darkened pigmentation and/or loss of coordination. At concentrations ≥0.32 mg/l, there was 100% mortality after 24 hours exposure. At concentrations ≥3.2 mg/l, the test media were hazy or opaque dispersions; other concentrations were clear and colorless; at ≥0.32 mg/l there was froth on the surfaces.  
NOEC < 0.1 mg/l  
96-hour LC<sub>0</sub> = 0.1 mg/l  
96-hour LC<sub>100</sub> = 0.32 mg/l

### Conclusions

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

2C

Remarks:

Reliable with restrictions; comparable to guideline  
study with acceptable restrictions.

### References

Jenkins, C. A. (1996) FARMIN DM60: Acute  
Toxicity to Rainbow Trout. Report No.  
96/KAS177/0231. Huntingdon Life Sciences Ltd.  
Eye, Suffolk, UK.  
Including cover letter from High Point Chemical to  
U.S. E.P.A. concerning referenced report.  
January 23, 1999.

### Other Available Reports

#### Other

Last Changed:

June 12, 2002

Order number for sorting:

4a

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin 16 R 302 D (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl)  
Purity: approximately 99%  
Remarks:

##### Method

Method/guideline followed: OECD 203; 84/449/EWG C.1./ UBA VV May 1984  
Type: Static  
GLP: Not stated  
Year: 1988  
Species/Strain/Supplier: *Brachydanio rerio*/Not stated/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study tested the acute toxicity of the test substance to the Zebra Fish under static exposure conditions. Tween 80 was used as the solvent in the test chambers. The control group was exposed to Tween 80 at 100 mg/l.

##### Results

Nominal concentrations (mg/l): 0 (control), 0.1, 1.0 and 10 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> >0.1 mg/l and <1 mg/l  
Remarks: At 1 and 10 mg/l symptoms and death occurred. On the last study day, symptoms, but no mortality, occurred at 0.1 mg/l.  
LC<sub>0</sub> = 0.1 mg/l after 48 and 96 hours.  
LC<sub>100</sub> = 1 mg/l after 48 and 96 hours.

##### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with minimal details provided.

**References**

Jung, R. 1988. Short Report: Acute Fish Toxicity.  
Report Number 87.1814. Pharma Forschung  
Toxikologie, Germany.

**Other Available Reports**

**Other**

Last Changed: June 7, 2002

Order number for sorting: 4g

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: 94%  
Remarks:

##### Method

Method/guideline followed: Test methods conformed to U.S. EPA Ecological Effects Test Guideline: OPPTS 850.1085: Fish Acute Toxicity Mitigated by Humic Acid.  
Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: Fathead minnow (*Pimephales promelas*)/NA/SP Inc., Salem, Massachusetts  
Analytical Monitoring: Yes, in the control, low, mid and high test concentrations  
Exposure Period: 96 hours  
Statistical Methods: NA  
Remarks: The study measured the acute toxicity of the test substance to fathead minnows during a 96-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 10 and 20 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was synthetic water (Dutch Standard Water). Test fish were received from the supplier and held in the laboratory until testing. During holding, fish were fed a commercial fish diet one to three times daily, five to seven times per week. Fish were not fed during the test. The mean length and wet weight of fish used in the test were 2.1 cm and 0.16 g, respectively. The fish appeared in good health prior to the test. To prepare the test concentrations, an aqueous stock of the test substance (0.11 g/l) was made and aliquots of the stock were diluted with dilution water. Test vessels were 9.9-liter containers holding 5 liters of test solution. Concentrations were replicated twice, with each replicate holding 10 fish (20 per concentration). Fish loading per chamber was 0.32 g/l. The treatment groups were 0 (control), 0.05, 0.09, 0.15, 0.27, and 0.49 mg/l. The test solutions were prepared, the fish were randomly placed in the test solutions and the test vessels were randomly placed in

the testing area. All test vessels were covered with a glass plate during the test. Test solutions were aerated during the test period. The testing area had a lighting regime of 16 hours light/8 hours dark. Dissolved oxygen and pH were measured daily, and temperature was measured continuously. Concentrations were measured in the control, 0.05, 0.15, and 0.49 mg/l test groups at 0, 24, 48 and/or 96 hours. Mortality and sublethal effects were recorded at a minimum at 0, 24, 48, 72 and 96 hours. Fish were considered dead when a lack of opercular movement was observed. Sublethal effects included erratic swimming, loss of reflex, increased excitability, lethargy, changes in physiology, discoloration, pigmentation, excessive mucus production, hyperventilation, opaque eyes, curved spine and haemorrhaging. Water quality parameters measured in the dilution water included acidity (0.3 mmol/l), alkalinity (1.6 mmol/l), conductivity (607  $\mu\text{S}/\text{cm}$ ), water hardness (12.06° dH, equivalent to 215 mg  $\text{CaCO}_3/\text{l}$ ), total suspended solids (0.03 mg/l), and nonpurgeable organic carbon (1.022 mg/l). Dissolved oxygen ranged from 8.4 to 9.0 mg/l and pH ranged from 8.0 to 8.2. Endpoint results are given based on nominal concentrations.

## Results

Nominal concentrations (mg/l):	0 (control), 0.05, 0.09, 0.15, 0.27, and 0.49 mg/l
Measured concentrations (mg/l):	Measured concentrations were 13 to 82% below the nominal concentrations. The control water measured 0.014 mg/l at 0 and 96 hours; the 0.05 mg/l test level measured 0.032 and 0.018 mg/l at 0 and 96 hours, respectively; the 0.15 mg/l test level measured 0.12, 0.05, and 0.02 mg/l at 0, 24 and 48 hours, respectively; and the 0.49 mg/l test level measured 0.40 and 0.21 mg/l at 0 and 24 hours, respectively.
Unit:	mg/l
Element Value:	96-hour $\text{LC}_{50}$
Statistical Results:	96-hour $\text{LC}_{50} = 0.11$ mg/l (95% confidence limit of 0.09 to 0.15 mg/l)
Remarks:	Complete mortality occurred at 0.15, 0.27, and 0.49 mg/l. No mortality or sublethal effects were noted in the fish at concentrations up to and including 0.09 mg/l.

Additional endpoints included:

72-hour NOEC = 0.09 mg/l

24-h LC<sub>50</sub> = 0.12 mg/l (0.11 – 0.12 mg/l)

48-h LC<sub>50</sub> = 0.11 mg/l (0.09 – 0.15 mg/l)

72-h LC<sub>50</sub> = 0.11 mg/l (0.09 – 0.15 mg/l)

### Conclusions

Remarks:

The 96-hour acute toxicity of 9-Octadecen-1-amine to fathead minnows was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Mark, U.E., I.C.M. Garttner, M.G.J. Geurts, M.W.F. Nielen, C.A. Stroo and A.G.M. Kroon. 1995. Acute Toxicity of Oleylamine to *Pimephales promelas*. Report No. RGL F95031. Akzo Nobel Central Research, Arnhem, The Netherlands.

### Other Available Reports

#### Other

Last Changed:

July 17, 2002

Order number for sorting:

14

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin SH 301 (CAS RN 4088-22-6;  
1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: EG-Guideline C.1. Acute Toxicity to Fish; Guideline 85/559/EWG; OECD Guideline for testing of chemicals, 203 Fish, Acute Toxicity Test  
Type: Static  
GLP: Yes  
Year: 1987  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/HOECHST AG, Kastengrund  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: None  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish were held in dilution water for at least 14 days before the beginning of the study. Water was maintained at  $22 \pm 1^\circ\text{C}$  by using a water bath calibrated thermometer and with  $\geq 80\%$  oxygen saturation. Lighting regime was 12-hour day/night cycles at approximately 700 lux. Feeding was twice daily. Immediately before the study start, as representatives for the batch of fish, 10 fish from each of two trials were measured for body length. These fish were not used in the study. The mean body length of the fish was 2.8 cm.  
The study was conducted with the following concentrations of test substance: 0, 100 and 500 mg/l. Dilution water was reconstituted water mixed to provide a composition following ISP/DIS 7346/1. The prepared dilution water was saturated with oxygen and the pH was measured before each trial. The pH was between 8.0 and 8.1. Test vessels were 10-liter glass aquariums (30 x 22 x 24 cm). Vessels were not aerated during the entire test time.  
Since the test substance is insoluble in water and since no better distribution was achieved using solvents and emulators, the test substance and dilution water were homogenized using the Ultra-Turrax and ultrasonic bath. This solution was added to the test vessel while

being stirred with a glass stirring rod. Finally, the contents of the test vessels were stirred for approx. 2 hours with a KPG-stirrer and a glass stir rod. The test assays showed substance depositing on the water surface. 10 fish were randomly distributed in each test vessel and in the control vessel. During the entire study time, the fish were not fed. After 2, 4, 24, 48, 72 and 96 hours, mortality and visible changes in appearance and behavior were noted. Dead fish were removed from the vessels. Fish were counted as dead when breathing was no longer seen and the fish no longer responded to a light mechanical stimulation. Water parameters were also measured at these times. pH values ranged from 7.5 to 8.2 in the test groups and 7.6 to 8.1 in the control. Oxygen content was 6.8 to 9.0 mg/l in the test groups and 7.5 to 9.1 mg/l in the control. Temperature ranged from 21.6 to 22.0°C in the test groups and 21.5 to 22.0°C in the control groups.

## Results

Nominal concentrations (mg/l): 0, 100 and 500 mg/l  
 Measured concentrations (mg/l): Not determined  
 Unit: mg/l  
 Element Value: 96-hour LC<sub>50</sub>  
 Statistical Results: 96-hour LC<sub>50</sub> > 100 mg/l and < 500 mg/l  
 Remarks: In the 500 mg/l group, symptoms and 90% mortality were observed after 96 hours. The 100 mg/l group displayed symptoms, but no mortality. Due to the insolubility of the test substance, no analytical determination of the substance concentration in the test water was carried out.  
 Additional endpoints included:  
 48-hour LC<sub>50</sub> = 500 mg/l  
 48-hour LC<sub>0</sub> = 100 mg/l; 96-hour LC<sub>0</sub> = 100 mg/l

Concentration (mg/l)	Mortality			
	48 hours		96 hours	
	Absolute	Percent	Absolute	Percent
0	0/20	0	0/20	0
100	0/10	0	0/10	0
500	5/10	50	9/10	90

### Conclusions

Remarks:

The inability to dispense or solubilize the test substance may have resulted in lower mortality as seen with similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1D

Remarks:

Reliable with restriction; guideline study but only two concentrations tested.

### References

Markert, I. and R. Jung. 1991. Genamin SH 301: Orientation Test of the Acute Toxicity of Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 91.0956. Pharma Entwicklung Toxikologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

### Other Available Reports

#### Other

Last Changed:

June 7, 2002

Order number for sorting:

77f

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: FARMIN DM80 (CAS RN 124-28-7;  
1-Octadecanamine, N,N-dimethyl)  
Purity: Approximately 97%.  
Remarks:

##### Method

Method/guideline followed: Not stated.  
Type: Static  
GLP: Not stated  
Year: 1996  
Species/Strain/Supplier: Rainbow trout (*Oncorhynchus mykiss*)/Fish Network Ltd., Devon.  
Analytical Monitoring: No.  
Exposure Period: 96 hours  
Statistical Methods: Non-linear interpolation between two concentrations, which bracket the 50% effect level.  
Remarks: The study measured the acute lethal toxicity of the test substance to rainbow trout during a 96-hour exposure period. There were 5 fish/group; mean wet-weight of the fish was 0.88 g and mean length was 4.3 cm. The test was conducted at 13.4 to 16.3 °C in treated tap water with a hardness of 238 to 252 mg/l as CaCO<sub>3</sub> and the pH in the range of 7.9 to 8.4. The media was gently aerated during the test. Water hardness slightly exceeded 250 mg/l recommended for this test but it was not thought to have affected the integrity of the test.

##### Results

Nominal concentrations (mg/l): 0, 0.1, 0.32, 1.0, 3.2, 10, 32, and 100 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.18 mg/l  
Remarks: At concentrations ≥1.0 mg/l, there was 100% mortality after 24 hours exposure and at 0.32 mg/l there was 100% mortality after 48 hours. No sub-lethal, treatment-related effects were noted during the test. At ≥3.2 mg/l, the test media were hazy or opaque dispersions; other concentrations were clear and colorless.  
NOEC = 0.1 mg/l  
96-hour LC<sub>0</sub> = 0.1 mg/l  
96-hour LC<sub>100</sub> = 0.32 mg/l

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

2C

Remarks:

Reliable with restrictions; comparable to guideline  
study with acceptable restrictions.

**References**

Jenkins, C. A. 1996. FARMIN DM80: Acute Toxicity  
to Rainbow Trout. Report No. 96/KAS184/0232.  
Huntingdon Life Sciences Ltd. Eye, Suffolk, UK.  
Including cover letter from High Point Chemical to  
U.S. E.P.A. concerning referenced report.  
January 23, 1999.

**Other Available Reports**

**Other**

Last Changed:

June 12, 2002

Order number for sorting:

38c

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin 18 R 302 D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: Test methods conformed to OECD 203; 84/449/EWGC.1.; UBA VV, May 1984  
Type: Static  
GLP: Not stated  
Year: 1987  
Species/Strain/Supplier: *Brachydanio rerio*/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to the Zebra Fish.

##### Results

Nominal concentrations (mg/l): 0 (control), 0.1 and 1.0 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> >0.1 and <1.0 mg/l  
Remarks: Symptoms and mortality developed at 0.1 and 1.0 mg/l. Additional endpoints included:  
48-hour LC<sub>50</sub> >0.1 and <1.0 mg/l  
LC<sub>100</sub> = 1.0 mg/l  
LC<sub>10</sub> = 0.1 mg/l.

##### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with minimal details provided.

##### References

Jung, R. 1987. Short Report: Acute Fish Toxicity. Report Number 87.1464. Pharma Forschung Toxikologie, Germany.

## **Other Available Reports**

### **Other**

Last Changed: June 7, 2002

Order number for sorting: 38e

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Amine KK (CAS RN 61788-46-3;  
Amines, coco alkyl)  
Purity:  $\geq 94\%$   
Remarks:

##### Method

Method/guideline followed: OECD Guideline 203, Fish, Acute Toxicity Test  
Type: Semistatic  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: Onchorhynchus mykiss/Parkwood Trout Farm,  
Wigmore, Kent, UK  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: Thomson 1947.  
Remarks: The study measured the acute toxicity of the test substance to Rainbow Trout during a 96-hour exposure period. The vehicle was 1% Tween 80-acetone. Fish size:  $44 \pm 1$  mm;  $1.13 \pm 0.15$  g. Loading was 0.56 g/l. Fish were fed until 24-hours pretest but were unfed during the test. Ten fish per group were exposed to the test substance at concentrations of 0 (untreated control), 0 (vehicle control at 0.1 ml/l), 0.10, 0.18, 0.32, 0.56 and 1.0 mg/l for 96 hours with daily renewal. Dilution water was dechlorinated laboratory tap water with the following chemistry parameters: hardness = 50 mg CaCO<sub>3</sub>/l; TOC = 0.9 mg/l; Ca/mg ratio = 1/3; Na/K ratio = 24/1 and pH = 8.7. Test conditions were: temperature = 14°C; Dissolved oxygen = 95-97%; pH = 7.3 to 7.6; and photoperiod = 16 hours. Tests were conducted in glass aquaria with 20-l test medium and 10 fish/treatment.

##### Results

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle), 0.10, 0.18, 0.32, 0.56, 1.0 mg/l  
Measured concentrations (mg/l): NA  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.16 mg/l  
(95% confidence limit of 0.13 to 0.19 mg/l)

Remarks: No fish died at concentrations  $\leq 0.10$  mg/l. Seventy percent mortality occurred at the 0.18 mg/l concentration and 100% mortality at concentration  $\geq 0.32$  mg/l. Dose-related effects at concentrations  $\geq 0.18$  mg/l included loss of equilibrium, swimming at bottom, increased pigmentation and /or lethargy. NOEC = 0.10 mg/l

### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability: 1D  
Remarks: Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Handley, J.W. and P.M. Wetton. 1991. The acute toxicity of Amine KK to Rainbow trout (*Onchorhynchus mykiss*). Project No 116/69. Berol Nobel Nacka AB, Safepharm Laboratories.

### Other Available Reports

#### Other

Last Changed: June 26, 2002  
Order number for sorting: 91a  
Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin CC 100D (CAS RN 61788-46-3;  
Amines, coco alkyl)  
Purity: 99 - 100%  
Remarks:

##### Method

Method/guideline followed: OECD Guideline 203, Fish, Acute Toxicity Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/  
Hoechst AG  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: Probit Analyses (Linder and Weber, Fieller)  
Remarks: The study measured the acute toxicity of the test  
substance to Zebra Fish during a 96-hour exposure  
period. The vehicle was ethanol (concentration of  
vehicle/solvent = 0.1 ml/l).  
Fish size: 25 – 31mm.  
Fish were fed twice daily in the pretreatment but were  
unfed during the test.  
Five tests in 16-L glass vessels containing 10-L of test  
medium with 10 fish/treatment:  
test 1: 0 (untreated), 0 (vehicle), 10 mg/l  
test 2: 0 (untreated), 1.0 mg/l  
test 3: 0 (untreated), 0.35, 0.5 mg/l  
test 4: 0 (untreated), 0.01 mg/l  
test 5: 0 (untreated), 0.12, 0.18, 0.25 mg/l.  
Test conditions: temperature = 21 to 23°C; dissolved  
oxygen ≥65%; pH = 7.1 to 8.3; photoperiod = 12 hours  
at ~700 lux. The five separate tests were performed  
within a period of two months under the same  
conditions and with comparable results.

##### Results

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle), 0.01, 0.12, 0.18, 0.25, 0.35,  
0.5, 1.0, 10 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 0.24 mg/l  
(95% confidence limit of 0.20 to 0.30 mg/l)  
Remarks: At concentrations ≤0.12 mg/l all fish survived; 30%

mortality was noted at 0.18 and 0.25 mg/l; and 100% mortality was observed at concentrations  $\geq 0.35$  mg/l. Clinical signs were noted in 0.12 to 1.0 mg/l concentrations and included irregular respiration, decreased or increased activity, fish at bottom or surface, open gill, dark coloration, swim attitude with difficult tail, increased or decreased shock reaction, laying on the back, problems with the fins and/or convulsions.

Additional endpoints included:

LC<sub>0</sub> = 0.12 mg/l

LC<sub>100</sub> = 0.35 mg/l

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

Remarks:

1D

Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Markert, M. and R. Jung. 1988. Genaminox CC 100 D Pruefung der akuten Toxizitaet am Fisch Zebraerbling (Brachydanio rerio). [Genaminox CC 100D Acute toxicity study in Zebra fish (Brachydanio rerio)] Study No 88.0558/88.0093. Hoechst AG, Hoechst AG.

### Other Available Reports

#### Other

Last Changed:

June 26, 2002

Order number for sorting:

91b

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin CS 302 D (CAS RN 61788-93-0;  
Amines, coco alkyldimethyl)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: OECD 203, 84/449/EWG C.1. and UBA VV  
May 1984  
Type: Static  
GLP: Not stated  
Year: 1987  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Not stated/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period.

##### Results

Nominal concentrations (mg/l): 0, 0.1 and 1 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> > 0.1 mg/l and < 1 mg/l  
Remarks: At 1 mg/l symptoms and 100% mortality occurred.  
Fish exposed to 0.1 mg/l showed symptoms on the first test day.  
Additional endpoint included:  
48-hour LC<sub>50</sub> > 0.1 mg/l and < 1 mg/l

##### Conclusions

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with minimal details provided.

## References

Jung, R. 1987. Genamin CS 302 D: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 87.1463. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

## Other Available Reports

### Other

Last Changed:

June 7, 2002

Order number for sorting:

228d

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin CS 301 (CAS RN 61788-62-3; Amines, dicoco alkylmethyl)  
Purity: Not stated  
Remarks:

##### Method

Method/guideline followed: EG-Guideline C.1. Acute Toxicity to Fish; Guideline 84/449/EWG; OECD Guideline for testing of chemicals, 203 Fish, Acute Toxicity Test  
Type: Static  
GLP: Yes  
Year: 1990  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/West Aquarium, Bad Lauterberg  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Probit analysis (Linder and Weber, confidence interval Fieller)  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish were held in dilution water for at least 14 days before the beginning of the study. Water was maintained at  $22 \pm 1^\circ\text{C}$  by using a water bath calibrated thermometer and with  $\geq 80\%$  oxygen saturation. Lighting regime was 12-hour day/night cycles at approximately 700 lux. Feeding was twice daily. Immediately before the study start, as representatives for the batch of fish, 10 fish were measured for body length. These fish were not used in the study. The mean body length of the fish was 3.0 cm.  
The study was conducted with the following concentrations of test substance: 0, 2.2, 5, 10 and 50 mg/l. Dilution water was reconstituted water mixed to provide a composition following ISP/DIS 7346/l. The prepared dilution water was saturated with oxygen and the pH was measured before each trial. The pH was between 8.0 and 8.3. Test vessels were 10-liter glass aquariums (30 x 22 x 24 cm). Vessels were not aerated during the entire test time.  
Since the test substance is insoluble in water and since no better distribution was achieved using solvents and emulators, the test substance mixed with dilution water was homogenized using the Ultra-Turrax and

ultrasonic bath. This solution was added to the test vessel while being stirred with a glass stirring rod. Finally, the contents of the test vessels were stirred for approx. 2 hours with a KPG-stirrer and a glass stir rod. At 2.2 and 10 mg/l, test substance deposits were observed. Ten fish were randomly distributed in each test vessel and in the control vessel. During the entire study time, the fish were not fed. After 2, 4, 24, 48, 72 and 96 hours, mortality and visible changes in appearance and behavior were noted. Dead fish were removed from the vessels. Fish were counted as dead when breathing was no longer seen and the fish no longer responded to a light mechanical stimulation. Water parameters were also measured at these times.

**Results**

Nominal concentrations (mg/l): 0, 2.2, 5, 10 and 50 mg/l  
 Measured concentrations (mg/l): Not stated  
 Unit: mg/l  
 Element Value: 96-hour LC<sub>50</sub>  
 Statistical Results: 96-hour LC<sub>50</sub> = 6.15 mg/l (confidence interval 4.5 to 8.3 mg/l)  
 Remarks: In all the test substance groups, impaired swimming, breathing as well as changed appearance and behavior were observed. Fish that died were pale or darkly colored and showed red gills and lockjaw.

Concentration (mg/l)	Mortality			
	48 hours		96 hours	
	Absolute	Percent	Absolute	Percent
0	0/30	0	0/30	0
2.2	0/10	0	0/10	0
5	0/10	0	3/10	30
10	3/10	30	9/10	90
50	10/10	100	10/10	100

Additional endpoints included:  
 48-hour LC<sub>0</sub> = 5 mg/l; 96-hour LC<sub>0</sub> = 2.2 mg/l  
 48-hour LC<sub>50</sub> = > 10 mg/l and < 50 mg/l  
 48-hour LC<sub>100</sub> = 50 mg/l; 96-hour LC<sub>100</sub> = 50 mg/l

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1D

Remarks:

Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Nölken, G. and R. Jung. 1990. Genamin CS 301: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) over 96 Hours. Report Number 90.0502. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other Available Reports**

**Other**

Last Changed:

June 7, 2002

Order number for sorting:

126d

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

##### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: Zebra fish (*Brachydanio rerio*)/Antwerp Aquaria  
Analytical Monitoring: Tracer (Li) measurement by ICP  
Exposure Period: 48 hours  
Statistical Methods: Probit procedure (D.J. Finney, 1971) based on measured concentrations..  
Remarks: The flow-through test measured the acute toxicity of the test substance to juvenile zebra fish during a 48-hour exposure period. Ten juvenile zebra fish, averaging  $3\pm 0.5$  cm long and  $0.4\pm 0.1$  g, were exposed to each of eight concentrations of the test substance and a negative control. No replicates were used in the test. Dilution water was a mixture of dechlorinated hard tap water and deionized water with the following characteristics: total hardness  $200\pm 20$  mg/l as  $\text{CaCO}_3$ , pH  $7.8\pm 0.2$  and dissolved oxygen above 80% saturation. The test substance was administered to respective vessels via a Mount & Brungs delivery system with a solution renewal time of 4 hours with a dilution factor  $>0.5$ . Following a 14-day acclimation period, 10 fish were impartially distributed to each test chamber. The test was run with no aeration at a temperature of  $22\pm 2^\circ\text{C}$  and fish were not fed during acclimation or testing. Mortalities were recorded at 24 and 48 hours. Dissolved oxygen and pH were measured at 0, 24 and 48 hours. The test solutions were sampled in triplicate at 48 hours into glass bottles preconditioned with formaldehyde (10 ml/l) and nonionic (5 mg/l) for tracer analysis to measure test substance concentrations.

**Results**

Nominal concentrations (mg/l): Not stated  
 Measured concentrations (mg/l): 0 (control), 0.11, 0.14, 0.23, 0.28, 0.53, 0.66, 1.17 and 1.47 mg/l  
 Unit: mg/l, as active ingredient  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results: 24-hour LC<sub>50</sub> = 1.08 mg/l (0.97-1.20 mg/l)  
 48-hour LC<sub>50</sub> = 0.47 mg/l (0.38-0.57 mg/l)

Results:

Concentration (mg/l)	# of Dead Fish After	
	24 h	48 h
1.47	7	10
1.17	6	10
0.66	1	8
0.53	1	7
0.28	1	2
0.23	0	1
0.14	0	0
0.11	0	0
0	0	0

Remarks:

No mortalities were observed in the control group nor in the 0.11 or 0.14 mg/L treatment groups. Mortality increased with concentration above 0.23 mg/l. Mortality rose from 60 and 70% in the 1.17 and 1.47 mg/l treatment groups, respectively, to 100% by 48 hours.

**Conclusions**

Remarks:

The acute toxicity of the test substance for 48 hours was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline.

**References**

De Henau, H. and H.T. de Oude. 1981. Flow-through Acute Fresh Water Fish Toxicity (*Brachydanio rerio*). Procter & Gamble ETC P&RS Laboratory. Unpublished report (No. E8013.01.02, ETS No. 67).

**Other Available Reports****Other**

Last Changed:

September 18, 2003

Order number for sorting: 335

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

##### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.

Type: Flow-through  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: Zebra fish (*Brachydanio rerio*)/Antwerp Aquaria  
Analytical Monitoring: Tracer (Li) measurement by ICP  
Exposure Period: 28 days  
Statistical Methods: Analysis of variance for % hatch, % survival, length and weight of larvae after 30-day survival (Steel and Torrie, 1960, randomized block design,  $p=0.05$ ) with arc sin square root transformation of percent data prior to analysis; Dunnett's Test (if required). The  $LC_{50}$  was estimated using the moving average angle method

Remarks: The experiment measured the growth and growth rate of juvenile fish after 14 and 28 days of exposure to the test and control substances. No significant mortalities occurred in the group of cultured fish the week prior to test initiation. Seven treatment groups were tested in duplicate in a flow-through exposure system: seven treatment concentrations, a control (dilution water) and a solvent control (benzoic acid). Flow rates of the test solutions were nominally 59 mL/min giving approximately 5.7 volume replacements per day; however, on two occasions the diluter cycle rate fell below the 5.0 replacements per day. Treatment vessels were 19.5-liter glass aquaria containing 15 liters of solution.

Dilution water was river water collected 3 times per week from Town River in West Bridgewater, MA. This water was characterized as having total hardness and alkalinity ranges as  $CaCO_3$  of 24-36 mg/l and 4-16 mg/l, respectively, a pH range of 5.9-6.5, specific conductance of 70-140  $\mu mhos/cm$ , total suspended solids (TSS) concentrations of 0.60-11 mg/l and methylene blue active substances (MCAS) concentrations of <0.043-0.13 mg/l. A 24-hr static

acute toxicity test with the water flea (*Daphnia magna*) was performed with each batch of water to determine if the water was acceptable for use. The total hardness and TSS of each batch of water was adjusted to 100 mg CaCO<sub>3</sub>/l and 62 mg/l, respectively.

Embryo exposure was initiated within 48 hours of fertilization. Sixty embryos were impartially distributed to each of 14 embryo cups which were respectively suspended in the 14 test vessels. A rocker arm gently oscillated the cups in the treatment solutions. Mortality and percentage hatch were monitored daily.

The 30-day larvae exposure was initiated by transfer of 40 larvae from each embryo cup to the respective aquaria upon hatch completion. Larvae were fed live brine shrimp (*Artemia salina* nauplii) three times daily during week and twice daily on weekends/holidays. Aquaria were cleaned approximately twice weekly. Behavior and appearance of larvae were observed daily and larvae were counted twice weekly. Mortality, mean total length, and average wet weight were determined upon test termination on day 30.

Dissolved oxygen concentration, pH and temperature were measure in aquaria on day 0, then daily in both replicate aquaria of one treatment such that each treatment was measure once per week. Total hardness was measured on day 0 and weekly thereafter in alternating replicates of th high and low treatments and controls. MBAS and TSS samples were taken weekly as composites of replicates from the high, middle and low treatments and controls and preserved with formaldehyde. All test solutions, including controls, were sampled on test day 0, day of hatch, day 1 post-hatch and weekly thereafter, and preserved with formaldehyde for subsequent shipment to sponsor for analysis of test substance concentration.

## Results

Nominal concentrations (mg/l):	0 (control), 0 (solvent control), 0.016, 0.031, 0.62, 0.12 and 0.25 mg/l
Measured concentrations (mg/l):	0 (control), 0 (solvent control), 0.027, 0.049, 0.050, 0.11 and 0.15 mg/l
Unit:	mg/l, as active ingredient
Element Value:	MATC = 0.05 - 0.11 mg/l

30-day  $LC_{50}$  = 0.0179 mg/l (0.072-0.087 mg/l)  
 NOEC<sub>30d</sub> = 0.050 mg/l

Statistical Results:  
 Results:

Mean Measured Concentration (mg/l)	Hatch (%)	30-Day Old Larvae		
		Survival (%)	Total Length (mm)	Avg. Weight (mg)
0 (control)	97.5	82	25	170
0 (solvent control)	97.5	95	25.5	155
0.027	96.5	92	25.5	170
0.049	99	86.5	25	175
0.050	96.5	75	24.5	145
0.11	96.5	66	24	155
0.15	94	0	--	--

Remarks:

Larvae survival was the only indicator of an effect of this test substance on the fathead minnow in river water. Survival of larvae exposed for 30 days (post-hatch) to a mean measured test substance concentration of 0.15 mg/l was significantly less ( $p < 0.05$ ) than survival of control and solvent control larvae. Survival of larvae exposed to 0.11 mg/l was significantly reduced as compared to that of the solvent control larvae. No adverse effects on embryo hatchability or survival and growth of larvae from exposure to mean measured concentrations  $\leq 0.05$  mg/l were observed.

The mean measured concentrations of the test substance averaged 60 to 170% of the nominal concentrations. The 160 and 170% recovery for the analysis of the 0.031 and 0.016 mg/l samples, respectively, were artificially high due to a cationic substance in the river water.

The water quality in test vessel during this test were as follows: average dissolved oxygen concentrations in replicate test vessel ranged from 7.8 to 8.5, pH ranged from 7.5-8.0 and temperature remained at 25°C. Additionally, total hardness was 100 mg CaCO<sub>3</sub>/l, MBAS ranged from 0.09 to 0.10 mg/l and TSS ranged from 7.1 to 14 mg/l.

The maximum acceptable toxicant concentration (MATC) of this test substance in river water for

fathead minnow embryos and larvae was estimated to be between 0.05 and 0.11 mg/l. The 30-day LC50 for fathead minnow larvae exposed to this test substance in river water was estimated to be 0.0179 mg/l (0.072-0.087 mg/l). The NOEC through 30 days post-hatch was 0.050 mg/l.

### Conclusions

Remarks:

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

De Henau, H. and M.A. Lewis. 1981. The Toxicity of E8013.01 in River Water to Fathead Minnow (*Pimephales promelas*) Embryos and Larvae. Unpublished Toxicity Test Report No. BW-82-6-1237, submitted to The Procter and Gamble Company, Cincinnati, OH, USA by EG&G Bionomics, Inc. Pensacola, FL, USA.

### Other Available Reports

#### Other

Last Changed:

September 18, 2003

Order number for sorting:

345

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Armeen HT (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: 99%  
Remarks:

##### Method

Method/guideline followed: Test methods complied with OECD Test Guideline No. 203 and EEC Test Guideline C.1.  
Type: Static-renewal, renewal at 48 hours  
GLP: Yes  
Year: 1991  
Species/Strain/Supplier: Zebra fish (*Brachydanio rerio*)/Local aquarium retailer (Rasbora, Veenendaal)  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: LC<sub>50</sub> calculations made by computer program (Akzo programme SKBT, V1.0) using trimmed Spearman-Kärber and binomial test methods.  
Remarks: The test measured the acute toxicity of the test substance to Zebra fish. Testing was conducted in 5-liter glass vessels containing 3 liters of test solution. Single vessels were used per treatment level with 7 fish in each vessel. Vessels were covered with glass plates during testing. Fish were approximately 3 cm in length and weighed approximately 0.3 – 0.4 g. Fish were held in the laboratory for at least 12 days and fed one to three times per day, six days/week. Feed was withheld the 24 hours prior to testing and during the test. Dilution water used in the test was Dutch Standard Water, having a pH of approximately 8.2 and a hardness of 11.7° dH. Exposure concentrations of the test substance were made as aqueous emulsions using Tween 80 as an emulsifier. An aqueous stock solution of the test substance was prepared by adding 1 gram of test substance with 1 g of Tween 80/1 in 100 ml of deionized water. The mixture was ultrasonically treated; thereafter, deionized water was added to bring the volume to 1 liter. Test concentrations were made by addition of aliquots of the stock solution to 3 liters of dilution water. Two control groups were included, one of dilution water and one of dilution water containing an amount of Tween 80 equivalent to that used to prepare the test concentrations. This procedure was repeated at 48 hours and the fish were transferred

to the fresh solutions. Biomass loading of the test vessels was approximately 0.7 g of biomass/l. Test solutions were aerated during the test. The test was carried out in a temperature-controlled incubator. The light regime in the room was 12 hours of ambient light per day, provided by fluorescent tubes. Measurements of pH and the dissolved oxygen concentration were carried out daily, and during the renewal day, measurements were done in both new and old solutions. The temperature ranged from 22.7 to 23.8°C, the pH ranged from 8.0 to 8.3, and the dissolved oxygen concentrations were  $\geq 79\%$  of the air saturation value. Mortalities were recorded at least at 24, 48, 72 and 96 hours.

## Results

Nominal concentrations (mg/l): 0 (control), 0 (Tween 80 control), 0.1, 0.18, 0.32, 0.58, and 1.05 mg/l

Measured concentrations (mg/l): NA

Unit: mg/l

Element Value: 96-hour LC<sub>50</sub>

Statistical Results: 96-hour LC<sub>50</sub> = 0.88 mg/l  
(95% confidence limit of 0.72 to 1.1 mg/l)

Remarks: After 96 hours, 5/7 fish had died in the highest test concentration. No fish died in any of the other test concentrations or controls. However, fish in the 0.18, 0.32, 0.58 and 1.05 mg/l showed reduced activity. The NOEC based on mortality was 0.58 mg/l; the NOEC based on the finding of reduced activity in the fish was 0.1 mg/l.

Additional endpoints included:  
72-hour LC<sub>50</sub> = 0.88 mg/l  
(95% confidence limit of 0.72 to 1.1 mg/l)

## Conclusions

Remarks: The 96-hour acute toxicity of Amines, hydrogenated tallow alkyl to Zebra fish was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 1D

Remarks: Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

**References**

Mark, U. and I. Arends. 1991. Acute Toxicity of ARMEEN HT to *Brachydanio rerio*. Report/Study No. CRL F91082. Akzo Research Laboratories Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed:

July 23, 2002

Order number for sorting:

106

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin SH 200 [CAS RN 61789-79-5;Amines, bis(hydrogenated tallow alkyl)]  
Purity: Not stated  
Remarks:

##### Method

Method/guideline followed: OECD 203 and 92/69/EWG C.1.  
Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Hamilton-Buchanan/HOECHST AG, Kastengrund  
Analytical Monitoring: None  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test substance to Zebra Fish during a 96-hour exposure period. The fish had a mean body length of 3.4 cm. The test substance was not soluble in water and could not be dispersed equally. The test substance was weighed into a beaker, mixed with dilution water, homogenized with the Ultra-Turrax and transferred quantitatively into a 10-liter glass vessel. After filling to 10 liters with test water, the assay was stirred with a magnetic stirrer for approximately 72 hours. The assay was filtered through a folded filter and placed in the test vessel. The test assays were clear solutions with substance deposits on the water surface. pH values ranged from 7.6 to 8.3 in the test groups and 7.8 to 8.2 in the control groups. Oxygen content ranged from 5.8 to 9.1 mg/l in the test groups and 6.6 to 9.7 mg/l in the control groups. Temperature ranged from 21.3 to 21.8°C in the test groups and 21.0 to 21.8°C in the control groups.

##### Results

Nominal concentrations (mg/l): 0, 100, 220, 500 and 1000 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> is between 220 and 500 mg/l  
Remarks: In the 220, 500 and 1000 mg/l exposure groups, symptoms and mortality occurred. The 100 mg/l test

substance group showed reversible symptoms and no mortality.

Additional endpoints included:

<b>Endpoint (mg/l)</b>	<b>24 Hours</b>	<b>48 Hours</b>	<b>72 Hours</b>	<b>96 Hours</b>
<b>LC<sub>0</sub></b>	100	100	100	100
<b>LC<sub>50</sub></b>	220 to 500	220 to 500	220 to 500	220 to 500
<b>LC<sub>100</sub></b>	500	500	500	500

### Conclusions

Remarks:

Solubility problems may preclude determination of an accurate LC<sub>50</sub> in this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1D

Remarks:

Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Jung, R and Zok. 1995. Genamin SH 200: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 95.0693. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

### Other Available Reports

#### Other

Last Changed:

June 7, 2002

Order number for sorting:

131a

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Ditallowmethylamine, hydrogenated  
(CAS RN 61788-63-4; Dihydrogenated tallow  
methylamine)  
Purity: 100.2%  
Remarks:

##### Method

Method/guideline followed: Testing conformed to EEC Directive 779/831, Annex V, Part C.1. Acute toxicity to fish; and OECD Guidelines for Testing of Chemicals, Guideline 203: Fish, Acute Toxicity Test.  
Type: Static-renewal, renewal of solutions at 48 hours.  
GLP: Yes  
Year: 1990  
Species/Strain/Supplier: Zebra fish (*Brachydanio rerio*)/Local aquarium retailer (Rasbora, Veenendaal).  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: None  
Remarks: The test measured the acute toxicity of the test substance to Zebra fish. Range-finding tests were conducted prior to the definitive study. In the range-finding tests, 1.0 mg/l was the highest concentration tested at which no solid particles of the test substance could be observed in the test fluid and all test substance appeared to be dispersed. At 100 and 1008 mg/l, solid particles were present in the test solutions. The definitive test was conducted as a limit test (single concentration) at 1000 mg/l. Testing was conducted in 5-liter glass vessels containing 3 liters of test solution. Dilution water used in the test was Dutch Standard Water, having a pH of approximately 8.2 and a hardness of 13° dH. Duplicate vessels containing 1000 mg/l of the test substance and a single vessel with dilution water were used in the test. The test substance was described as “practically insoluble” in water. The 1000 mg/l test concentration was prepared by heating the dilution water to approximately 45°C and adding the melted test substance to the dilution water under stirring. Once the temperature was reduced to testing temperature, the test substance solidified again and fat-like particles were formed. To each vessel was added 7 fish. Biomass loading per vessel was approximately 0.23 g of biomass/l. During the test the solutions were

aerated; fish were not fed. The vessels were placed in a temperature-controlled incubator between 21 and 25°C. The lighting regime was 12 hours of ambient light/day provided by fluorescent lights. Measurements of pH and the dissolved oxygen concentration were carried out daily. The temperature ranged from 22.9 to 23.7°C, the pH ranged from 8.1 to 8.3, and the dissolved oxygen concentrations were  $\geq 8.4$  mg/l. One control group with seven fish was included in the test. The quality of the batch fish used in this test was checked by means of a test with potassium dichromate as the reference substance.

### Results

Nominal concentrations (mg/l):	0 (control) and 1000 mg/l
Measured concentrations (mg/l):	NA
Unit:	mg/l
Statistical Results:	NA
Result:	96-hour $LC_{50} = > 1000$ mg/l
Remarks:	No mortality or adverse effects were observed in any of the fish used in the test.

### Conclusions

Remarks:	Solubility problems preclude definitive determination of the $LC_{50}$ in this study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)
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### Data Quality

Reliability (Klimisch):	1D
Remarks:	Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Mark, U., and E.E. Hantink-de Rooij. 1990. Acute Toxicity of ARMEEN M2HT to *Brachydanio rerio*. Study/Report No. CRL F90146, Akzo Research Laboratories Arnhem, The Netherlands.

### Other Available Reports

#### Other

Last Changed:	July 25, 2002
Order number for sorting:	99
Remarks:	

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: Bluegill (*Lepomis macrochirus*)/commercial supplier in CT.  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: LC<sub>50</sub> values based on nominal concentrations were calculated by binomial probability  
Remarks: The test measured the acute toxicity of the test substance to juvenile bluegill during a 96-hour static exposure period. Juvenile bluegills (10 per group), averaging 36 mm in total length and 0.59 g in weight, were exposed to five concentrations of the test substance, a solvent and negative control. Test chambers were 19.6-l glass jars holding 15 l of test solution. No replicates were used in the test. Dilution water was soft water reconstituted from deionized water with the following characteristics: total hardness 44 mg/l as CaCO<sub>3</sub>, alkalinity 32 mg/l as CaCO<sub>3</sub>, pH 7.4 and specific conductance 120 µmhos/cm. Exposure concentrations of the test substance were prepared by diluting a working stock solution that had been prepared in isopropanol. Following a 14-day acclimation period, 10 fish were impartially distributed to each test chamber. The test was run with no aeration at a temperature of 22±1°C under a 16 h light/8 h dark photoperiod and fish were not fed during testing. Mortalities were recorded at 24, 48, 72 and 96 hours. Dissolved oxygen and pH were measured at 0, 24, 48, 72 and 96 hours. Temperature was monitored in the negative control chamber.

##### Results

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 6.5, 11, 18, 30, 50 mg/l

Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: LC<sub>50</sub> (95% Confidence Interval)  
Statistical Results: 24-hour LC<sub>50</sub> = 30 mg/l (18-50 mg/l)  
48-hour LC<sub>50</sub> = 23 mg/l (18-30 mg/l)  
72-hour LC<sub>50</sub> = 23 mg/l (18-30 mg/l)  
96-hour LC<sub>50</sub> = 23 mg/l (18-30 mg/l)  
Remarks: No mortalities were observed in either control nor in the 6.5, 11 or 18 mg/L treatment levels. Mortality in the 30 mg/l treatment group was 30% within 24 hours of initiation and 100% by 48 hours. 100% mortality was observed within the first 24 hours of the test in the highest treatment group, 50 mg/l. The no-observed-effect level was 18 mg/l based on 0% mortality occurring at that concentration.

Temperature in the negative control chamber ranged from 21 to 22°C throughout the test. Dissolved oxygen remained above 60% saturation (~5.3 mg/l at 22°C) for the first 48 hours of the test, except in the 6.5 mg/l test chamber (57%), and ranged from 41 to 63% (3.6 to 5.5 mg/l) over the remaining 48 hours in the controls, 6.5, 11 and 18 mg/l test chambers. The pH in the test chambers ranged from 6.6 to 7.3 during the test with consistently higher pH in the control chambers.

### Conclusions

Remarks: The acute toxicity of the test substance to bluegill was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1A  
Remarks: Reliable without restriction; guideline study

### References

Sousa, J.V. and G.A. LeBlanc. 1981. Acute Toxicity of B0390.01 to Bluegill (*Lepomis macrochirus*). Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-81-9-1017.

### Other Available Reports

### Other

Last Changed: September 18, 2003

Order number for sorting: 332

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: Bluegill (*Lepomis macrochirus*)/commercial supplier in CT.  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: Calculation, based on nominal concentrations, of the 48-hour LC50 required binomial averaging, while calculation of the 72- and 96-hour LC50 employed the moving average angle method.  
Remarks: The test measured the acute toxicity of the test substance to juvenile bluegill during a 96-hour static exposure period. Juvenile bluegills (10/group), averaging 36 mm in total length and 0.52 g in weight, were exposed to one of seven concentrations of the test substance, a solvent control or a negative control. Test chambers were 19.6-l glass jars holding 15 l of test solution. No replicates were used. Dilution water was Town River water with the following characteristics: total hardness 66 mg/l as CaCO<sub>3</sub>, alkalinity 18 mg/l as CaCO<sub>3</sub>, pH 7.0, specific conductance 260 µmhos/cm, total suspended solids (TSS, adjusted) 240 mg/l and methyl blue active substances (MBAS) 0.18 mg/l. Test solutions were prepared by diluting a working stock solution that had been prepared in isopropanol (0.5 ml/l). Following a 14-day acclimation period, 10 fish were impartially distributed to each test chamber. The test was run with no aeration at a temperature of 22±1°C under a 16 h light/8 h dark photoperiod and fish were not fed during testing. Mortalities were recorded at 24, 48, 72 and 96 hours. Dissolved oxygen and pH were measured at 0, 24, 48, 72 and 96 hours. Temperature was monitored in the negative control chamber.

## Results

Nominal concentrations (mg/l):	0 (negative control), 0 (solvent control), 23, 40, 67, 110, 180, 300 and 500 mg/l
Measured concentrations (mg/l):	Not determined
Unit:	mg/l
Element Value:	LC <sub>50</sub> (95% Confidence Interval)
Statistical Results:	24-hour LC <sub>50</sub> > 500 mg/l (empirical estimate); 48-hour LC <sub>50</sub> = 390 mg/l (300-500 mg/l); 72-hour LC <sub>50</sub> = 270 mg/l (220-360 mg/l); 96-hour LC <sub>50</sub> = 180 mg/l (140-230 mg/l)
Remarks:	No mortalities were observed in either control nor in the 23, 40 or 67 mg/L treatment levels. Mortality in the 110 mg/l treatment group was 10% by 72 hours and did not change for the remainder of the test, while mortality in the 180 mg/l treatment group was 30% by 96 hours. A 70% mortality in the 300 mg/l treatment group in 72 hours led to 100% mortality by test termination. All of the fish in the highest treatment group, 500 mg/l, appeared lethargic by 24 hours and died within 48 hours of test initiation. The no-observed-effect level was 67 mg/l based on 0% mortality occurring at that concentration.

By 48 hours, all surviving fish (except in the negative control group) were at the surface and respiring rapidly. These observations, albeit more variable among treatments, were reported throughout the remainder of the test.

Temperature in the negative control chamber was 22±0°C throughout the test. Dissolved oxygen remained below 40% saturation for the duration of the test in all test chambers except for the negative control. The pH in the test chambers ranged from 6.3 to 7.0 during the test with consistently higher pH in the control chambers. A white precipitate was observed on the surface of each treatment throughout the test. This precipitate appeared to settle to the bottom of the aquaria after 24 hours.

## Conclusions

Remarks:	The acute toxicity of the test substance to bluegill was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)
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**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study

**References**

Sousa, J.V. and G.A. LeBlanc. 1981. Acute Toxicity of B0390.01 in River Water to Bluegill (*Lepomis macrochirus*)/11-19-81. Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-81-11-1036.

**Other Available Reports**

**Other**

Last Changed:

September 18, 2003

Order number for sorting:

333

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1985  
Species/Strain/Supplier: Bluegill (*Lepomis macrochirus*)/commercial supplier  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: Computer program, developed by C.E Stephan to calculate LC<sub>50</sub> by moving average, probit and binomial probability (Stephan, C.E. 1982. US EPA Environmental Research Laboratory, Duluth, MN. Personal communication to Dr. Lowell Bahner, Chairman ASTM Task Group on Calculating LC<sub>50</sub>'s)  
Remarks: The test measured the acute toxicity of the test substance to juvenile bluegill during a 96 hour static exposure period. Juvenile bluegills were exposed to six concentrations of the test substance, a solvent and negative control. Test chambers were 19.6-l glass jars holding 15 l of test solution. Solution depth was 27.5 cm and the surface area was 545 cm<sup>2</sup>. No replicates were used in the test. Dilution water was river water having the following characteristics: total hardness 50 mg/l as CaCO<sub>3</sub>, alkalinity 24 mg/l as CaCO<sub>3</sub>, pH 7.7 and specific conductance 360 µmhos/cm. Exposure concentrations of the test substance were prepared by diluting a working stock solution that had been prepared in acetone. Aliquots of the stock were added to dilution water, stirred and apportioned among triplicate test chambers for each treatment group. The test was run at a temperature of 22±1°C under a 16 h light/8 h dark photoperiod. At test initiation, 10 fish were impartially distributed to each test chamber. Fish were not fed during testing, and mortalities were recorded at 24, 48, 72 and 96 hours. Dissolved oxygen and pH were measured at 0, 48, 72 and 96 hours in one replicate vessel of the control, solvent control, and the low, middle and high

exposure groups. Temperature was measured in one control vessel at 0, 24, 48, 72 and 96 hours. All water quality factors were within the correct ranges during the test.

## Results

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 8.0, 12, 24, 36, 60, 100 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> = 9.3 mg/l (95% confidence interval of 6.3 to 12 mg/l)  
Remarks: The no-observed-effect level was <8.0 mg/l based on 30% mortality occurring at that concentration. Complete mortality occurred in the 100, 60, 36, and 24 mg/l treatments. 80% mortality occurred at 12 mg/l.

## Conclusions

Remarks: The acute toxicity of the test substance to bluegill was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 1D  
Remarks: Reliable with restriction; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

## References

Springborn Bionomics, Inc. 1986. Acute Toxicity of Adogen 170D to Bluegill (*Lepomis macrochirus*) in River Water. Toxicity test report submitted to Sherex Chemical Company, Dublin, Ohio. Bionomics Report No. BW-86-3-1955; Study No. 11,187-0585-6101-100.

## Other Available Reports

### Other

Last Changed: July 25, 2002  
Order number for sorting: 214a  
Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin TA 100 D (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: 100%  
Remarks:

##### Method

Method/guideline followed: OECD 203 “Fish, Acute Toxicity Test”  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Brachydanio rerio*/Hoechst AG  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Probit analyses (Linder and Weber, Fieller)  
Remarks: The fish were 24-31 mm in length; fed twice daily *ad libitum* with Tetra Min pretreatment and were not fed during treatment. Tween 80 was used as the vehicle/solvent at a concentration of 0.1 ml/l. Dilution water was reconstituted water according to ISO/DIN 7346/1; pH of 7.8 to 8.2; O<sub>2</sub> 100%. Exposure conditions: vessels were 16 L glass vessels containing 10 liters of test medium; 10 fish per treatment level; temperature = 21 to 23 °C; dissolved oxygen = ≥60%; pH = 7.2 to 8.2; photoperiod = 12 hour at ~ 700 lux. The test consisted of six separate tests performed within a period of 2 months under the same conditions and with comparable results. Each test run included an untreated control group.

##### Results

Nominal concentrations (mg/l): 0 (negative control), 0 (vehicle control), 0.01, 0.12, 0.18, 0.25, 0.35, 0.5, 1 and 10 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> >0.18 mg/l and < 0.25 mg/l  
Remarks: At 1 and 10 mg/l test substance was observed at the water surface (the test substance was stated as insoluble); at the relevant test concentrations (around the LC<sub>50</sub>), slight turbidity was observed. Following are the mortality results (number dead/number treated):  
0 (untreated control) = 0/60  
0 (vehicle control) = 0/10  
0.01 mg/l = 0/10

0.12 mg/l = 0/10

0.18 mg/l = 0/10

0.25 mg/l = 8/10

0.35 mg/l = 10/10

0.5 mg/l = 10/10

1 mg/l = 10/10

10 mg/l = 10/10

Other effects include: Clinical signs including, swimming with the nose up, decreased or increased activity, respiration or shock reaction, irregular respiration, fish at the bottom or at surface, active movement upwards and passive movement downwards, open gill, dark discoloration, problems with the fins, white tops of fins and/or convulsions, were noted in the 0.12 to 1 mg/l dose groups. At 0.01 mg/l some fish showed open gills until 48 hours after start of test.

### Conclusions

Remarks:

The acute toxicity of the test substance was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1D

Reliable with restrictions; guideline study but no analyses were performed to confirm the nominal test concentrations according to guideline.

### References

Markert, M. and R. Jung. 1988. Genamin TA 100 D Pruefung der akuten Toxizitaet am Fisch Zebrabaerbling (Brachydanio rerio) ueber 96 [Genamin TA 100 D Acute toxicity study in Zebra fish over 96 hours] Stunden (88.0614/88.0098). Hoechst AG.

### Other Available Reports

#### Other

Last Changed:

August 9, 2002

Order number for sorting:

214b

Remarks:

#### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

##### Test Substance

Identity: Genamin SO 302 D (CAS RN 61788-91-8;  
Amines, dimethylsoya alkyl)  
Purity: Approximately 99%  
Remarks:

##### Method

Method/guideline followed: OECD 203, 84/449/EWG C.1. and UBA VV  
May 1984  
Type: Static  
GLP: Not stated  
Year: 1987  
Species/Strain/Supplier: Zebra Fish (*Brachydanio rerio*)/Not stated  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the acute toxicity of the test  
substance to Zebra Fish during a 96-hour exposure  
period.

##### Results

Nominal concentrations (mg/l): 0, 0.1, 1.0 and 10 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
Element Value: 96-hour LC<sub>50</sub>  
Statistical Results: 96-hour LC<sub>50</sub> >0.1 and < 1 mg/l  
Remarks: At 1 and 10 mg/l, symptoms and 100% mortality  
occurred. Fish exposed to 0.1 mg/l showed symptoms  
but no mortality.  
Additional endpoints included:  
48-hour LC<sub>50</sub> >0.1 and < 1 mg/l  
LC<sub>0</sub> = 0.1 mg/l, after 48 and 96 hours;  
LC<sub>100</sub> = 1 mg/l after 48 and 96 hours.

##### Conclusions

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

##### Data Quality

Reliability: 1D  
Remarks: Reliable without restriction; guideline study with  
minimal details provided.

## References

Jung, R. 1987. Genamin SO 302 D: Study of the Acute Toxicity to Fish – Zebra Fish (*Brachydanio rerio*) – over 96 Hours. Report Number 87.1813. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

## Other Available Reports

### Other

Last Changed:

June 7, 2002

Order number for sorting:

104b

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Sododecyloxypropylaminopropylamine  
(CAS RN 68479-04-9; 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched)

Purity: NA

Remarks:

### Method

Method/guideline followed: Test methods were based on ASTM Standard 4729-80, Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians, and EPA-660/3-75-009, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.

Type: Static-renewal, renewal at 24 hours

GLP: Yes

Year: 1993

Species/Strain/Supplier: *Ceriodaphnia dubia*/NA/Laboratory culture

Analytical Monitoring: No

Exposure Period: 48 hours

Statistical Methods: LC<sub>50</sub> values calculated using a computer program that performed the moving average method.

Remarks: The test measured the acute toxicity of the test substance to *Ceriodaphnia dubia*. The test was conducted in 30-ml polypropylene cups filled with 25 ml of test solution. Ten animals were used in each of four replicate containers (40 fish per test concentration). Test solutions were renewed at 24 hours. The dilution water used in testing was spring water diluted with deionized water. Test concentrations were prepared by adding aliquots of an aqueous stock solution to moderately-hard spring water. Dissolved oxygen, pH, temperature and conductivity were measured daily in all test levels. A photoperiod of 16 hours light/8 hours dark was provided during testing. Alkalinity was measured initially in the control and all test concentrations. Dissolved oxygen ranged from 7.8 to 9.2 mg/l, pH ranged from 8.0 to 8.1, temperature remained steady at 21°C. Conductivity and alkalinity was not provided in the reviewed report. Test chambers were monitored for mortalities daily. Death was defined as the absence of movement.

## Results

Nominal concentrations (mg/l): 0 (control), 0.04, 0.07, 0.15, 0.3, and 0.6 mg/l  
Measured concentrations (mg/l): NA  
Unit: mg/l  
LC<sub>50</sub> (48 hour): 0.132 mg/l  
(95% confidence limit of 0.113 to 0.153 mg/l)  
NOEC (48 hour): 0.07 mg/l  
Result: Percent mortality at 48-hours is presented in the following table:

Nominal Concentration (mg/l)	0	0.04	0.07	0.15	0.3	0.6
Mortality (%) at 96-hours	0	2.5	7.5	45	100	100

Remarks:

## Conclusions

The 48-hour acute toxicity of *Ceriodaphnia dubia* to 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 2C  
Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions.

## References

MacGregor, R., III. 1993. Alkyl Amine DA-16, Evaluation of the Static Renewal Acute Toxicity to *Ceriodaphnia dubia* and *Pimephales promelas*. Final Report No. ATR-30-93-034, Halliburton NUS Environmental Corporation, Houston, Texas. EPA Document No. 88-930000335.

## Other Available Reports

### Other

Last Changed: July 27, 2002  
Order number for sorting: 118a  
Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Genamin LA 302 D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: 99.9%  
Remarks:

### Method

Method/guideline followed: DIN 38 412 Part 11, Guideline 84/449/EWG (C2),  
OECD Guideline 202 (I) and ISO 6341.  
Type: Acute  
GLP: Yes  
Year: 1994  
Species/Strain/Supplier: *Daphnia magna*/Straus/*Daphnia* Breeders Hoechst AG,  
Environmental Protection Division  
Analytical Monitoring: Yes  
Exposure Period: 48 hours  
Statistical Methods: Not stated  
Remarks: The test measured the EC<sub>50</sub>, the EC<sub>0</sub> and the EC<sub>100</sub> of  
the test substance to *Daphnia magna*. Test vessels  
were  
150-ml beakers filled with 100 ml test volume. Eight  
test concentrations were run; 0.10, 0.14, 0.20, 0.28,  
0.40, 0.57, 0.80 and 1.13 mg/l. Duplications of each  
concentration were run. Twenty animals were inserted  
into each test concentration. A control assay  
consisting of water without test substance, and a  
parallel consisting of 100 mg/l of the carrier solution,  
Tween 80, were run. In addition, the reference  
substance, K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>, was tested at concentrations of  
0.9, 1.9 and 2.4 mg/l. During the 48 hours of the  
study, the assays were stored in a temperature  
controlled, darkened clean room with activated  
charcoal-filtered air. The test temperature was 20°C.  
After 24 and 48 hours, the mobility of the *Daphnia*  
were checked. The nominal concentrations of 0.10,  
0.14, 0.80 and 1.13 mg/l were measured by gas  
chromatography

### Results

Nominal concentrations (mg/l): 0.10, 0.14, 0.80 and 1.13 mg/l  
Measured concentrations (mg/l): At 0 hour: 0.09, 0.14, 0.87 and 1.14 mg/l  
At 48 hour (mean): 0.06, 0.075, 0.52 and 0.565 mg/l  
(Standard deviation: 16.7, 6.7, 0 and 6.2%,  
respectively)  
Unit: mg/l

EC<sub>50</sub> (48 hour): 0.083 mg/l  
 NOEC (48 hour): < 0.06 mg/l  
 Result: Additional endpoints included:  
 48-hour EC<sub>100</sub> = 0.16 mg/l;  
 24-hour EC<sub>100</sub> 0.33 to 0.57 mg/l;  
 24-hour EC<sub>50</sub> = 0.16 to 0.40 mg/l; and  
 24-hour EC<sub>0</sub> = 0.16 to 0.28 mg/l.  
 Percent immobility at 48-hours is provided in the following table:

<b>Nominal Concentration (mg/l)</b>	<b>0.10</b>	<b>0.14</b>	<b>0.20</b>	<b>0.28</b>	<b>0.40</b>	<b>0.57</b>	<b>0.80</b>	<b>1.13</b>
<b>Measured Concentration (mg/l)</b>	<b>0.06</b>	<b>0.075</b>					<b>0.52</b>	<b>0.565</b>
<b>Immobility (%) at 48-hours</b>	5	12	90	100	100	100	100	100

Remarks: The carrier solution of 100 mg/l of Tween 80 resulted in 0% inhibition at 24 and 48 hours. The reference substance resulted in 10, 80 and 100% inhibition at 24 hours at concentrations of 0.9, 1.9 and 2.4 mg/l, respectively.  
 The measured test concentrations at 48 hours were 66.7, 53.6, 59.8 and 49.6% of the nominal test concentrations of 0.10, 0.14, 0.80 and 1.13 mg/l, respectively. At 0 and 48 hours, pH values were 7.8 and 7.6, respectively, at all concentrations. Dissolved oxygen ranged from 8.9 to 9.0 at 0 hours, and 8.6 to 8.9 at 48 hours. After 48 hours, the following inhibition to mobility resulted:

### Conclusions

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

### References

Stuhlfauth. 1995. Study of the Toxic Effect of Genamin LA 302 D to *Daphnia magna*. Study Number 93-0161-32. Hoechst AG, Frankfurt, Germany.

## **Other Available Reports**

### **Other**

Last Changed: June 7, 2002

Order number for sorting: 124g

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Genamin SH 100 D (CAS RN 124-30-1; Octadecylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test.  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Daphnia magna*/Straus/Institut fuer Wasser-, Boden- and Lufthygiene des Bundesgesundheitsamtes, Berlin  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Could not be adequately translated.  
Remarks: The test measured the EC<sub>50</sub>, the EC<sub>0</sub> and the EC<sub>100</sub> of the test substance to *Daphnia magna*. *Daphnia* were 2 to 24 hours old at the start of the test and were fed algae during pretreatment; feeding during treatment was not specified in the study report. Test vessels were 50-ml beakers filled with 20 ml test medium. Dilution water was EWG 84/449 with the following chemistry parameters: hardness = 236 mg CaCO<sub>3</sub>/l; pH = 7.7; O<sub>2</sub> concentration = 95% and conductance = 638 µS/cm. No vehicle or solvent was used. Eight test concentrations were run; 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, and 0.58 mg/l with four replicates of each concentration. Five daphnids were inserted into each test concentration. In addition, the reference substance, K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>, was tested at concentrations of 0.32 – 3.2 mg/l; 2 replicates per treatment and 10 animals per replicate. During the 48 hours of the study, the assays were stored in a temperature controlled room with a 10 hour photoperiod. The test conditions were as follows: temperature = 21 to 22°C; dissolved oxygen ≥ 89%; and pH = 7.5 to 7.6. The test parameter evaluated was immobility.

### Results

Nominal concentrations (mg/l): 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, 0.58 mg/l  
Measured concentrations (mg/l): NA  
Unit: mg/l  
EC<sub>50</sub> (48 hour): 0.13 mg/l (95% confidence limit of 0.10 to 0.18 mg/l)

NOEC (48 hour): Not determined  
 Result: Additional endpoints included:  
 48-hour EC<sub>100</sub> = 0.58 mg/l;  
 48-hour EC<sub>0</sub> = 0.018 mg/l (report indicated EC<sub>0</sub> = 0.032 mg/l)  
 Percent immobility at 48-hours is provided in the following table:

Nominal Concentration (mg/l)	0	0.018	0.032	0.058	0.10	0.18	0.32	0.58
Immobility (%) at 48-hours	0	0	10	15	20	45	75	100

Remarks: The 24-hour EC<sub>50</sub> of the reference substance was 1.1 mg/l

**Conclusions** The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A  
 Remarks: Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48h) an *Daphnia magna* STRAUS von Genamin SH 100D. [Acute immobilization study (48 hours) in *Daphnia magna* STRAUS with Genamin SH 100D] Study No. 940905HM/DAI42621. Dr. U. Noack-Laboratory for Applied Biology. Sarstedt, Germany.

**Other Available Reports**

**Other**

Last Changed: June 24, 2002  
 Order number for sorting: 55a  
 Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: 94%  
Remarks:

### Method

Method/guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline 202 and U.S. EPA Ecological Effects Test Guideline, OPPTS 850.1085: Fish acute toxicity mitigated by humic acid.

Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: *Daphnia magna* from Laboratory culture  
Analytical Monitoring: Yes, in the control, low, mid and high concentration levels  
Exposure Period: 48 hours  
Statistical Methods: NA  
Remarks: The study measured the acute toxicity of the test substance to *Daphnia magna* during a 48-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 10 and 20 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was synthetic water (Dutch Standard Water) having a pH of 8.2 and a hardness of approximately 12°dH (214 mg CaCO<sub>3</sub>/l). Daphnids had been cultured in synthetic culture medium M4-medium and fed with algae (*Chlorella* sp.). Daphnids used in the test were between 6 and 24 hours old at the beginning of the test. To prepare the test concentrations, an aqueous stock of the test substance (0.1 g/l) was made and aliquots of the stock were diluted with dilution water. Test vessels were 250-ml beakers holding 200 ml of test solution. Concentrations were replicated four times, with each replicate holding 5 daphnids (20 per concentration). The treatment groups were 0 (control), 0.006, 0.011, 0.023, 0.045, and 0.090 mg/l. The test solutions were prepared, the daphnids were randomly placed in the test solutions and the test vessels were randomly placed in the testing area. All test vessels were covered with a glass plate during the test. Test

solutions were not aerated during the test period. The testing area had a lighting regime of 16 hours light/8 hours dark. Dissolved oxygen and pH were measured at the beginning and end, and temperature was measured continuously in one replicate test vessel. The target temperature was  $20 \pm 2^\circ\text{C}$ . Observations of immobilization were recorded at a minimum at 0, 24, and 48 hours. Daphnids were considered immobile if they were not able to swim within 15 seconds after gentle agitation of the test vessel. If daphnids were trapped at the air-water interface, they were gently pushed under the surface with a drop of test solution. Water quality parameters measured in the dilution water included acidity (0.3 mmol/l), alkalinity (1.5 mmol/l), conductivity (605  $\mu\text{S}/\text{cm}$ ), water hardness (11.5° dH, equivalent to 205 mg  $\text{CaCO}_3/\text{l}$ ), total suspended solids (0.12 mg/l), and nonpurgeable organic carbon (2.269 mg/l). Dissolved oxygen ranged from 9.0 to 9.1 mg/l, pH ranged from 8.0 to 8.1 and temperature ranged from 19.1 to 19.6°C. Measurements of the test substance in the exposure solutions were made at 0 and 48 hours in the control, low, mid and high treatment levels. Endpoint results are given based on nominal concentrations.

## Results

Nominal concentrations (mg/l):	0 (control), 0.006, 0.011, 0.023, 0.045, and 0.090 mg/l.
Measured concentrations (mg/l):	Measured concentrations of the test substance decreased between 0 and 48 hours. 0-hour measured concentrations in the control, 0.011, 0.023 and 0.090 mg/l nominal solutions were 0.007, 0.013, 0.020, and 0.077 mg/l, respectively, while 48-hour measured concentrations in those same exposure solutions were 0.007, 0.010, 0.011, and 0.048 mg/l, respectively. Percentages of nominal concentrations ranged 48 to 118%.
Unit:	mg/l
EC <sub>50</sub> (48 hour):	48-h EC <sub>50</sub> = 0.011 mg/l (95% confidence interval of 0.009 to 0.013 mg/l)
NOEC (48 hour):	0.0056 mg/l
Result:	Additional endpoints included: 24-h EC <sub>50</sub> = 0.029 mg/l (0.026 – 0.032 mg/l)

Percent immobility at 48-hours is provided in the following table:

<b>Nominal Concentration (mg/l)</b>	<b>0</b>	<b>0.006</b>	<b>0.011</b>	<b>0.023</b>	<b>0.045</b>	<b>0.090</b>
<b>Immobility (%) at 48-hours</b>	5	0	60	95	100	100

Remarks:

**Conclusions**

The 48-hour toxicity of 9-Octadecen-1-amine to *Daphnia magna* was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

**References**

Mark, U.E., I.C.M. Garttner, M.G.J. Geurts, M.W.F. Nielen, C.A. Stroo and A.G.M. Kroon. 1995. Acute Toxicity of Oleylamine to *Daphnia magna*. Report No. RGL F95063. Akzo Nobel Central Research, Arnhem, The Netherlands.

**Other Available Reports**

**Other**

Last Changed:  
Order number for sorting:  
Remarks:

July 17, 2002  
15

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Octadecylamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: Test methods conformed to ASTM Standard E729-80, Standard Practice for Conducting Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians.

Type: Static  
GLP: Yes  
Year: 1987  
Species/Strain/Supplier: *Mysidopsis bahia*/NA/Laboratory culture  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: Derivation of LC<sub>50</sub> values by either probit, moving average or nonlinear interpolation methods using computer program (Stephan 1977).

Remarks: The study measured the acute toxicity of the test substance to the saltwater mysid. Juvenile mysids, less than 24 hours old were selected for use in the test. Individuals were impartially distributed to each test concentration within 20 minutes after the test solutions had been prepared. Test vessels consisted of 1.6-l glass containers holding 1000 ml of test solution. Test vessels were not aerated and were covered with a glass plate during testing. Each treatment and control were replicated twice and each replicate vessel held 10 mysids (total 20/concentration). Mysids were fed brine shrimp each day of the test. Test solutions were prepared by diluting a stock solution of the test substance dissolved in isopropyl alcohol with dilution water. Dilution water was natural filtered seawater having a salinity of 30 parts/thousand (ppt) and a pH of 8.0. Water pH, dissolved oxygen concentration, salinity and temperature were measured at 0-hours and at each 24-hour interval during the test. Lighting was established at a 16 hour light/8 hour dark cycle with an intensity of 40 – 100 foot-candles at the surface of the test solutions. Water pH ranged from 7.9 to 8.0, dissolved oxygen ranged from 5.0 to 7.5, salinity ranged from 30 – 32 ppt and temperature ranged from 24 - 25°C. Observations of the test organisms were made at the beginning of the test and at 24, 48, 72 and 96 hours.

**Results**

Nominal concentrations (mg/l): 0 (control), 0 (solvent control), 0.052, 0.088, 0.140, 0.240, and 0.400 mg/l  
 Measured concentrations (mg/l): NA  
 Unit: µg/l converted to mg/l  
 EC<sub>50</sub> (96 hour): NA  
 LC<sub>50</sub> (96 hour): 0.074 mg/l  
 (95% confidence limit of 0.062 to 0.085 mg/l)  
 NOEC (96 hour): NA  
 Result: Percent mortality at 96-hours is presented in the following table:

Nominal Concentration (mg/l)	0	0	0.052	0.088	0.140	0.240	0.400
Mortality (%) at 96-hours	0	0	20	60	100	100	100

Remarks:

**Conclusions**

The 96-hour acute toxicity of Octadecylamine to the saltwater mysid was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2C  
 Remarks: Reliable with restrictions; comparable to guideline study with acceptable restrictions

**References**

Springborn Laboratories. 1987. Acute Toxicity of B0793.02 to Mysid Shrimp (*Mysidopsis bahia*). Unpublished Report No. BW-87-4-2359. Springborn Bionomics, Inc., MA, USA. Contained in: Initial Submission, Toxicological Investigation of N,N-dimethyloctyldecylamine. U.S. EPA Doc. No. FYI-OTS-0794-1164.

**Other Available Reports**

**Other**

Last Changed: July 18, 2002  
 Order number for sorting: 36  
 Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Amine KK (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: > 94%  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202, Part 1, Daphnia sp., Acute Immobilization Test.  
Type: Static  
GLP: Yes  
Year: 1991  
Species/Strain/Supplier: Daphnia magna/ STRAUS/ Institut National de Recherché Chimique Appliquee (I.R.CH.A), France.  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Thomson, W.R. 1947.  
Remarks: Daphnia were bred in dechlorinated and aged tap water (21°C) and were less than 24 hours old at the start of the test. Animals were fed mixed algae during pretreatment; feeding during the test was not discussed in the report. Stock solutions of the test substance were prepared in 1% Tween 80-Acetone. Vessels were covered glass jars with 200 ml test solution. Dilution water was dechlorinated and aged laboratory tap water with the following chemistry parameters: hardness = 50 mg CaCO<sub>3</sub>/l; TOC = 0.9 mg/l; Ca/Mg ratio = 1/3; Na/K ratio = 24/1; and pH = 8.7. There were 10 fish per replicate and 2 replicates per treatment group. Test conditions were as follows: temperature = 21°C; dissolved oxygen = 90 to 94%; pH = 7.5 to 7.7; and photoperiod = 16 hour light. Daphnia were observed for immobility.

**Results**

Nominal concentrations (mg/l): 0.010, 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, and 1.0 mg/l  
 Measured concentrations (mg/l): NA  
 Unit: mg/l  
 EC<sub>50</sub> (48 hour): 0.045 mg/l  
 (95% confidence limit of 0.042 to 0.049mg/l)  
 NOEC (48 hour): 0.032 mg/l  
 Results: Percent immobility at 48-hours is provided in the following table:

<b>Nominal Concentration (mg/l)</b>	<b>0</b>	<b>0.010</b>	<b>0.018</b>	<b>0.032</b>	<b>0.056</b>	<b>0.10</b>	<b>0.18</b>	<b>0.32</b>	<b>0.56</b>	<b>1.0</b>
<b>Immobility (%) at 48-hours</b>	0	0	0	0	90	100	100	100	100	100

Remarks:

**Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A  
 Remarks: Reliable without restriction; guideline study.

**References**

Handley, J.W. and P.M. Wetton. 1991. The Acute Toxicity of Amine KK to Daphnia magna. Project No 116/68. Safepharm Laboratories.

**Other Available Reports**

**Other**

Last Changed: August 12, 2002  
 Order number for sorting: 92c  
 Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Genamin CC 100 D (CAS RN 61788-46-3;  
Amines, coco alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202, Part 1, Daphnia sp., Acute Immobilization Test.  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: Daphnia magna/ STRAUS/ Institut für Wasser-, Boden- und Lufthygiene des Bundesgesundheitsamtes, Berlin.  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Probitanalyse, Methoden der Wasseruntersuchungen Bd. II, 1982.  
Remarks: Daphnia were bred in glass beakers containing culture medium (Elendt) at 20-25°C and 10 hour light. Animals were fed algae during pretreatment; feeding during the test was not discussed in the report. No vehicle was used during the test. The reference substance was calcium dichromate. Dilution water source was EWG 84/449 with the following chemistry parameters: hardness = 236 mg CaCO<sub>3</sub>/l; O<sub>2</sub> = 95%; pH = 8.7; and conductance = 638 uS/cm. There were five fish per replicate and four replicates per treatment group; the reference substance contained 10 fish per replicate and two replicates per treatment. Test conditions were as follows: temperature = 21 to 22°C; dissolved oxygen ≥89%; pH = 7.5 to 7.7; and photoperiod = 10 hour light. Daphnia were observed for immobility.

### Results

Nominal concentrations (mg/l): 0, 0.018, 0.032, 0.058, 0.10, 0.18, 0.32, 0.58 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
EC<sub>50</sub> (48 hour): 0.09 mg/l (95% confidence limit of 0.08 to 0.10 mg/l)  
Result: Additional endpoints included:  
EC<sub>0</sub> = 0.018 mg/l  
EC<sub>100</sub> = 0.18 mg/l  
24 hour EC<sub>50</sub> = 1.1 mg/l

Percent immobility at 48-hours is provided in the following table:

<b>Nominal Concentration (mg/l)</b>	<b>0</b>	<b>0.018</b>	<b>0.032</b>	<b>0.058</b>	<b>0.10</b>	<b>0.18</b>	<b>0.32</b>	<b>0.58</b>
<b>Immobility (%) at 48-hours</b>	0	0	5	5	60	100	100	100

Remarks:

**Conclusions**

The end point was adequately characterized.  
(American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48h) an *Daphnia magna* STRAUS von Genamin CC 100 D. [Acute immobilization study (48 hours) with *Daphnia magna* STRAUS with Genamin CC 100 D] Project No. 940905HM/DAI4259-.

**Other Available Reports**

**Other**

Last Changed:

August 12, 2002

Order number for sorting:

92d

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Adogen-160, coco oil (primary) amine  
(CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: NA  
Remarks:

### Method

Method/guideline followed: No specific guideline followed  
Type: Static  
GLP: No  
Year: 1970  
Species/Strain/Supplier: *Culex pipiens quinquefasciatus*/NA/Laboratory bred  
*Aedes aegypti*/NA/Laboratory bred  
*Aedes nigromaculis*/NA/Field collected from  
pastureland  
*Anopheles albimanus*/NA/Laboratory bred  
Analytical Monitoring: No  
Exposure Period: 24 hours  
Statistical Methods: Estimation of LC<sub>50</sub> and LC<sub>90</sub> values made from plot of  
percent mortality versus log concentration on probit  
log paper  
Remarks: Stock solutions of the test substance were prepared in  
acetone. Twenty 4<sup>th</sup>-instar larvae or 24-hour old pupae  
were placed in 4-oz. Dixie<sup>®</sup> cups containing 100 ml of  
tap water. Stock solutions were added (1 ml or less) to  
each cup to achieve the required concentration. Each  
concentration was tested three times and replicated  
twice in each test. Twenty-four hours after application  
of the test substance, mortality counts were made.

### Results

Nominal concentrations (mg/l): Not stated  
Measured concentrations (mg/l): NA  
Unit: ppm  
LC<sub>50</sub> (24 hour): *C. p. quinquefasciatus*  
LC<sub>50</sub> larvae = 2.2 ppm  
LC<sub>50</sub> pupae = 13.0  
*A. aegypti*  
LC<sub>50</sub> larvae = 2.0  
LC<sub>50</sub> pupae = 10.0  
*A. albimanus*  
LC<sub>50</sub> larvae = 3.0  
LC<sub>50</sub> pupae = 3.5

Result:

*A. nigromaculis*  
LC<sub>50</sub> larvae = 3.0  
LC<sub>50</sub> pupae = 3.5  
Additional endpoints included:  
*C. p. quinquefasciatus*  
LC<sub>90</sub> larvae = 4.4  
LC<sub>90</sub> pupae = 30.0  
*A. aegypti*  
LC<sub>90</sub> larvae = 5.2  
LC<sub>90</sub> pupae = 18.0  
*A. albimanus*  
LC<sub>90</sub> larvae = 6.0  
LC<sub>90</sub> pupae = 7.0  
*A. nigromaculis*  
LC<sub>90</sub> larvae = 6.0  
LC<sub>90</sub> pupae = 7.0

Remarks:

## Conclusions

The multiple mosquito species used in the study and the agreement of the endpoints provides a weight of evidence for adequate characterization of the acute toxicity of Amines, coco alkyl to aquatic invertebrates. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):  
Remarks:

2D  
Reliable with restrictions: used nonstandard test species.

## References

Mulla, M.S., H.A. Darwazeh and P.A. Gillies. 1970. Evaluation of Aliphatic Amines Against Larvae and Pupae of Mosquitoes. J. Economic Entomology. 63:1472-1475

## Other Available Reports

### Other

Last Changed:  
Order number for sorting:  
Remarks:

July 24, 2002  
92

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1980  
Species/Strain/Supplier: *Daphnia magna*/ex-IRCHA  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Method developed by D.J. Finney, 1971 based on nominal concentrations.  
Remarks: The test measured the acute toxicity of the test substance to the water flea, *Daphnia magna*, during a 48-h static exposure period. Dilution water was a mixture of hard and soft tap water and was characterized as follows: total hardness 250 mg/l as CaCO<sub>3</sub>, pH 7.9±0.2 and dissolved oxygen >80% saturation. Five daphnids, <24 h old, were impartially distributed to each test chamber (250-ml beakers) containing one of eight test solutions. Daphnids were observed for immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was maintained at 20±2°C for the duration of the test.

### Results

Nominal concentrations (mg/l): 0.29, 0.37, 0.48, 0.62, 0.8, 1.0, 1.3 and 1.7 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l, as active ingredient  
Element Value: LC<sub>50</sub> (95% Confidence Interval)  
Statistical Results: 24-hour LC<sub>50</sub> = 1.08 mg/l (0.98-1.20 mg/l)  
48-hour LC<sub>50</sub> = 0.38 mg/l (0.33-0.42 mg/l)

Results:

Nominal Concentration (mg/l)	% Mortality	
	24 h	48 h
0.29	0	20
0.37	0	55
0.48	0	75
0.62	15	100
0.8	30	100
1.0	35	100
1.3	65	100
1.7	100	100

Remarks:

Mortality reached 100% within 48 h in all treatment groups 0.62 mg/l and above. Mortality in the 0.29, 0.37 and 0.48 mg/l treatment groups reached 20, 55 and 75, respectively. Mortality during the first 24 h was concentration dependent.

### Conclusions

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

### References

De Henau, H. and H.T. de Oude. 1980. Static Acute Freshwater Invertebrate Toxicity Study of ETHOMEEN HT/12. Procter & Gamble ETC P&RS Laboratory. Unpublished report (No. E8013.01.03, ETS No. 67).

### Other Available Reports

### Other

Last Changed:  
Order number for sorting:  
Remarks:

September 18, 2003  
339

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: FARMIN TH (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: >98%  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test.  
Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: *Daphnia magna*/not stated/Centro de Investigacion y Desarrollo Aplicado, S.A.L laboratories  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Litchfield and Wilcoxon  
Remarks: The test measured the EC<sub>50</sub>, the EC<sub>0</sub> and the EC<sub>100</sub> of the test substance to *Daphnia magna*. *Daphnia* cultures were grown in glass containers with a maximum capacity of 84 liters. Twenty-four hours before the test began, a suitable number of adult *Daphnia* with eggs were separated and transferred to 10 ml test tubes. *Daphnia* were fed during pretreatment but not during treatment. Test vessels were filled with 75 ml test medium. Five test concentrations were run; 0.05, 0.10, 0.19, 0.39, and 0.78 mg/l. Two replicates of each concentration were run. Ten animals (< 24 hours old) were inserted into each test concentration. In addition, untreated and vehicle (100 mg Tween 80/liter) controls were included with four replicates per treatment. Dilution water was reconstituted water according to ISO 6341 with the following chemistry parameters: alkalinity = 0.8 mmol/l; hardness = 249 to 285 mg CaCO<sub>3</sub>/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; pH = 7.8; and O<sub>2</sub> = 100%. The test conditions were as follows: temperature = 22°C; dissolved oxygen = 62 to 100% and pH = 7.3 to 8.1. The study was run as two separate tests performed one week apart. Both tests were performed with untreated and vehicle control groups. The first test included test concentrations of 0.05 through 0.39 mg/l and the second test was run with only the highest concentrations, 0.78 mg/l

**Results**

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle), 0.05, 0.10, 0.19, 0.39, 0.78 mg/l

Measured concentrations (mg/l): Not determined

Unit: mg/l

EC<sub>50</sub> (48 hour): 0.16 mg/l

NOEC (48 hour): 0.05 mg/l

Result: Additional endpoints included:  
48-hour EC<sub>100</sub> = 0.78 mg/l;  
48-hour EC<sub>0</sub> = 0.05 mg/l  
Percent inhibition at 48-hours is provided in the following table:

Nominal Concentration (mg/l)	0 (untreated)	0 (vehicle)	0.05	0.10	0.19	0.39	0.78
Inhibition (%) at 48-hours	0	0	0	30	70	85	100

Remarks:

**Conclusions**

The endpoint has been adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:  
Remarks:

1A  
Reliable without restriction; guideline study.

**References**

Mayordomo, L. 1995. Acute Immobilization Test in Daphnia. Test Substance: FARMIN TH. Report No CD-95/4307T. KAO Corporation S.A..

**Other Available Reports****Other**

Last Changed:  
Order number for sorting:  
Remarks:

September 16, 2002  
106a

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: NORAM SH (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: >95%  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test.  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Daphnia magna*/STRAUS clone 5 or A/Centre Technique du Bois et de l'Ameublement, France  
Analytical Monitoring: Yes  
Exposure Period: 48 hours  
Statistical Methods: Probit Analysis (Finney's method, Bliss's method, Fieller's method)  
Remarks: The test measured the EC<sub>50</sub>, the EC<sub>0</sub> and the EC<sub>100</sub> of the test substance to *Daphnia magna*. *Daphnia* cultures were grown in M4 medium. *Daphnia* were not fed during treatment. The test consisted of six test concentrations; 1.0, 2.2, 4.8, 10.6, 23 and 50 mg/l; with four replicates of each concentration. Five animals (6 to 24 hours old) were inserted into each replicate. In addition, an untreated control group was included with four replicates per treatment. Dilution water was reconstituted water (M4) with the following chemistry parameters: hardness = 291 to 354 mg CaCO<sub>3</sub>/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; and conductance = <10 µS/cm. The test substance was heated to 65°C before being added to M4 water at 60 to 70°C. The stock solutions were allowed to cool to room temperature overnight under continuous stirring. Before dilution, the stock solution was centrifuged for one hour and the supernatant was collected. Test vessels were beakers containing 50 ml of the test solution. The test conditions were as follows: temperature = 19.5 to 20°C; dissolved oxygen > 95%; and pH = 7.5 to 8.4; and the photoperiod was 16 hours. Analysis method: extraction followed by GC-FID and quantified as the sum of four peaks (mixture of amines with different chain lengths). Sampling times were 0, 24 and 48 hours.

**Results**

Nominal concentrations (mg/l): 0, 1, 2.2, 4.8, 10.6, 23, 50 mg/l  
 Measured concentrations (mg/l): All below LOQ (1 mg/l)  
 Unit: mg/l  
 EC<sub>50</sub> (48 hour): <1 mg/l (LOQ)  
 NOEC (48 hour): Not determined  
 Result: At 23 mg/l, one daphnid was found dead, stuck to the wall of the beaker.  
 Additional endpoint included:  
 48-hour EC<sub>100</sub> = <1 mg/l  
 Percent inhibition at 48-hours is provided in the following table:

Nominal Concentration (mg/l)	0	1	2.2	4.8	10.6	23	50
Inhibition (%) at 48-hours	5	20	0	30	80	100	100

Remarks:

**Conclusions**

Based on analytical values less than the LOQ of 1.0 mg/l, the test substance was not solubilized in the system. Therefore, the EC<sub>50</sub> is stated as less than the LOQ, which provides a value consistent with other tests for this and similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability: 1A  
 Remarks: Reliable without restriction; guideline study.

**References**

Thomas, P.C. 1995. Acute Toxicity of Daphnia; NORAM SH. Study No. 12947 EAM. Centre International de Toxicologie (C.I.T), France.

**Other Available Reports****Other**

Last Changed: September 16, 2002  
 Order number for sorting: 106b  
 Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Ditallowmethylamine, hydrogenated  
(CAS RN 61788-63-4; Dihydrogenated tallow  
methylamine)  
Purity: 100.2%  
Remarks:

### Method

Method/guideline followed: Test methods conformed to EEC Method C.2. and  
OECD Guideline 202  
Type: Static  
GLP: Yes  
Year: 1990  
Species/Strain/Supplier: *Daphnia magna*/NA/Laboratory cultures  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: LC<sub>50</sub> values were calculated using the binomial method  
(described in Stephan 1977) and the trimmed  
Spearman-Kärber method (Hamilton et al. 1977).  
Remarks: The study measured the acute toxicity of the test  
substance to *Daphnia magna* during a 48-hour  
exposure period. The dilution water used in the test  
was synthetic water (Dutch Standard Water) having a  
pH of 8.2 and a hardness of approximately 13° dH.  
Daphnids used in the test were less than 24 hours old at  
the beginning of the test and were obtained from parent  
animals having an age of 2 – 4 weeks. Test vessels  
were 400-ml beakers holding 250 ml of test solution.  
Vessels were partly covered with a glass plate.  
Concentrations were replicated four times, with each  
replicate holding 5 daphnids (20 per concentration). To  
prepare the test concentrations, a stock solution of the  
test substance (320 g/l) was made by adding the test  
substance to methylethylketone and bringing the  
mixture to the boiling point (79.6°C). Aliquots of the  
stock were added to dilution water to achieve the  
desired test concentrations. Five test concentrations of  
the test substance, a dilution water control, and a  
solvent control, which contained methylethylketone at  
21.8 µl/l were used. All exposure solutions containing  
the test substance contained fat-like particles that  
floated at the surface or stuck to the sides of the test  
vessels. Once the test solutions were prepared, the  
daphnids were placed in the test solutions and the test  
vessels were placed in a temperature-controlled room

at 20°C. A lighting regime of 16 hours light/8 hours dark was provided by fluorescent tubes. Dissolved oxygen and pH were measured at the beginning and end of the test in one random beaker per test concentration and control. Dissolved oxygen concentrations ranged from 9.0 to 9.2 mg/l, water pH ranged from 7.7 to 7.9, and the air temperature in the test room ranged from 19 to 20°C. Observations of immobilization were recorded at a minimum at 0, 24, and 48 hours. Daphnids were considered immobile if they were not able to swim within 15 seconds after gentle agitation of the test vessel. Endpoint results are given based on nominal concentrations.

**Results**

Nominal concentrations (mg/l): 0 (control), 0 (solvent control), 2.2, 4.6, 10, 22, and 46 mg/l.  
 Measured concentrations (mg/l): Not determined  
 Unit: mg/l  
 EC<sub>50</sub> (48 hour): 35.2 mg/l (95% confidence limit of 29.1 to 42.6 mg/l)  
 NOEC (48 hour): 10 mg/l  
 Result: Percent immobility at 48-hours is presented in the following table:

Nominal Concentration (mg/l)	0 (negative control)	0 (solvent control)	2.2	4.6	10	22	46
Immobility (%) at 96-hours	0	0	5	0	0	15	70

Remarks:

**Conclusions**

The solubility problems may preclude identification of an accurate EC<sub>50</sub>. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A  
 Remarks: Reliable without restriction; guideline study.

**References**

Mark, U. and E.E. Hantink-de Rooij. 1990. Acute Toxicity of ARMEEN M2HT to *Daphnia magna*. Study/Report No. CRL F90215, Akzo Research Laboratories Arnhem, The Netherlands.

## **Other Available Reports**

### **Other**

Last Changed: July 25, 2002

Order number for sorting: 100

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: NORAM M2SH ND8 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: ISO 6341  
Type: Static  
GLP: Not stated  
Year: 1991  
Species/Strain/Supplier: *Daphnia magna*  
Analytical Monitoring: Not stated  
Exposure Period: 48 hours  
Statistical Methods: Not stated  
Remarks: Young *Daphnia*, 24-hours old, were exposed to the test substance at concentrations of 0, 0.15, 0.3, 0.45, 0.6, 0.75 and 0.9 g/l for 48 hours. Immobility was examined at 48 hours. The following criteria must be met in order for the test to be valid: 1) the EC<sub>50</sub> at 24 hours of the reference substance, potassium dichromate, must be 0.9 to 2.0 mg/l ; 2) the dissolved oxygen content at the lowest concentration giving 100% immobility must be > 2.0 mg/l; and 3) the percent immobilization in the control vessels at the end of 24 hours must be ≤ 10%.

### Results

Nominal concentrations (mg/l): 0, 150, 300 450, 600, 750, 950 mg/l  
Measured concentrations (mg/l): Not stated  
Unit: mg/l  
EC<sub>50</sub> (48 hour): 790 mg/l  
LC<sub>100</sub> (24 and 48 hours): > 900 mg/l  
NOEC (24 and 48 hours): 100 mg/l and 50 mg/l, respectively  
Result: EC<sub>50</sub> (48 hours) = 790 mg/l  
Remarks: Precipitation was observed between 450 and 900 mg/l

### Conclusions

The solubility problems may preclude identification of an accurate EC<sub>50</sub>. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1A  
Remarks: Reliable without restriction; guideline study.

**References**

Moncel, N. and J.C. Boutonnet. 1991. Rapport d'essai inhibition de la mobilite de *Daphnia magna*. [Report for the study of the inhibition of mobility of *Daphnia magna*] Atochem.

**Other**

Last Changed:

July 25, 2002

Order number for sorting:

103a

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: LC<sub>50</sub> values, based on nominal concentrations, were calculated by the moving average angle method  
Remarks: The test measured the acute toxicity of the test substance to the water flea, *Daphnia magna*, during a 48-h static exposure period. Dilution water was deionized water reconstituted from well water with the following characteristics: total hardness 165±15 mg/l as CaCO<sub>3</sub>, alkalinity 120±10 mg/l as CaCO<sub>3</sub>, pH 7.9-8.3 and specific conductance 500±100 µmhos/cm. Test chambers were 250-ml beakers containing one of six test solutions, dilution water (negative control) or diluted solvent (solvent control, 0.5ml/l isopropanol). Fifteen daphnids, <24 h old, were impartially distributed among the three replicate chambers for each test concentration (5 daphnids/chamber; 3 chambers/treatment). The test was run with no aeration at a temperature of 22±1° under fluorescent lighting (50-70 footcandles) and daphnids were not fed during testing. Daphnids were observed for immobility and mortality at 24 h and 48 h. Dissolved oxygen and pH were measured at test initiation (0 h) and termination (48 h). Temperature was monitored in one replicate of the negative control chamber.

### Results

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 2.4, 4.0, 6.6, 11, 18 and 30 mg/l  
Measured concentrations (mg/l): Not determined  
Unit: mg/l  
Element Value: LC<sub>50</sub> (95% Confidence Interval)

**Statistical Results:**24-hour LC<sub>50</sub> = 11 mg/l (8.1-15 mg/l)48-hour LC<sub>50</sub> = 3.1 mg/l (2.6-3.7mg/l)**Results:**

Nominal Concentration (mg/l)	Mean % Mortality <sup>a</sup>	
	24 h	48 h
(-) control	0	0
solvent control	0	0
2.4	0	7
4.0	20 <sup>b,c</sup>	93 <sup>c</sup>
6.6	27 <sup>b,c</sup>	100 <sup>c</sup>
11	53 <sup>b,c</sup>	100
18	73 <sup>b,c</sup>	100
30	80 <sup>b</sup>	100

<sup>a</sup> N=3.<sup>b</sup> Several daphnids were lethargic.<sup>c</sup> Several daphnids were caught at the air-water interface of the test solution.**Remarks:**

No mortality or abnormal behavior was observed in either control group. The death of one daphnid in one replicate of 2.4 mg/l treatment group resulted in the mean 48-h mortality of 7%. Two of the three 4.0 mg/l treatment groups experienced 100% mortality by 48 h, yielding a mean mortality of 93%. The 48-h mean mortality was 100% in the four remaining treatment groups (6.6, 11, 18 and 30 mg/l), for which lethargy was noted in all surviving daphnia at 24 h.

Temperature in the negative control chamber remained at 22°C throughout the test. Dissolved oxygen was 94% saturation in all test chambers at test initiation and ranged from 88 to 91% over the remaining 24 hours of the test. The pH in the test chambers remained at 8.2 in all test chambers throughout the test.

A film was present on the surface of each replicate test solution and the three highest test concentrations were cloudy throughout the study period.

**Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

## References

G.A. LeBlanc and D.C. Surprenant. 1981. Acute Toxicity of B0390.01 to the Water Flea (*Daphnia magna*). Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-81-10-1027.

## Other Available Reports

### Other

Last Changed:

September 18, 2003

Order number for sorting:

336

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Adogen 343 (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Yes  
Year: 1981  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: LC<sub>50</sub> values, based on nominal concentrations, were calculated by the moving average angle method.  
Remarks: The test measured the acute toxicity of the test substance to the water flea, *Daphnia magna*, during a 48-h static exposure period. Dilution water was collected from Town River in Bridgewater, MA, approximately 0.5 km downstream from the Bridgewater sewage treatment plant, and was characterized as follows: total hardness 66 mg/l as CaCO<sub>3</sub>, alkalinity 18 mg/l as CaCO<sub>3</sub>, pH 7.0, specific conductance 260 µmhos/cm, total suspended solids (TSS, adjusted) 240 mg/l and methylene blue active substances (MBAS) 4 mg/l. Test chambers were 250-ml beakers containing one of six test solutions, dilution water (negative control) or diluted solvent (solvent control, 0.5ml/l isopropanol). Fifteen daphnids, <24 h old, were impartially distributed among the three replicate chambers for each test concentration (5 daphnids/chamber; 3 chambers/treatment). The test was run with no aeration at a temperature of 22±1°C under fluorescent lighting (50-70 footcandles) and daphnids were not fed during testing. Daphnids were observed for immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was monitored in one replicate of the negative control chamber.

### Results

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 2.4, 4.0, 6.6, 11, 18 and 30 mg/l  
Measured concentrations (mg/l): Not determined

Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results: 24-hour LC<sub>50</sub> > 50 mg/l (empirically estimated)  
 48-hour LC<sub>50</sub> = 21 mg/l (17-25 mg/l)

Results:

Nominal Concentration (mg/l)	Mean % Mortality <sup>a</sup>	
	24 h	48 h
(-) control	0	0
solvent control	0	0
4.0	0	0
6.5	0	0
11	0	0
18	0	40 <sup>c</sup>
30	0	87 <sup>b</sup>
50	0 <sup>b</sup>	100

<sup>a</sup> N=3.

<sup>b</sup> Several daphnids were lethargic.

<sup>c</sup> Several daphnids were caught at the air-water interface of the test solution.

Remarks:

No mortality or abnormal behavior was observed in either control group, nor in the 4.0, 6.5 or 11 mg/l treatment groups. Mortality averaged 40% and 87% in the 18 and 30 mg/l treatment groups, respectively, by the end of the test with some degree of immobilization observed in each group at 48 h. Mortality in the highest treatment group, 50 mg/l, was 100% by 48 h, with lethargy reported for several daphnids at 24 h.

Temperature in the negative control chamber remained at 22°C throughout the test. Dissolved oxygen was 3-94% saturation in all treatment levels and solvent control (97% in negative control) at test initiation and dropped to 22-31% (52% and 87% in the solvent and negative controls, respectively) over the remaining 24 hours of the test. The pH in the test chambers was 7.2 at initiation in all test chambers and dropped to approximately 6.6 (6.7 and 7.1 in solvent and negative controls, respectively).

All test solutions and controls were tan in color and had a particulate matter which settled to the bottom of each test vessel. Test solutions were cloudy and had a surface film throughout the duration of the test.

**Conclusions**

The end point was adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

G.A. LeBlanc and D.C. Surprenant. 1981. Acute  
Toxicity of B0390.01 in River Water to the Water Flea  
(*Daphnia magna*). Toxicity test report submitted to  
The Procter & Gamble Company, Cincinnati, OH,  
USA, by EG&G, Bionomics, Aquatic Toxicology  
Laboratory, Wareham, MA, USA, Report No.  
BW-81-11-1037.

**Other Available Reports**

**Other**

Last Changed:

September 18, 2003

Order number for sorting:

337

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: DV Base; Adogen 343 (CAS No. 61788-63-4; Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Yes  
Year: 1985  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: LC<sub>50</sub> values, based on nominal concentrations, were calculated by the moving average angle method.  
Remarks: The test measured the acute toxicity of the test substance to the water flea, *Daphnia magna*, during a 48-h static exposure period. Dilution water was fortified well water and was characterized as follows: total hardness 160 mg/l as CaCO<sub>3</sub>, alkalinity 120 mg/l as CaCO<sub>3</sub>, pH 6.1 and specific conductance 500 µmhos/cm. Test chambers were 250-ml beakers containing one of five test solutions, dilution water (negative control) or diluted solvent (solvent control, 0.5ml/l isopropanol). Fifteen daphnids, <24 h old, were impartially distributed among the three replicate chambers for each test concentration (5 daphnids/chamber; 3 chambers/treatment). The test was run with no aeration at a temperature of 20±1° under fluorescent lighting (7 hectolux at surface) 16 h per day and daphnids were not fed during testing. Daphnids were observed for immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was monitored in one replicate of the negative control chamber.

**Results**

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 1.3, 2.2, 3.6, 6.0 and 10 mg/l

Measured concentrations (mg/l): Not determined

Unit: mg/l

Element Value: LC<sub>50</sub> (95% Confidence Interval)

Statistical Results: 24-hour LC<sub>50</sub> = 2.6 mg/l (2.2-3.1 mg/l)

48-hour LC<sub>50</sub> = 2.0 mg/l (1.6-2.5 mg/l)

Results:

Nominal Concentration (mg/l)	Mean % Mortality <sup>a</sup>	
	24 h	48 h
(-) control	0	0
solvent control	0	0
1.3	0 <sup>b</sup>	20 <sup>b</sup>
2.2	27 <sup>c</sup>	47 <sup>c</sup>
3.6	87 <sup>c</sup>	93 <sup>c</sup>
6.0	100	100
10	100	100

<sup>a</sup> N=3.

<sup>b</sup> Several surviving daphnids were lethargic.

<sup>c</sup> All surviving daphnids were lethargic.

Remarks:

No mortality or abnormal behavior was observed in either control group. Mortality in the 1.3 mg/l treatment group averaged 20% due a single death in each replicate between 24 and 48 h. Mortality at 48 h averaged 47% and 93% in the 2.2 and 3.6 mg/l treatment groups, respectively. All of the surviving daphnids in this group were exhibiting signs of lethargy. Mortality in the 6.0 and 10 mg/l treatment groups was 100% within the first 24 hours.

Temperature in the negative control chamber remained at 20°C throughout the test. Dissolved oxygen was >90% in all test chambers throughout the duration of the test. The pH in the test chambers ranged from 7.9 to 8.3 at initiation and termination of the test.

The 3.6, 6.0 and 10 mg/l test solutions were cloudy throughout the duration of the test.

**Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks: Reliable without restriction; guideline study.

**References**

Nicholson, R.B. and D.C. Surprenant. 1985. 48-Hour Static Toxicity Test: Freshwater Invertebrate. Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by Springborn Bionomics, Inc., Wareham, MA, USA, Report No. BW-85-7-1807/Study No. 1011-0385-6133-110.

**Other Available Reports**

**Other**

Last Changed: September 18, 2003

Order number for sorting: 338

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: DV-base (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks: The test material in this study was a (64:36) mixture of DV-base and HTFA. HTFA is *hardened tallow fatty acid* (96.7% pure).

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Yes  
Year: 1985  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: The LC<sub>50</sub> was calculated by probit analysis  
Remarks: The test measured the acute toxicity of a formulated mixture containing the test substance to the water flea, *Daphnia magna*, during a 48-h static exposure period. Two compounds, HTFA and DV-base (ditallow methyl amine, 83.5%; tritallow amine, 11.6%; and tallow dimethyl amine, 4.9%), were dissolved in isopropyl alcohol to make two separate stock solutions then added individually to test solutions. The resulting ratio of compounds (HTFA:DV-base) in each test solution was 36:64, respectively. Dilution water was fortified well water filtered through a carbon filter and Amberlite XAD-7 resin column to remove any potential organic contaminants. This water was characterized as follows: total hardness of 170 mg/l as CaCO<sub>3</sub>, alkalinity of 130 mg/l as CaCO<sub>3</sub>, pH of 8.1 and a specific conductance of 600 µmhos/cm. Test chambers were 250-ml beakers containing 200 ml of one of five test solutions, dilution water (negative control) or diluted solvent (solvent control, 0.5ml/l isopropyl alcohol).

Fifteen daphnids, <24 h old, were impartially distributed among the three replicate chambers for each test concentration (5 daphnids/chamber; 3 chambers/treatment) within 15 min. of test solution preparation. The temperature during the test was maintained at 20±1°C under Growlux<sup>®</sup> and fluorescent lighting (7 hectolux). Photoperiod was 16 hours of light

and 8 hours of darkness. Test vessels were not aerated during the test. Daphnids were observed for immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was monitored in one replicate of the negative control chamber at 0, 24 and 48 hours.

**Results**

Nominal concentrations: 0 (negative control), 0 (solvent control), 1.3, 2.2, 3.6, 6.0 and 10 mg/l  
 Measured concentrations: Not determined  
 Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results: 24-hour LC<sub>50</sub> > 10 mg/l (estimated empirically)  
 48-hour LC<sub>50</sub> = 6.5 mg/l (5.0-9.5 mg/l)

Results:

Nominal Concentration (mg/l)	Mean Cumulative Mortality (%) <sup>a</sup>	
	24 h	48 h
(-) control	0	0
solvent control	0	0
3.2	0	0
5.4	0	0
9.0	0	0
15	0	13 <sup>c</sup>
25	0 <sup>b</sup>	67 <sup>d</sup>

<sup>a</sup> N=3.

<sup>b</sup> All surviving daphnids were lethargic and trailing exoskeletons.

<sup>c</sup> Several of the surviving daphnids were lethargic and on the bottom of the test vessel.

<sup>d</sup> All surviving daphnids were lethargic and on the bottom of the test vessel.

Remarks:

No mortality or abnormal behavior was observed in either control group, nor in the 3.2, 5.4 or 9.0 mg/l treatment groups. Mortality averaged 13% and 67% in the 15 and 25 mg/l treatment groups, respectively, by the end of the test with some degree of immobilization observed in each group at 48 h. Effect concentrations are based on nominal concentrations of the formulated mixture (HTFA and DV-base).

A 48-hour LC<sub>50</sub> (95% confidence interval) was 5.3 (3.2-9.0) mg/l was reported for a separate reference study testing the toxicity of sodium lauryl sulfate on the same daphnia population.

Temperature in the negative control chamber remained

at  $21 \pm 1^\circ\text{C}$  throughout the test. Dissolved oxygen concentrations ranged from 7.4 to 8.5 (80-94% saturation) during the test, with consistently higher values measured at 48 hours compared to those measured at test initiation. The pH in the test chambers increased from 7.8 at initiation to 8.1 (8.2 in solvent control) by 48 hours.

All test solutions (except controls) contained white precipitate on the bottom of the test vessels in proportion to the concentration of test materials throughout the study period.

### Conclusions

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Nicholson, R.B. and D.C. Surprenant. 1985. Acute Toxicity of P1943.01 + P1944.01 (36:64) to *Daphnia magna*. Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by Springborn Bionomics, Inc., Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-85-7-1806.

### Other Available Reports

#### Other

Last Changed:

September 24, 2003

Order number for sorting:

353

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: DV-base (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks: The test material in this study was a mixture of DV-  
base, PEG (polyethylene glycol) and HFTA (*hardened  
tallow fatty acid*).

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity  
tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Yes  
Year: 1985  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: The LC<sub>50</sub> was calculated by the moving average angle  
analysis .  
Remarks: The test measured the acute toxicity of a formulated  
prill containing the test substance to the water flea,  
*Daphnia magna*, during a 48-h static exposure period.  
A single stock solution was made up by dissolving a  
formulated prill of HTFA (34.4%), PEG (2.9%) and  
DV-base in isopropyl alcohol at 70°C which was then  
volumetrically added directly to dilution water to  
achieve five test solutions. The dilution water consisted  
of fortified well water filtered through a carbon filter  
and Amberlite XAD-7 resin column to remove any  
potential organic contaminants. This water was  
characterized as follows: total hardness of 160mg/l as  
CaCO<sub>3</sub>, alkalinity of 120 mg/l as CaCO<sub>3</sub>, pH of 8.1 and  
a specific conductance of 500 µmhos/cm. Test  
chambers were 250-ml beakers containing 200 ml of  
one of five test solutions, dilution water (negative  
control) or diluted solvent (solvent control, 0.5ml/l  
isopropyl alcohol).

Fifteen daphnids, <24 h old, were impartially distributed  
among the three replicate chambers for each test  
concentration (5 daphnids/chamber; 3  
chambers/treatment) within 15 min. of test solution  
preparation. The temperature during the test was  
maintained at 20±1°C under Growlux<sup>®</sup> and fluorescent  
lighting (7 hectolux). Photoperiod was 16 hours of light

and 8 hours of darkness. Test chambers were not aerated during the test. Daphnids were observed for immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was monitored in one replicate of the negative control chamber at 0, 24 and 48 hours.

**Results**

Nominal concentrations: 0 (negative control), 0 (solvent control), 3.2, 5.4, 9.0, 15 and 25 mg/l  
 Measured concentrations: Not determined  
 Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results: 24-hour LC<sub>50</sub> > 25 mg/l (estimated empirically)  
 48-hour LC<sub>50</sub> = 22 mg/l (18-28 mg/l)

Results:

Nominal Concentration (mg/l)	Mean Cumulative Mortality (%) <sup>a</sup>	
	24 h	48 h
(-) control	0	0
solvent control	0	0
1.3	0 <sup>b</sup>	7
2.2	0 <sup>b</sup>	0 <sup>d</sup>
3.6	0 <sup>b</sup>	13 <sup>d</sup>
6.0	0 <sup>b,c</sup>	53 <sup>b</sup>
10	7 <sup>c</sup>	73 <sup>b</sup>

<sup>a</sup> N=3.

<sup>b</sup> Several surviving daphnids were trailing exoskeletons.

<sup>c</sup> Several surviving daphnids were lethargic and trailing exoskeletons.

<sup>d</sup> One daphnid was lethargic.

Remarks:

No mortality or abnormal behavior was observed in either control group. While no mortalities were observed in the 2.2 mg/l treatment group and 1 daphnid died in the 1.3 mg/l treatment group at 48 hours, bringing the average cumulative mortality for the lowest treatment group to 7%. Several surviving daphnids were trailing exoskeletons in these two groups at 24 hours and only 1 daphnid in the 2.2 mg/l treatment group was lethargic by 48 hours.

Mortality averaged 13, 53 and 73% in the 3.6, 6.0 and 10 mg/l treatment groups, respectively, by the end of the test with some degree of immobilization observed in each group throughout the exposure period. Effect concentrations are based on nominal concentrations of the formulated prill.

A 48-hour LC50 (95% confidence interval) was 5.3 (3.2-9.0) mg/l was reported for a separate reference study testing the toxicity of sodium lauryl sulfate on the same daphnia population.

Temperature in the negative control chamber remained at 20°C throughout the test. Dissolved oxygen concentrations ranged from 8.3 to 8.5 (90-92% saturation) in the treatment solutions and averaged 8.9 (94%) in the controls throughout the test. The pH in the test chambers increased from approximately 8.0 at initiation to 8.3 by 48 hours. The solvent control remained at a pH of 8.0 throughout the test.

The surface of all test solutions (except controls) contained white precipitate throughout the study period.

## Conclusions

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

## References

Nicholson, R.B. and D.C. Surprenant. 1985. Acute Toxicity of P1927.01 to *Daphnia magna*. Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by Springborn Bionomics, Inc., Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-85-6-1797.

## Other Available Reports

## Other

Last Changed:  
Order number for sorting:  
Remarks:

September 24, 2003  
354

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: DV-base (CAS No. 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 100%  
Remarks: The test material in this study was a mixture of DV-  
base, PEG (polyethylene glycol) and HFTA (*hardened  
tallow fatty acid*).

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity  
tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Yes  
Year: 1985  
Species/Strain/Supplier: *Daphnia magna*/Bionomics culture facility  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: The LC<sub>50</sub> was calculated by the moving average angle  
analysis.  
Remarks: The test measured the acute toxicity to the water flea,  
*Daphnia magna*, of a formulated prill, containing the  
test substance, during a 48-h static exposure period. A  
single stock solution was made up by dissolving a  
formulated prill of HTFA (34.4%), PEG (2.9%) and  
DV-base in isopropyl alcohol at 70°C which was then  
volumetrically added directly to dilution water to  
achieve five test solutions. The dilution water consisted  
was freshwater collected from Town River (West  
Bridgewater, MA), and was characterized as follows:  
total hardness of 35 mg/l as CaCO<sub>3</sub>, alkalinity of 15  
mg/l as CaCO<sub>3</sub>, pH of 6.4 and a specific conductance of  
180 µmhos/cm. Test chambers were 250-ml beakers  
containing 200 ml of one of five test solutions, dilution  
water (negative control) or diluted solvent (solvent  
control, 0.5ml/l isopropyl alcohol).

Fifteen daphnids, <24 h old, were impartially distributed  
among the three replicate chambers for each test  
concentration (5 daphnids/chamber; 3  
chambers/treatment) within 15 min. of test solution  
preparation. The temperature during the test was  
maintained at 20±1°C under Growlux<sup>®</sup> and fluorescent  
lighting (7 hectolux). Photoperiod was 16 hours of light  
and 8 hours of darkness. Test chambers were not  
aerated during the test. Daphnids were observed for

immobility and mortality at 24 and 48 h. Dissolved oxygen and pH were measured at 0 h and 48 h. Temperature was monitored in one replicate of the negative control chamber at 0, 24 and 48 hours.

**Results**

Nominal concentrations: 0 (negative control), 0 (solvent control), 13, 22, 36, 60 and 100 mg/l  
 Measured concentrations: Not determined  
 Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results: 24-hour LC<sub>50</sub> > 100 mg/l (estimated empirically)  
 48-hour LC<sub>50</sub> = 60 mg/l (51-72 mg/l)

Results:

Nominal Concentration (mg/l)	Mean Cumulative Mortality (%) [n=3]	
	24 h	48 h
(-) control	0	0
solvent control	0	0
13	0	0
22	0	0
36	0	7
60	0	33
100	0	100

Remarks:

No mortality or abnormal behavior was observed in any test solution or control group during the first 24 hours of exposure or in the 13, 22 or 36 mg/l treatment group by 48 hours. Cumulative mortality averaged 7, 33 and 100% in the 36, 60 and 100 mg/l treatment groups, respectively, by the end of the test; however no abnormal effects were observed. Effect concentrations are based on nominal concentrations of the formulated prill.

A 48-hour LC<sub>50</sub> (95% confidence interval) of 5.3 (3.2-9.0) mg/l was reported for a separate reference study testing the toxicity of sodium lauryl sulfate (positive control) on the same daphnia population.

Temperature in the negative control chamber remained at 20°C throughout the test. Dissolved oxygen concentrations decreased from approximately 9.2 (100% saturation) in all test chambers at test initiation to approximately 8.5 (92% saturation) by 48 hours. The pH in all test chambers increased from approximately 6.3 at initiation to 7.1 by 48 hours.

The surface of all test solutions (except controls) contained white precipitate throughout the study period.

### **Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):  
Remarks:

1D  
Reliable without restriction; similar to guideline study using river water.

### **References**

Nicholson, R.B. and D.C. Surprenant. 1985. Acute Toxicity of P1927.01 in River Water to *Daphnia magna*. Toxicity test report submitted to The Procter & Gamble Company, Cincinnati, OH, USA, by Springborn Bionomics, Inc., Aquatic Toxicology Laboratory, Wareham, MA, USA, Report No. BW-85-6-1796.

### **Other Available Reports**

#### **Other**

Last Changed:  
Order number for sorting:  
Remarks:

September 24, 2003  
352

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Tallow amine (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: U.S. EPA 600/3-75-009: Methods for acute toxicity tests with fish, macroinvertebrates, and amphibians.  
Type: Static  
GLP: Not stated  
Year: 1985  
Species/Strain/Supplier: *Daphnia magna* /In-house cultures  
Analytical Monitoring: No  
Exposure Period: 48-hours  
Statistical Methods: Computer program, developed by C.E Stephan, (1982. US EPA Environmental Research Laboratory, Duluth, MN. Personal communication to Dr. Lowell Bahner, Chairman ASTM Task Group on Calculating LC<sub>50</sub>'s), to calculate LC<sub>50</sub> by moving average, probit and binomial probability  
Remarks: The test measured the acute toxicity of the test substance to *Daphnia magna* under static test conditions. Daphnids less than 24 hours old were exposed to six concentrations of the test substance, a solvent control and a negative control for a period of 48 hours. Each treatment groups consisted of three replicate test chambers. Test chambers were 250-ml glass beakers holding 200 ml of test solution. Dilution water was river water having the following characteristics: total hardness 50 mg/l as CaCO<sub>3</sub>, alkalinity 24 mg/l as CaCO<sub>3</sub>, pH 7.7 and specific conductance 360 µmhos/cm. Exposure concentrations of the test substance were prepared by diluting a working stock solution that had been prepared in acetone. Aliquots of the stock were added to dilution water, stirred and apportioned among triplicate test chambers for each treatment group. The test was run at a temperature of 21±1°C under a 16 h light:8 h dark photoperiod. Light intensity was 7 hectolux during the light period. At test initiation, five daphnids were impartially distributed to each test chamber. Daphnids were not fed during testing, and mortalities were recorded at 24 and 48 hours. Dissolved oxygen and pH were measured at 0 and 48 hours in one replicate

vessel of the control, solvent control, and the low, middle and high exposure groups. Temperature was measured in one control vessel at 0, 24 and 48 hours. All water quality factors were within the correct ranges during the test.

**Results**

Nominal concentrations (mg/l): 0 (negative control), 0 (solvent control), 0.04, 0.065, 0.11, 0.18, 0.30, and 0.50 mg/l.  
 Measured concentrations (mg/l): Not determined  
 Unit: mg/l  
 EC<sub>50</sub> (48 hour): Toxicity reported as LC<sub>50</sub>.  
 LC<sub>50</sub> (48 hour): 0.093 mg/l (95% confidence interval of 0.076 to 0.11 mg/l)  
 NOEC (48 hour): 0.040 mg/l  
 Result: Percent mortality at 48-hours is provided in the following table:

Nominal Concentration (mg/l)	0 (Negative control)	0 (Solvent control)	0.04	0.065	0.11	0.18	0.30	0.50
Mortality (%) at 48 Hours	0	0	0	53	67	73	100	100

Remarks: After 24 hours, the LC<sub>50</sub> was 0.23 mg/l with 95% confidence interval of 0.040 to 0.30 mg/l.

**Conclusions**

The acute toxicity of the test substance to *Daphnia magna* was adequately characterized by the study. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1B  
 Remarks: Reliable without restriction; comparable to guideline study.

**References**

Springborn Bionomics, Inc. 1986. Acute Toxicity of Adogen 170D to Daphnids (*Daphnia magna*) in River Water. Toxicity test report submitted to Sherex Chemical Company, Dublin, Ohio. Bionomics Report No. BW-86-3-1956; Study No. 11,187-0585-6101-110.

## **Other Available Reports**

### **Other**

Last Changed: July 25, 2002

Order number for sorting: 214

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: Genamin TA 100 D (CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test.  
Type: Static  
GLP: Yes  
Year: 1994  
Species/Strain/Supplier: *Daphnia magna* STRAUS/Institut fuer Wasser-, Boden- und Lefthygiene des Bundesgesundheitsamtes, Berlin.  
Analytical Monitoring: No  
Exposure Period: 48 hours  
Statistical Methods: Probit analysis, Methoden der Wasseruntersuchungen Bd. II (1982).  
Remarks: Daphnids were bred in glass beakers containing culture medium (Elendt) at 20 to 25°C and 10 hour light. Daphnids, 2 to 24 hours old, were fed algae during pretreatment but feeding during the test was not specified. Dilution water information: Source was EWG 84/449; hardness = 236 mg CaCO<sub>3</sub>/l; pH = 7.7; O<sub>2</sub> = 95%; conductivity = 638 S/cm. Exposure vessels were 50 ml glass beakers containing 20 ml test medium. Number of animals = 5 per replicate; 4 replicates per treatment; reference substance with 10 daphnids per replicate (2 replicates per treatment). Test conditions: temperature = 21 to 22°C; dissolved oxygen = ≥89%; pH = 7.5 to 7.6; photoperiod = 12 hours. Immobility was the test parameter evaluated.

### Results

Nominal concentrations (mg/l): 0, 0.032, 0.058, 0.10, 0.18, 0.32 and 0.58 mg/l  
Measured concentrations (mg/l): NA  
Unit: mg/l  
EC<sub>50</sub> (48 hour): 0.09 mg/l (95% confidence limit of 0.07 to 0.11 mg/l)  
NOEC (48 hour): Not determined

Result: Percent immobility at 48-hours is provided in the following table:

<b>Nominal Concentration (mg/l)</b>	<b>0</b>	<b>0.032</b>	<b>0.058</b>	<b>0.10</b>	<b>0.18</b>	<b>0.32</b>	<b>0.58</b>
<b>Immobility (%) at 48-hours</b>	0	5	10	70	80	100	100

Remarks:

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Noack, M. 1994. Akuter Immobilisierungstest (48 h) an *Daphnia magna* STRAUS von Genamin TA 100 D [Acute immobilization study (48 hours) in *Daphnia magna* STRAUS with Genamin TA 100 D] (940905HM/DAI42611).

**Other Available Reports****Other**

Last Changed:

August 9, 2002

Order number for sorting:

214c

Remarks:

## 4.2 TOXICITY TO AQUATIC INVERTEBRATES

### Test Substance

Identity: NORMAN S(CAS No. 61790-33-8; Amines, tallow alkyl)  
Purity: >95%  
Remarks:

### Method

Method/guideline followed: OECD Guideline 202 (I), *Daphnia* sp. Acute Immobilisation Test.  
Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: *Daphnia magna* STRAUS-clone 5 or A/Centre Technique du Bois et de l'Ameublement, France.  
Analytical Monitoring: Yes  
Exposure Period: 48 hours  
Statistical Methods: Probit analysis, (Finney's method, Bliss's method, Fieller's method)  
Remarks: Daphnids were bred in culture M4-medium with pH of 7.5 to 8.5, 18 - 22°C; O<sub>2</sub> >80%; and 16 hour light. Daphnids, 6 to 24 hours old and were not fed during the test. The test substance was heated to 65°C before being added to preheated water. The stock solutions were allowed to cool to room temperature overnight under continuous stirring. Before dilution, the stock solution was centrifuged and the supernate was collected. Dilution water information: Reconstituted water (M4); hardness = 296 to 401 mg CaCO<sub>3</sub>/l; Ca/Mg ratio = 4/1; Na/K ratio = 10/1; conductivity = <10uS/cm. Exposure vessels were beakers containing 50 ml test medium. Number of daphnia = 5 per replicate; 4 replicates per treatment. Test conditions: temperature = 19 to 20°C; dissolved oxygen = >81%; pH = 7.8 to 8.3; photoperiod = 16 hours. Immobility was the test parameter evaluated.  
Analytical method: Extraction followed by GC-FID and quantified as the sum of 4 peaks (mixture of amines with different chain lengths); sampled at 0, 24 and 48 hours.

### Results

Nominal concentrations (mg/l): 0, 1, 2.2, 4.8, 4.8, 10.6, 23 and 50 mg/l  
Measured concentrations (mg/l): All below LOQ (<0.25 mg/l)  
Unit: mg/l  
EC<sub>50</sub> (48 hour): < LOQ (0.25 mg/l)

NOEC (48 hour):

Not determined

Result:

Percent immobility at 48-hours is provided in the following table:

Nominal Concentration (mg/l)	0	1	2.2	4.8	10.6	23	50
Immobility (%) at 48-hours	0	0	0	0	20	100	100

Remarks:

**Conclusions**

Based on analytical values less than the LOQ of 0.25 mg/l, the test substance was not solubilized in the system. Therefore, the EC<sub>50</sub> is stated as less than the LOQ, which provides a value consistent with other tests for this and similar chemicals. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Thomas, P.C. 1995. Acute Toxicity in Daphnia NORAM S. Study No. 12946 EAM. Centre International de Toxicologie (C.I.T.), France.

**Other Available Reports****Other**

Last Changed:

August 9, 2002

Order number for sorting:

214d

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin LA 302 D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: 99.3%  
Remarks:

#### Method

Method/guideline followed: Modified OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 2000  
Species/Strain/Supplier: *Scenedesmus subspicatus* CHODAT SAG 86.81/Algae cultures (SAG) from Pflanzenphysiologisches Institut der Universität, Nikolausberger Weg 18, D-37073 Göttingen, and fresh cultures prepared every month on Z-Agar.  
Element Basis: Biomass and growth rate  
Analytical Monitoring: No  
Exposure Period: 72 hours  
Statistical Methods: NOEC: One way analysis of variance (ANOVA) and DUNNETT'S test of biomass integrals and growth rate ( $\alpha = 0.05$ ).  
EC<sub>50</sub>-values: confidence intervals.  
Remarks: The study measured the growth inhibition of the test substance to *Scenedesmus subspicatus* during a 72-hour exposure period. Two different natural waters (rivers Elbe and Böhme) were used as the test medium. Tests with Elbe water used seven concentrations of the test substance ranging from 10 to 640 µg/l. Tests with Böhme water used six concentrations of the test substance ranging from 10 to 320 µg/l. Three replicates were tested for each concentration and six replicated for the control. No vehicle was used to dissolve the test substance. In addition, a parallel test with OECD-medium and two concentrations of test substance (10 and 100 µg/l and control) was carried out. Initial cell density was nominally 10<sup>4</sup> cells/ml. Test conditions: The incubation took place in Erlenmeyer flasks in accordance with quoted guidelines at 23 ± 2°C over a 3 day period during which the solutions were shaken on a rotary shaker and oscillated at approximately 70 rpm. Light intensity was 60 – 120 µE/m<sup>2</sup> at the water surface for 24 hours/day. Test flasks were 250 ml Erlenmeyer flasks

containing 100 ml solution. The algae were acclimated to the test substance for three days prior to the test. Fluorescence was measured prior to application of the test item, and after 24, 48 and 72 hours.

Biomass and growth rate were measured after 24, 48 and 72 hours.

## Results

Nominal concentrations (mg/l): 0 (control), 0.01, 0.02, 0.04, 0.08, 0.16, and 0.32 mg/l plus 0.64 mg/l for Elbe water only.

Measured concentrations (mg/l): NA

Unit: mg/l

Element value: 72-hour  $E_bC_{50}$  (biomass)

72-hour  $E_rC_{50}$  (growth rate)

NOEC (biomass and growth rate)

Satisfactory control response: Yes

Result:

	<b>Inhibition of biomass (mg/l)</b>		
	<b>Elbe</b>	<b>Böhme</b>	<b>OECD-Medium</b>
<b><math>E_bC_{50}</math></b>	0.056	0.034	0.006
<b>95% confidence interval</b>	51 to 62	0.03 to 0.038	NA
<b>NOEC</b>	0.02	0.01	<0.01
	<b>Growth rate-related inhibition (mg/l)</b>		
	<b>Elbe</b>	<b>Böhme</b>	<b>OECD-Medium</b>
<b><math>E_rC_{50}</math></b>	0.092	0.056	0.014
<b>95% confidence interval</b>	0.082 to 0.102	0.051 to 0.062	NA
<b>NOEC</b>	0.02	0.02	<0.01

Remarks:

### Elbe Water:

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0.64</b>	100.00	100.00
<b>0.32</b>	100.00	100.00
<b>0.16</b>	95.63	84.86
<b>0.08</b>	58.53	26.72
<b>0.04</b>	35.83	15.01
<b>0.02</b>	-3.62	1.38
<b>0.01</b>	-2.24	3.77

**Böhme Water:**

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0.32</b>	100.00	100.00
<b>0.16</b>	97.22	100.00
<b>0.08</b>	89.63	74.29
<b>0.04</b>	55.30	25.18
<b>0.02</b>	25.32	5.13
<b>0.01</b>	-0.06	-1.87

**OECD-Medium:**

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0.1</b>	97.64	100.00
<b>0.01</b>	65.23	26.20

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
Remarks:

1D  
Reliable without restriction; modified OECD 201  
guideline study

**References**

Noack, U. 2000. Genamin LA 302 D. Alga, Growth  
Inhibition Test with 2 Natural River Waters, with  
*Scenedesmus subspicatus*, 72 h.. Study No. SSO7535N.  
Dr. U. Noack-Laboratory for Applied Biology.  
Sarstedt, Germany.

**Other**

Last Changed:  
Order number for sorting:  
Remarks:

June 12, 2002  
124d

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin LA 302 D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: 99.9%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: *Scenedesmus subspicatus* – Nr. 8681 SAG/supplier not stated.  
Element Basis: Biomass and growth rate  
Exposure Period: 72 hours  
Analytical Monitoring: Yes  
Statistical Methods: Not stated  
Remarks: The study measured the growth inhibition of the test substance to *Scenedesmus subspicatus* during a 72-hour exposure period. Five concentrations of the test substance ranging from 2.6 to 40 µg/l were evaluated. In addition, two controls groups were evaluated; one with untreated water and one containing 1 mg/l of Tween 80.  
Test conditions: The incubation took place in Erlenmeyer flasks in accordance with quoted guidelines at  $23 \pm 1^\circ\text{C}$  over a 3 day period during which the solutions were stirred. Test flasks were 100 ml Erlenmeyer flasks containing 100 ml solution. The algae were not acclimated to the test substance prior to the test. The test was run with six replicate flasks of the control group and three replicate flasks of each test solution and the Tween 80 test group. Biomass and growth ratio were measured after 24, 48 and 72 hours.

#### Results

Nominal concentrations (mg/l): 0 (control), 0.0026, 0.005, 0.01, 0.02 and 0.04 mg/l  
Measured concentrations (mg/l): Immediately after the start of the test, the highest test concentration was analyzed by gas chromatographic analysis giving a concentration of 80% of the nominal concentration. Since the measured concentrations were below the nominal concentrations, all effect concentrations ( $E_bC$  and  $E_rC$ ) were reported with the symbol " $\leq$ ".

Unit: mg/l  
 Element value: 72-hour  $E_bC_{50}$  (biomass)  
 72-hour  $E_rC_{50}$  (growth rate)  
 Result:  $E_bC_{50} \leq 0.0133$  mg/l  
 $E_rC_{50} \leq 0.0235$  mg/l  
 NOEC  $NOE_bC > 0.0026$  mg/l  
 $NOE_rC > 0.0026$  mg/l  
 Satisfactory control response: Yes  
 Remarks:

Concentration	72-hour Biomass Inhibition (%)	72-hour Growth Rate Inhibition (%)
<b>Tween 80</b>	-3.34	-0.78
<b>0.0026 mg/l</b>	3.38	0.61
<b>0.005 mg/l</b>	7.12	1.64
<b>0.01 mg/l</b>	24.80	5.86
<b>0.02 mg/l</b>	66.56	26.74
<b>0.04 mg/l</b>	94.82	74.98

Additional endpoints included the following:

$E_bC_{10} \leq 0.0047$  mg/l

$E_bC_{90} \leq 0.0308$  mg/l

$E_rC_{10} \leq 0.007$  mg/l

$E_rC_{90} \leq 0.0786$  mg/l

## Conclusions

Genamin LA 302 D was very toxic to algae, *Scenedesmus subspicatus*. (Author of report)  
 The endpoint has been adequately characterized.  
 (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

## References

Reinhardt, D.I. 1995. Prüfung der Schädwirkung gegenüber Algen (Algentoxizität) von Genamin LA 302D. [Study of the adverse effects in algae (algae toxicity) with Genamin LA 302D] Report No. 93-0161-22. Hoechst AG, Abteilung Umweltschutz Biologische Laboratorien, Germany.

## Other

Last Changed:

June 7, 2002

Order number for sorting:

124L

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin SH 100 D (CAS RN 124-30-1;  
Octadecylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus* – CHODAT SAG 86.81  
/Supplier: Pflanzenphysiologischen Institut der  
Universitaet, Goettingen  
Analytical Monitoring: No  
Exposure Period: 72 hours  
Statistical Methods: SigmaPlot, Jandel Scientific Version 5.0, 1992.  
Remarks: The study measured the growth inhibition of  
*Scenedesmus subspicatus* during a 72-hour exposure  
period to the test substance. Concentrations of the test  
substance were 0, 1, 3.2, 10, 32, 100 and 320 µg/l.  
Test conditions: The incubation took place in 20-ml  
plastic cuvettes with 10-ml test medium at 23°C  
(pH = 7.9 to 8.2) over a 3 day period during which the  
solutions were continuously exposed to light (2333 to  
4667 lux). The test was run with four replicates. Cell  
density was measured at 24-hours, 48-hours and  
72-hours by chlorophyll a-fluorescence. The light  
intensity (2333 – 4667 lux) was lower than  
recommended in the OECD 201 guideline (8000 lux).  
Since the control growth rate was acceptable, factor 23  
in 72 hours (OECD = at least factor 16 in 72 hours) the  
lower light intensity did not affect the integrity of the  
study.

#### Results

Nominal concentrations (mg/l): 0 (control), 0.001, 0.0032, 0.01, 0.032, 0.1 and  
0.32 mg/l  
Measured concentrations (mg/l): NA  
Unit: mg/l  
Element value: 72-hour  $E_bC_{50}$  (biomass)  
72-hour  $E_rC_{50}$  (growth rate)  
Result:  $E_bC_{50}$  = 0.062 mg/l  
 $E_rC_{50}$  = 0.12 mg/l

Remarks:

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0</b>	0	0
<b>0.001</b>	9	4
<b>0.0032</b>	4	5
<b>0.01</b>	4	5
<b>0.032</b>	16	10
<b>0.1</b>	74	45
<b>0.32</b>	100	100

Additional endpoints included the following:

 $E_bC_0 = 0.01$  mg/l $E_bC_{10} = 0.018$  mg/l $E_rC_{10} = 0.029$  mg/l**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1A

Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1994. Pruefung auf Hemmung der  
Algencellvermehrung von Genamin SH 100 D. [Algae  
inhibition study with Genamin SH 100 D] Study No.  
94905HM/SS042621. Dr. U. Noack-Laboratory for  
Applied Biology. Sarstedt, Germany

**Other**

Last Changed:

Order number for sorting:

Remarks:

June 24, 2002

56a

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: 9-Octadecen-1-amine; oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: 94%  
Remarks:

#### Method

Method/guideline followed: Test methods conformed to U.S. EPA Test Guideline No. 797.1075, which conforms to OECD Guideline No. 201. Test methods also adapted from U.S. EPA OPTS Guideline No. 850.1085, Fish Acute Toxicity Mitigated by Humic Acid.

Type: Static acute  
GLP: Yes  
Year: 1995  
Species/Strain/Supplier: *Selenastrum capricornutum*/CCAP 276/4B/Culture Collection of Algae and Protozoa, The Ferry House, Cumbria, Ambleside, United Kingdom

Element Basis: Area under the growth curve ( $E_bC$ ) or growth rate ( $E_rC$ )

Exposure Period: 96 hours  
Analytical Monitoring: Yes  
Statistical Methods:  $EC_{50}$  values determined by probit analysis. The NOEC and LOEC were determined using Williams test (Biometrics 28:519-531.).

Remarks: The study measured the growth inhibition of the test substance to *Selenastrum capricornutum* during a 96-hour exposure period. Exposures were conducted without humic acid and with humic acid in the dilution water at 5 and 10 mg/l. The summary includes data only for the portion of the study that reports the exposure without humic acid present in the dilution water. The dilution water used in the test was a mineral salts medium described by EPA Guideline No. 797.1075. Test flasks were 100-ml Erlenmeyer flasks containing 40-ml of test solution. The test was run with six replicate flasks of the control group and three replicate flasks of each test solution. The test solutions were prepared by diluting an aqueous stock solution of the test substance (1.001 g/l target concentration) with nutrient medium. Test solutions were distributed to the flasks, and the flasks were inoculated with *Selenastrum capricornutum* cells to achieve an initial cell density of  $2 \times 10^3$  cells/ml. Algal cells used in preparation of the inoculum were

obtained from a culture of exponentially growing algal cells. Test flasks were placed in a testing area having continuous uniform illumination of 150 to 200  $\mu\text{mol m}^{-2}\text{s}^{-1}$  and a temperature of  $20\pm 2^\circ\text{C}$ . The spectral range of light was 400 to 700 nm produced by 30 W fluorescent lamps of the type “universal white” (color temperature approximately 4000 K). Flasks were continuously rotated at 100 rpm to prevent sedimentation of the algal cells. Cell densities were determined photometrically using a UV/VIS spectrophotometer. Chemical analyses of the test solutions were made at 0 and 96 hours in the control, low level, mid level and high level test concentration. Cell densities obtained by the photometric analysis were converted to growth and growth rate. Nominal concentrations were used in the calculation of endpoints values.

## Results

Nominal concentrations (mg/l):	0 (control), 0.01, 0.02, 0.04, 0.08, and 0.15 mg/l
Measured concentrations (mg/l):	0-hour measurements in control, 0.01, 0.04 and 0.15 mg/l were 0, 0.006, 0.011, and ND mg/l, respectively. 96-hour measurements in control, 0.01, 0.04 and 0.15 mg/l were 0, ND, 0.016, and 0.11 mg/l, respectively. ND indicates that the samples were not properly analyzed and contained analytical disturbances. Percent of nominal concentrations ranged from 28 to 73%.
Unit:	mg/l
Element value:	96-hour $E_bC_{50}$ (endpoint based on area under the growth curve) 96-hour $E_rC_{50}$ (endpoint based on growth rate)
Result:	$E_bC_{50} = 0.03$ mg/l (95% confidence limit of 0.03 to 0.03 mg/l) $E_rC_{50} = 0.04$ mg/l (95% confidence limit of 0.04 to 0.04 mg/l)
NOEC, LOEC:	LOEC = 0.02 mg/l NOEC = 0.01 mg/l
Satisfactory control response:	Yes
Remarks:	Additional endpoints included the following: $E_bC_{20} = 0.02$ mg/l (0.02 – 0.02 mg/l) $E_bC_{80} = 0.04$ mg/l (0.04 – 0.04 mg/l) $E_rC_{20} = 0.03$ mg/l (0.03 – 0.03 mg/l) $E_rC_{80} = 0.05$ mg/l (0.05 – 0.05 mg/l)

**Conclusions**

The 96-hour toxicity of 9-Octadecen-1-amine to *Selenastrum capricornutum* was adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Kroon, A.G.M., M.G.J. Geurts and C. de Ruitter. 1995. Toxicity of Oleylamine to the Freshwater Alga *Selenastrum capricornutum*. Report No. RGL F95037. Akzo Nobel Central Research, Arnhem, The Netherlands.

**Other**

Last Changed:

July 17, 2002

Order number for sorting:

16

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Octadecylamine (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

#### Method

Method/guideline followed: Method developed by Payne, A.G. and R.H. Hall. 1979. A Method for Measuring Algal Toxicity and its Application to the Safety Assessment of New Chemicals. American Society for Testing and Materials, ASTM STP 667.

Type: Static  
GLP: No, but appeared to follow spirit of GLPs.  
Year: 1986  
Species/Strain/Supplier: *Selenastrum capricornutum*/NA/Laboratory culture  
*Microcystis aeruginosa*/UTEX L2061/Laboratory culture

Element Basis: Biomass  
Exposure Period: 5 days exposure, 9 days recovery  
Analytical Monitoring: No  
Statistical Methods: Algistatic and algicidal concentrations defined using an inverse estimation method and computer program developed by the sponsor of the study.

Remarks: Test vessels were 250-ml Erlenmeyer flasks holding 50 ml of test solution. Test solutions were made by adding aliquots of a test substance stock solution made in dimethylformamide to U.S. EPA AAP growth medium. Treatment groups were replicated three times. An inoculum of each species of algae was prepared in AAP medium and each flask was inoculated with an aliquot of the inoculum. The nominal initial cell density was 20,000 cells/ml for *Selenastrum* and 50,000 cells/ml for *Microcystis*. Flasks were kept in a controlled temperature incubator at  $24 \pm 2^\circ\text{C}$ . Flasks were continuously shaken at 100 oscillations/minute. Illumination was  $4304 \pm 650$  lumens/m<sup>2</sup> for *Selenastrum* and  $2152 \pm 323$  lumne/m<sup>2</sup> for *Microcystis* using cool-white fluorescent lights. Flasks were randomly repositioned each day to minimize spatial effects of light variation. At the end of the 5-day exposure period, samples from the flasks containing cell densities similar to or less than the initial inoculum level were taken, washed with AAP medium and resuspended in test material-free

AAP medium for a 9-day recovery period. Those flasks were replaced in the incubator under original environmental conditions. Biomass measurements during the test were estimated from cell counts using an electronic particle counter. Measurements were made on days 3 and 5 of the exposure and on days 2, 6 and 9 of the recovery period.

## Results

Nominal concentrations (mg/l): *Selenastrum*: 0 (control), 0 (solvent control, 0.5 ml/l), 0.001, 0.002, 0.004, 0.008, 0.016, and 0.032 mg/l

*Microcystis*: 0 (control), 0 (solvent control, 0.5 ml/l), 0.01, 0.02, 0.04, 0.08, 0.16, and 0.32 mg/l

Measured concentrations (mg/l): Not determined

Unit: mg/l

Element value: Algistatic Concentration

Result: Algistatic Concentration (*Selenastrum*) = 0.029 mg/l  
(95% confidence interval of 0.015 to 0.064 mg/l)

Algicidal Concentration (*Selenastrum*) = >0.032 mg/l

Algistatic Concentration (*Microcystis*) = 0.11 mg/l  
(95% confidence interval of 0.04 to 0.27 mg/l)

Algicidal Concentration (*Microcystis*) = 0.16 mg/l

NOEC Not available

Satisfactory control response: Yes

Remarks: The endpoints of the test were defined as the following:

Algistatic Concentration = The concentration that causes no net increase in cell numbers after the 5-day exposure period, but permits regrowth when the cells are resuspended in test material-free medium.

Algicidal Concentration = The lowest concentration tested which causes no net increase in cell numbers during either the exposure or recovery period (i.e. cells do not recover when transferred to test material-free medium).

## Conclusions

The study provides useful information on the toxicity of the test substance to *Selenastrum capricornutum* and *Microcystis aeruginosa*. Additional studies are needed to define an EC<sub>50</sub>. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

2D

Remarks:

Reliable with restrictions; endpoint of the test was not defined in terms of an EC<sub>50</sub>.

## References

Hughes, J.S. 1986. Toxicity of B0793.02 to *Selenastrum capricornutum* and *Microcystis aeruginosa*. Malcom Pirnie Report Nos. 165-14-1100-1 and -2. Contained in: Initial Submission, Toxicological Investigation of N,N-dimethyloctyldecylamine. U.S. EPA Doc. No. FYI-OTS-0794-1164.

## Other

Last Changed:

July 10, 2002

Order number for sorting:

36

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin CC100 D (CAS RN 61788-46-3  
Amines, coco alkyl)  
Purity: 99.1%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus* /CHODAT SAG 86.81/  
Pflanzenphysiologischen Institut der Universitaet,  
Goettingen  
Analytical Monitoring: No  
Exposure Period: 72 hours  
Statistical Methods: SigmaPlot, Jandel Scientific Version 5.0, 1992.  
Remarks: The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 3.2, 10, 32, 100, 320, and 1000 µg/l. Source of the dilution water was OECD medium. The test took place in 20-ml plastic cuvettes with 10-ml test medium at 23°C over a 3-day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The pH was 7.9 to 8.1 during the test. The test was run with four replicates. Initial cell concentration was 6 to 7 x 10<sup>3</sup> cells/ml. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll a-fluorescence. The light intensity (2333 – 4667 lux) was lower than recommended in the OECD 201 guideline (8000 lux). Since the control growth rate was acceptable, factor 23 in 72 hours (OECD = at least factor 16 in 72 hours) the lower light intensity did not affect the integrity of the study.

#### Results

Nominal concentrations (mg/l): 0 (control), 0.0032, 0.01, 0.032, 0.1, 0.32 and 1.0 mg/l  
Measured concentrations (mg/l): Not reported  
Unit: mg/l  
Element value: 72-hour E<sub>b</sub>C<sub>50</sub> (biomass)  
72-hour E<sub>r</sub>C<sub>50</sub> (growth rate)  
Result: E<sub>b</sub>C<sub>50</sub> = 0.14 mg/l

Remarks:  $E_rC_{50} = 0.17$  mg/l  
The growth factor for the control was 23 in 72 hours.

Concentration (mg/l)	72-hour Growth Rate Inhibition (%)	72-hour Biomass Inhibition (%)
0	0	0
0.0032	4	0
0.01	3	-1
0.032	3	4
0.1	13	32
0.32	100	100
1.0	100	100

Additional endpoints included the following:

$E_bC_0 = 0.032$  mg/l

$E_bC_{10} = 0.041$  mg/l

$E_rC_{10} = 0.07$  mg/l

### Conclusions

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1A

Reliable without restriction; guideline study.

### References

Scheerbaum, D. 1994. Pruefung auf der Algenzellvermehrung von Genamin CC 100 D. [Algae inhibition study with Genamin CC 100 D] Project No. 40905HM/SS042591. Hoechst AG, Dr. U. Noack-Laboratorium fuer angewandte biologische.

### Other

Last Changed:

Order number for sorting:

Remarks:

June 26, 2002

92a

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Amine KK (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 94%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus*/CCAP 276/20/Culture Centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, UK.  
Analytical Monitoring: No  
Exposure Period: 96 hours  
Statistical Methods: SigmaPlot, Jandel Scientific Version 5.0, 1992.  
Remarks: The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 96-hour exposure period. Concentrations of the test substance were 0 (untreated control), 0 (vehicle control), 0.1, 0.2, 0.4, 0.8, 1.6 µg/l. The vehicle was 1% Tween 80 acetone. Test conditions: The incubation took place in 250-ml flasks with 100-ml test medium at 24°C over a 3 day period during which the solutions were continuously exposed to light (7000 lux). The test was run with three replicates. Test vessels were pre-rinsed with test solution because the test substance can sorb to the glass surface. Cell growth was measured spectrophotometrically.

#### Results

Nominal concentrations (mg/l): 0 (untreated), 0 (vehicle) 0.0001, 0.0002, 0.0004, 0.0008, 0.0016 mg/l  
Measured concentrations (mg/l): Not reported  
Unit: mg/l  
Element value: 96-hour  $E_bC_{50}$  (biomass)  
96-hour  $E_rC_{50}$  (growth rate)  
Result:  $E_bC_{50} = 0.00075$  mg/l  
 $E_rC_{50} = 0.0011$  mg/l

**Remarks:**

Additional endpoints include the following:

 $E_bC_{10} = 0.00021$  mg/l $E_rC_{10} = 0.00024$  mg/l

Control growth factor was 21 to 25 in 96 hours.

<b>Concentration (mg/l)</b>	<b>96-hour Biomass Inhibition (%)</b>	<b>96-hour Growth Rate Inhibition (%)</b>
<b>0 (untreated)</b>	0	0
<b>0 (vehicle)</b>	1	1
<b>0.0001</b>	-1	1
<b>0.0002</b>	1	0
<b>0.0004</b>	20	7
<b>0.0008</b>	49	32
<b>0.0016</b>	83	75

Additional endpoints included the following:

LOEC: 0.0002 mg/l

 $E_bC_{10} = 0.00021$  mg/l $E_rC_{10} = 0.00024$  mg/l**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Handley, J.W. and C. Mead. 1991. Assessment of the  
Algistatic Effect of Amine KK. Project No. 116/70.  
Berol Nobel Nacka AB, Safepharm Laboratories.

**Other**

Last Changed:

June 26, 2002

Order number for sorting:

92b

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Amine HBG (CAS RN 61788-45-2;  
Amines, hydrogenated tallow alkyl)  
Purity: >95%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus*/CCAP 276/20/Culture centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, UK  
Analytical Monitoring: Not stated  
Exposure Period: 96 hours  
Statistical Methods: Not stated  
Remarks: The study measured the growth inhibition of *Scenedesmus subspicatus* during a 96-hour exposure period to the test substance. Concentrations of the test substance were 0.001, 0.002, 0.004, 0.008, 0.016 mg/l and untreated and vehicle (100 µl/l isopropyl alcohol) controls. Pretreatment: culture medium inoculated from a master culture, incubated under continuous illumination(7000 lux) aerated, 24°C to give an algal suspension with an exponential growth. The initial cell concentration was  $2.8 \times 10^4$  cells/ml.  
Test conditions: The incubation took place in 250-ml flasks with 100-ml test medium shaken constantly at 24°C over a 3 day period during which the solutions were continuously exposed to light (~7000 lux). The pH of the test solutions was 8.0 to 9.0. Dilution water was nutrient medium as described in OECD 201. Test medium chemistry: Hardness = 0.18 mmol/l Ca & Mg; EDTA =  $3 \times 10^{-4}$  mmol/l; P = 0.36 mg/l; and N = 4 mg/l. The test was run with three replicates. Cell growth was measured spectrophotometrically at 0-, 24-, 48-, 72- and 96-hours.

#### Results

Nominal concentrations (mg/l): 0 (untreated), 0(vehicle), 0.001, 0.002, 0.004, 0.008, 0.016 mg/l  
Measured concentrations (mg/l): Not reported  
Unit: µg/l

Element value: 96-hour  $E_bC_{50}$  (biomass)  
 96-hour  $E_rC_{50}$  (growth rate)  
 NOEC

Result:  $E_bC_{50}$  = 0.012 mg/l  
 $E_rC_{50}$  = ca. 0.016 mg/l  
 NOEC = 0.008 mg/l

Remarks: At 0.16 mg/l, the cells were clumped together, paler in color with visible cell debris.

Concentration (mg/l)	96-hour Biomass Inhibition (%)	96-hour Growth Rate Inhibition (%)
<b>0 (untreated)</b>	0	0
<b>0 (vehicle)</b>	0	1
<b>0.001</b>	-1	1
<b>0.002</b>	-3	0
<b>0.004</b>	0	1
<b>0.008</b>	4	0
<b>0.016</b>	85	50

**Conclusions**

The endpoint has been adequately characterized.  
 (American Chemistry Council Fatty Nitrogen  
 Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
 Remarks:

1A  
 Reliable without restriction; guideline study

**References**

Handley, J.W. and C. Mead. 1991. Assessment of the Algistatic Effect of Amine. Project No. 116/78. Berol Nobel Nacka AB, Safepharm Laboratories Limited, HBG.

**Other**

Last Changed:  
 Order number for sorting:  
 Remarks:

September 16, 2002  
 106c

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Ditallowmethylamine, hydrogenated  
(CAS RN 61788-63-4; Dihydrogenated tallow  
methylamine)  
Purity: ca. 100%  
Remarks:

#### Method

Method/guideline followed: Test methods conformed to OECD Guidelines for Testing of Chemicals, Guideline No. 201, Alga, Growth Inhibition Test, and EEC Method, Algal Inhibition Test, Official Journal of the European Communities, L133.

Type: Static  
GLP: Yes  
Year: 1990  
Species/Strain/Supplier: *Selenastrum capricornutum*/ATCC 22662/Laboratory cultures

Element Basis: Growth rate and area under the growth curve  
Exposure Period: 72 hours  
Analytical Monitoring: No  
Statistical Methods: The EC<sub>50</sub> values were computed from the best fitted line (least square method) through the points given by the probit of the percentage inhibition and the logarithm of the concentration of the test substance.

Remarks: Test vessels were 100-ml Erlenmeyer flasks holding 40 ml of test solution. Test solutions were made by adding aliquots of a test substance stock solution made in deionized water at 50°C to 40 ml of mineral salts medium. Flasks were inoculated with *Selenastrum* taken from a culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 22 - 24°C. Flasks were continuously shaken at 100 rpm to prevent sedimentation of the cells. Continuous illumination in the range 6000 to 10000 lux was provided by 30W fluorescent lamps (color temperature of approximately 4300 K). Cell densities were measured spectrophotometrically using a relationship established for light extinction and cell density. Measurements were taken from each test flask at 0, 24, 48 and 72 hours of the test. The measured extinction values were used to determine growth of the cultures by the area under the curve method and growth rate. EC<sub>50</sub> values were determined for the area under the growth curve (E<sub>b</sub>C<sub>50</sub>) and for the growth rate (E<sub>r</sub>C<sub>50</sub>). A range-finding study was conducted to

determine dose levels for the definitive study.

## Results

Nominal concentrations (mg/l):	0 (control), 0.010, 0.030, 0.090, 0.270, and 0.810 mg/l.
Measured concentrations (mg/l):	Not stated
Unit:	mg/l
Element value:	72-hour $E_bC_{50}$ (biomass) 72-hour $E_rC_{50}$ (growth rate)
Result:	72-hour $E_bC_{50}$ = 0.05 mg/l (95% confidence limit of 0.04 to 0.06 mg/l) 72-hour $E_rC_{50}$ = 0.12 mg/l (0.10 to 0.14 mg/l) Additional endpoints included the following: 72-hour $E_bC_{20}$ = 0.02 mg/l (0.01 to 0.02 mg/l) 72-hour $E_bC_{80}$ = 0.14 mg/l (0.11 to 0.18 mg/l) 72-hour $E_rC_{20}$ = 0.04 mg/l (0.03 to 0.05 mg/l) 72-hour $E_rC_{80}$ = 0.32 mg/l (0.26 to 0.42 mg/l)
NOEC	~0.01 mg/l
Satisfactory control response:	Yes
Remarks:	The growth rate, $\mu$ , was calculated to be $0.069 \text{ h}^{-1}$ .

## Conclusions

The 72-hour growth inhibition of Amines, bis(hydrogenated tallow alkyl) methyl to *Selenastrum capricornutum* has been adequately characterized by this study. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):	1A
Remarks:	Reliable without restriction; guideline study.

## References

Kroon, A.G.M. and C.G. van Ginkel. 1990. Algal Growth Inhibition Test with ARMEEN M2HT. Study/Report No. CRL F90155, Akzo Research Laboratories Arnhem, The Netherlands.

## Other

Last Changed:	July 25, 2002
Order number for sorting:	101
Remarks:	

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: ca. 100%  
Remarks:

#### Method

Method/guideline followed: Payne, A.G. and R.H. Hall. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. ASTM STP 667; U.S. EPA. 1978. The *Selenastrum capricornutum* Printz Algal Assay Bottle Test, Environmental Research Laboratory, Corvallis, OR.

Type: Static  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: *Selenastrum capricornutum* Printz /U.S. EPA, Environmental Research Laboratory, Corvallis, OR.

Element Basis: Cell density  
Exposure Period: 5 days  
Analytical Monitoring: No  
Statistical Methods: The 5-day algistatic concentration ( $AC_{d5}$ ) was determined by linear regression analysis of the  $\log_{10}$  of the ratio of cell density<sub>day5</sub> to cell density<sub>day0</sub> ( $\delta_{d5}/\delta_{d0}$ ) versus treatment concentration, followed by the “inverse estimation” of the concentration corresponding to a  $\delta_{d5}/\delta_{d0} = 1$  with 95% confidence.

Remarks: Test vessels were 125-ml flasks holding 50 ml of test solution. Test solutions were made by serial dilution of a test substance stock solution dissolved in isopropanol. Medium was a regular algal assay procedure medium prepared with deionized water. Negative (algal test medium only) and solvent (0.4 ml isopropanol/l test media) controls were also maintained. Flasks of each treatment were inoculated in triplicate with *S. capricornutum* taken from a culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 23-25°C with continuous illumination at approximately 420 ft-c. Biomass measurements were estimated by cell counts and chlorophyll-*a* relative fluorescence for *S. capricornutum*. Cell counts were made after 3 and 5 days of exposure to test solution and 2, 6 and 9 days of recovery. Chlorophyll *a* relative fluorescence measurements were made daily during the exposure

period and days 2, 6 and 9 of the recovery period

**Results**

Nominal concentrations (mg/l): 0 (growth medium control), 0 (solvent control), 16, 31, 62, 125 and 250 µg/l.  
 Measured concentrations (mg/l): Not stated  
 Unit: µg/l  
 Element value: 5-day algistatic concentration (AC<sub>d5</sub>) based on cell density (95% Confidence limits)  
 Result: AC<sub>d5</sub> = 52 µg/l (22-177 µg/l)

5-Day Exposure Period Results:

Nominal Concentration (mg/l)	% Change in Cell Density (Day 5) <sup>a</sup>	% Change in Relative Fluorescence (Day 5) <sup>a</sup>
Control	+4	0
Solvent Control	--- <sup>b</sup>	--- <sup>b</sup>
16	+3	+2
31	-2	-14
62	-99	-99
125	-100	-99
250	-100	-100

<sup>a</sup> Average of three replicates.

<sup>b</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control at day 5.

9-Day Recovery Period Results:

Nominal Concentration (mg/l)	Cell Density <sup>a</sup> (x 10 <sup>4</sup> /ml)		Relative Fluorescence Units <sup>a</sup>	
	Day 0	Day 9 <sup>b</sup>	Day 0 <sup>b</sup>	Day 9 <sup>b</sup>
Solvent Control	0.3	367 (36)	62 (2)	5493 (378)
62	0.2	225 (29)	0.3	2987 (378)
125	< 0.1	0 (0)	0 (0)	0.0 (0)
250	< 0.1	0 (0)	0 (0)	0.0 (0)

<sup>a</sup> Average of three replicates.

<sup>b</sup> Standard deviations (1±SD) are in parentheses.

Satisfactory control response:

Yes

Remarks:

The decrease in cell density over 5 days of exposure to various test concentrations as compared to the solvent control ranged from 2%, in the 31 µg/l treatment, to 100%,

in the 125 and 250 µg/l treatment. Measurements of *in vivo* chlorophyll *a* showed a growth-concentration response similar to the observed effect based on cell density. After 5 days of exposure, the decrease in relative fluorescence units ranged from 14%, in the 31 µg/l treatment, to 100%, in the 250 µg/l treatment. Based on both cell density and relative fluorescence, the recovery of culture exposed to 62 µg/l treatment was comparable that of the control during the 9-day recovery period, indicating no apparent residual effects. Growth was not observed in the cultures exposed to the 125 or 250 µg/l treatment during the recovery period.

**Conclusions**

The end point was adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

**References**

Hollister, T.A. and W.F. Holman. 1981. Effects of B0390.01 on the freshwater alga *Selenastrum capricornutum*. Unpublished Toxicity Test Report No. BP-81-11-170, submitted to The Procter and Gamble Company, Cincinnati, OH, USA by EG&G Bionomics, Pensacola, FL, USA.

**Other**

Last Changed:  
Order number for sorting:  
Remarks:

June 16, 2003  
342

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: ca. 100%  
Remarks:

#### Method

Method/guideline followed: Payne, A.G. and R.H. Hall. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. ASTM STP 667; U.S. EPA. 1978. The *Selenastrum capricornutum* Printz Algal Assay Bottle Test, Environmental Research Laboratory, Corvallis, OR.

Type: Static  
GLP: Not stated  
Year: 1983  
Species/Strain/Supplier: *Microcystis aeruginosa*/University of Texas at Austin, Austin, TX.  
Element Basis: Cell density  
Exposure Period: 5 days  
Analytical Monitoring: No  
Statistical Methods: The 5-day algistatic concentration ( $AC_{d5}$ ) was determined by linear regression analysis of the  $\log_{10}$  of the ratio of cell density<sub>day5</sub> to cell density<sub>day0</sub> ( $\delta_{d5}/\delta_{d0}$ ) versus treatment concentration, followed by the “inverse estimation” of the concentration corresponding to a  $\delta_{d5}/\delta_{d0} = 1$  with 95% confidence.

Remarks: Test vessels were 125-ml flasks holding 50 ml of test solution. Test solutions were made by serial dilution of a test substance stock solution dissolved in isopropanol. Medium was a regular algal assay procedure medium prepared with deionized water. Negative (algal test medium only) and solvent (0.4 ml isopropanol/l test media) controls were also maintained. Flasks of each treatment were inoculated in triplicate with *M. aeruginosa* ( $5 \times 10^4$  cells/ml) taken from a culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 23-25°C under approximately 2000 lux illumination. Biomass measurements were estimated by cell density of *M. aeruginosa*. Cell counts were made after 3 and 5 days of exposure to test solution and 2, 6 and 9 days of the recovery. Based on the results of the exposure phase of the test, only cultures exposed to the 1.25 and 2.5 mg/l treatment and the control cultures were placed

into the 9-day recovery phase.

**Results**

Nominal concentrations (mg/l): 0 (growth medium control), 0 (solvent control), 0.16, 0.31, 0.62, 1.25, 2.5 and 5.0 mg/l.  
 Measured concentrations (mg/l): Not stated  
 Unit: mg/l  
 Element value: 5-day algistic concentration (AC<sub>d5</sub>) based on cell density (95% Confidence limits)  
 Result: AC<sub>d5</sub> = 0.96 mg/l (0.60-1.47mg/l)

Nominal Concentration (mg/l)	% Change in Cell Density <sup>a</sup>	
	Exposure <sup>b</sup>	Recovery <sup>c</sup>
Control	-5	-4
Solvent Control	--- <sup>b</sup>	--- <sup>b</sup>
0.16	-44	NA
0.31	-45	NA
0.62	-55	NA
1.25	-99	-59
2.50	-100	-100
5.00	-100	NA

<sup>a</sup> Average of three replicates; NA = not applicable  
<sup>b</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control over the 5-day exposure phase.  
<sup>c</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control over the 9-day recovery phase.

Satisfactory control response:  
 Remarks:

Not stated.  
 The decrease in cell density over 5 days of exposure to various test concentrations as compared to the solvent control ranged from 44%, in the 0.16 mg/l treatment, to 100%, in the 2.5 and 5.0 mg/l treatments. The pH of the test solutions during the exposure period ranged from 7.4 in all treatments at initiation to 7.7 by termination in many solutions. The pH at the initiation of the recovery period was 7.6 in all cultures and ranged from 7.0 to 7.7 by day 9. The decreases in cell density in the 1.25 and 2.5 mg/l cultures relative to that of the control after 9 days of recovery were 59% and 100%, respectively. The results of this study indicated a residual treatment effect.

**Conclusions**

The end point was adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Maziarz, T.P. and W.F. Holman. 1983. Effects of  
B0390.01 on the freshwater alga *Microcystis*  
*aeruginosa*. Unpublished Toxicity Test Report No.  
BP-83-9-98, submitted to The Procter and Gamble  
Company, Cincinnati, OH, USA by EG&G  
Bionomics, Pensacola, FL, USA.

**Other**

Last Changed:

September 18, 2003

Order number for sorting:

343a [*M. aeruginosa*]

Remarks:

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 97%  
Remarks:

#### Method

Method/guideline followed: Payne, A.G. and R.H. Hall. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. ASTM STP 667; U.S. EPA. 1978. The *Selenastrum capricornutum* Printz Algal Assay Bottle Test, Environmental Research Laboratory, Corvallis, OR.

Type: Static  
GLP: Not stated  
Year: 1983  
Species/Strain/Supplier: *Navicula seminulum* / University of Texas at Austin, Austin, TX.

Element Basis: Cell density  
Exposure Period: 5 days  
Analytical Monitoring: No  
Statistical Methods: The 5-day algistatic concentration ( $AC_{d5}$ ) was determined by linear regression analysis of the  $\log_{10}$  of the ratio of cell density<sub>day5</sub> to cell density<sub>day0</sub> ( $\delta_{d5}/\delta_{d0}$ ) versus treatment concentration, followed by the “inverse estimation” of the concentration corresponding to a  $\delta_{d5}/\delta_{d0} = 1$  with 95% confidence.

Remarks: Test vessels were 125-ml flasks holding 50 ml of test solution. Test solutions were made by serial dilution of a test substance stock solution dissolved in isopropanol. Medium was a regular algal assay procedure medium prepared in deionized water with 0.2 g/l sodium silicate. Negative (algal test medium only) and solvent (0.4 ml isopropanol/l test media) controls were also maintained. Flasks of each treatment were inoculated in triplicate with *N. seminulum*, slightly older than the prescribed 1-2 weeks, taken from a healthy culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 19-21°C under approximately 4500 lux illumination. Biomass measurements were estimated by cell counts and chlorophyll-*a* relative fluorescence for *N. seminulum*. Cell counts were made after 3 and 5 days of exposure to test solution and 2, 6 and 9 days of the recovery. Chlorophyll *a* relative fluorescence measurements were made daily during the

exposure period and days 2, 6 and 9 of the recovery period. Based on the results of the exposure phase of the test, only cultures exposed to the 5.0 and 10.0 mg/l treatment and the control cultures were placed into the 9-day recovery phase.

**Results**

Nominal concentrations (mg/l): 0 (growth medium control), 0 (solvent control), 0.312, 0.625, 1.25, 2.5, 5.0 and 10 mg/l.  
 Measured concentrations (mg/l): Not stated  
 Unit: mg/l  
 Element value: 5-day algistic concentration (AC<sub>d5</sub>) based on cell density (95% Confidence limits)  
 Result: AC<sub>d5</sub> = 4.60 mg/l (2.30-9.52 mg/l)

5-Day Exposure Period Results:

Nominal Concentration (mg/l)	% Change in Cell Density <sup>a</sup>	% Change in Relative Fluorescence <sup>a</sup>
Control	+1	+14
Solvent Control	--- <sup>b</sup>	--- <sup>b</sup>
0.312	-90	-96
0.625	-94	-97
1.25	-96	-98
2.50	-97	-99
5.0	-98	-100
10.0	-99	-100

<sup>a</sup> Average of three replicates.

<sup>b</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control over 5 days.

9-Day Recovery Period Results:

Nominal Concentration (mg/l)	% Change in Cell Density <sup>a</sup>	% Change in Relative Fluorescence <sup>a</sup>
Control	-6	-1
Solvent Control	--- <sup>b</sup>	--- <sup>b</sup>
5.0	-55	-30
10.0	-51	-28

<sup>a</sup> Average of three replicates.

<sup>b</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control over 9 days.

Satisfactory control response:  
 Remarks:

Not stated.  
 The decrease in cell density over 5 days of exposure to

various test concentrations as compared to the solvent control ranged from 90%, in the 0.312 mg/l treatment, to 99%, in the 10 mg/l treatment. Measurements of *in vivo* chlorophyll *a* showed a growth-concentration response similar to the observed effect based on cell density. After 5 days of exposure, the decrease in relative fluorescence units ranged from 96%, in the 0.312 mg/l treatment, to 100%, in the 5 and 10 mg/l treatments. The decreases in cell density in the 5.0 and 10.0 mg/l cultures relative to that of the control after 9 days of recovery were 55% and 51%, respectively. The results of this study indicated a slight residual treatment effect.

### Conclusions

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

### References

Maziarz, T.P. and W.F. Holman. 1983. Effects of B0390.01 on the freshwater diatom *Navicula seminulum*. Unpublished Toxicity Test Report No. BP-83-7-88, submitted to The Procter and Gamble Company, Cincinnati, OH, USA by EG&G Bionomics, Pensacola, FL, USA.

### Other

Last Changed:  
Order number for sorting:  
Remarks:

September 18, 2003  
343b [*N. seminulum*]

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: 97%  
Remarks:

#### Method

Method/guideline followed: Payne, A.G. and R.H. Hall. 1979. A method for measuring algal toxicity and its application to the safety assessment of new chemicals. ASTM STP 667; U.S. EPA. 1978. The *Selenastrum capricornutum* Printz Algal Assay Bottle Test, Environmental Research Laboratory, Corvallis, OR.

Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Navicula pelliculosa* / University of Texas at Austin, Austin, TX.

Element Basis: Cell density  
Exposure Period: 5 days  
Analytical Monitoring: No  
Statistical Methods: The 5-day algistatic concentration ( $AC_{d5}$ ) was determined by linear regression analysis of the  $\log_{10}$  of the ratio of cell density<sub>day5</sub> to cell density<sub>day0</sub> ( $\delta_{d5}/\delta_{d0}$ ) versus treatment concentration, followed by the “inverse estimation” of the concentration corresponding to a  $\delta_{d5}/\delta_{d0} = 1$  with 95% confidence.

Remarks: Test vessels were 125-ml flasks holding 50 ml of test solution. Test solutions were made by serial dilution of a test substance stock solution dissolved in isopropanol. Medium was a regular algal assay procedure medium prepared in deionized water with 0.2 g/l sodium silicate. Negative (algal test medium only) and solvent (0.4 ml isopropanol/l test media) controls were also maintained. Flasks of each treatment were inoculated in triplicate with *N. pelliculosa* ( $2 \times 10^4$  cells/ml), slightly older than the prescribed 1-2 weeks, taken from a healthy culture of exponentially growing cells. Flasks were kept in a controlled temperature incubator at 20-24°C under approximately 4,700 lux illumination and shaking at 150 rpm. Biomass measurements were estimated by cell counts of *N. pelliculosa*. Cell counts were only made on day 5 of the exposure period and day 9 of the recovery period due to the clumping nature of *N. pelliculosa* cells and the potential disturbance to cells

posed by dispersal. Based on the results of the exposure phase of the test, only cultures exposed to the 1.0, 2.0, and 4.0 mg/l treatment and the control cultures were placed into the 9-day recovery phase.

**Results**

Nominal concentrations (mg/l): 0 (growth medium control), 0 (solvent control), 0.25, 0.50, 1.0, 2.0, 4.0 and 8.0 mg/l.  
 Measured concentrations (mg/l): Not stated  
 Unit: mg/l  
 Element value: 5-day algistic concentration (AC<sub>d5</sub>) based on cell density (95% Confidence limits)  
 Result: AC<sub>d5</sub> = 1.14 mg/l (0.74 - 1.75 mg/l)

5-Day Exposure Period Results:

Nominal Concentration (mg/l)	% Change in Cell Density <sup>a</sup>
Control	-7
Solvent Control	-- <sup>b</sup>
0.25	-2
0.50	-88
1.0	-96
2.0	-99
4.0	-100
8.0	-100

<sup>a</sup> Average of three replicates.

<sup>b</sup> Percent change is increase or decrease in exposed cultures and negative control as compared to the solvent control over 5 days.

9-Day Recovery Period Results:

Nominal Concentration (mg/l)	Cell Density <sup>a</sup> (x 10 <sup>4</sup> /ml)	
	Day 0	Day 9 <sup>b</sup>
Control	1.96	186.3 (23.4)
Solvent Control	1.96	154.3 (25.7)
1.0	0.42	172.7 (25)
2.0	0.20	168.7 (20.6)
4.0	0.03	2.3 (0.5)

<sup>a</sup> Average of three replicates.

<sup>b</sup> Standard deviations (1±SD) are in parentheses.

Satisfactory control response:  
 Remarks:

Not stated.  
 The decrease in cell density over 5 days of exposure to various test concentrations as compared to the solvent

control ranged from -2%, in the 0.25 mg/l treatment, to 100%, in the 4.0 and 8.0 mg/l treatments. The pH was initially 7.5, but ranged from 6.9 to 7.9 by day 5 of the exposure period. Based on cell densities, the growth of cultures exposed to 1.0, 2.0 and 4.0 mg/l were +12, +9 and -99% relative to growth quantified in the solvent control cultures over the 9-day recovery period. The cells in the 4.0 mg/l culture did not recover at the same rate nor to the same extent as the control and 1.0 and 2.0 mg/l cultures. No algicidal activity was observed at concentrations below 4.0 mg/l. Based on the slight increase in recovery, 4.0 mg/l is considered algistatic although clearly close to an algicidal concentration. .

### Conclusions

The end point was adequately characterized.  
(American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

### References

Maziarz, T.P. and R.H.Hall. 1984. Toxicity of B0390.01 on freshwater alga, *Navicula pelliculosa*. Unpublished Toxicity Test Report No. BP-84-7-62, submitted to The Procter and Gamble Company, Cincinnati, OH, USA by Springborn Bionomics, Inc. Pensacola, FL, USA.

### Other

Last Changed:  
Order number for sorting:  
Remarks:

September 24, 2003  
344

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin TA 100 D (CAS RN 61790-33-8;  
Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus* – CHODAT SAG 86.81/  
Pflanzenphysiologischen Institut der Universitaet,  
Goettingen  
Element Basis: Biomass and growth rate  
Analytical Monitoring: Not stated  
Exposure Period: 72 hours  
Statistical Methods: SigmaPlot, Jandel Scientific Version 5.0, 1992.  
Remarks: The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 0.32, 1.0, 3.2, 10, 32 and 100 µg/l. Test conditions: The incubation took place in 20-ml plastic cuvettes with 10-ml test medium at 23°C, with a pH of 8.0 to 8.2, over a 3 day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The test was run with three replicates. Initial cell concentration was 7 to 8 E3 cells/ml. Dilution water source was OECD-medium. Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll-a fluorescence.

#### Results

Nominal concentrations (mg/l): 0 (control), 0.00032, 0.001, 0.0032, 0.010, 0.032 and 0.1 mg/l  
Measured concentrations (mg/l): Not reported  
Unit: mg/l  
Element value: 72-hour E<sub>b</sub>C<sub>50</sub> (biomass)  
72-hour E<sub>r</sub>C<sub>50</sub> (growth rate)  
Result: E<sub>b</sub>C<sub>50</sub> = 0.052 mg/l  
E<sub>r</sub>C<sub>50</sub> = 0.059 mg/l

Remarks:

The light intensity was lower than recommended (2333 to 4667 lux, OECD 201 8000 lux). Since the control growth was acceptable (factor 39 in 72 hours) this did not affect the integrity of the study.

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0</b>	0	0
<b>0.00032</b>	2	1
<b>0.0010</b>	-6	-1
<b>0.0032</b>	-8	1
<b>0.01</b>	4	5
<b>0.032</b>	14	6
<b>0.100</b>	97	88

Additional endpoints included the following:

$E_bC_{10} = 0.021$  mg/l

$E_rC_{10} = 0.033$  mg/l

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1A

Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1994. Pruefung auf der Algenzellvermehrung von Genamin TA 100 D [Algae inhibition study with Genamin TA 100 D] (940905HM/SS042611). Dr U. Noack-laboratorium fuer angewandte biologie. Hoechst AG.

**Other**

Last Changed:

Order number for sorting:

Remarks:

August 9, 2002

217a

### 4.3 TOXICITY TO AQUATIC PLANTS (ALGAE)

#### Test Substance

Identity: Genamin TA 100 D (CAS RN 61790-33-8;  
Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 201. Algal Growth Inhibition Test  
Type: Static  
GLP: Yes  
Year: 1984  
Species/Strain/Supplier: *Scenedesmus subspicatus* – CHODAT SAG 86.81 / Pflanzenphysiologischen Institut der Universitaet, Goettingen  
Element Basis: Biomass and growth rate  
Analytical Monitoring: No  
Exposure Period: 72 hours  
Statistical Methods: SigmaPlot, Jandel Scientific Version 5.0, 1992.  
Remarks: The study measured the growth inhibition of *Scenedesmus subspicatus* to the test substance during a 72-hour exposure period. Concentrations of the test substance were 0, 1.0, 3.2, 10, 32, 100, and 320 µg/l. Test conditions: The incubation took place in 20-ml plastic cuvettes with 10-ml test medium at 22-23°C, with a pH of 7.6 to 8.4, over a 3 day period during which the solutions were continuously exposed to light (2333 to 4667 lux). The test was run with three replicates. Initial cell concentration was 0.9 to 1.1 E4 cells/ml. Dilution water source was OECD-medium.  
Cell density was measured at 24-hours, 48-hours and 72-hours by chlorophyll-a fluorescence.

#### Results

Nominal concentrations (mg/l): 0 (control), 0.001, 0.0032, 0.01, 0.032, 0.1, 0.32 mg/l  
Measured concentrations (mg/l): NA  
Unit: Mg/l  
Element value: 72-hour  $E_bC_{50}$  (biomass)  
72-hour  $E_rC_{50}$  (growth rate)  
Result:  $E_bC_{50} = 0.068$  mg/l  
 $E_rC_{50} = 0.083$  mg/l

**Remarks:**

The light intensity was lower than recommended (2333 to 4667 lux, OECD 201 = 8000 lux). Since the control growth was acceptable (factor 39 in 72 hours) this did not affect the integrity of the study.

<b>Concentration (mg/l)</b>	<b>72-hour Biomass Inhibition (%)</b>	<b>72-hour Growth Rate Inhibition (%)</b>
<b>0</b>	0	0
<b>0.001</b>	3	-1
<b>0.0032</b>	-3	-2
<b>0.01</b>	-5	1
<b>0.032</b>	5	3
<b>0.1</b>	80	40
<b>0.32</b>	103	114

Additional endpoints included the following:

$$E_b C_{10} = 0.036 \text{ mg/l}$$

$$E_r C_{10} = 0.045 \text{ mg/l}$$

**Conclusions**

The endpoint has been adequately characterized.  
(American Chemistry Council Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1A

Reliable without restriction; guideline study.

**References**

Scheerbaum, D. 1996. Genamin TA 100 D Algen, Zellvermehrungs-Hemtest. Study [Genamin TA 100 D Algae inhibition study] No. 960105HM/SS049481. Hoechst AG, Dr. U. Noack-Laboratorium fuer angewandte biologie.

**Other**

Last Changed:

Order number for sorting:

Remarks:

August 9, 2002

217b

#### 4.5.2 CHRONIC TOXICITY TO AQUATIC ORGANISMS

##### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

##### Method

Method/guideline followed: Staatsuitgeverij. 1980. Chap. 5, 10.5.1;  
Degradability, Ecotoxicity and Bio-accumulation: The  
determination of the possible effects of chemicals and  
wastes on the aquatic environment. Government  
Publishing Office, The Hague, The Netherlands.  
[TNO Test Methods book.]  
Type: Static-renewal  
GLP: Not stated  
Year: 1980  
Species/Strain/Supplier: *Daphnia magna*/Strauss 1820/ex-IRCHA  
Analytical Monitoring: Determined by sponsor; not reported.  
Exposure Period: 21 days  
Statistical Methods: Kooijman, S.A.L.M. 1981. Parametric analyses of  
mortality rates in bioassays. *Water Res.* 15:107-119  
Based on nominal concentrations..  
Remarks: The experiment measured the survival and  
reproduction of *Daphnia magna* over a 21-day  
exposure to the test and control solutions. Twelve  
treatment groups were tested in duplicate in a static-  
renewal exposure system: 10 test concentrations  
selected on the basis of a range-finding test, a negative  
control and a solvent control (benzoic acid). The  
dilution water was a synthetic medium of reconstituted  
fresh water (DSW) to which several salts were added.  
The equilibrium pH of the DSW after aeration was  
usually 8.0-8.2 and the hardness was approximately  
210 mg/l as CaCO<sub>3</sub>. Replicate test vessels consisted of  
1-l glass beakers each containing 1 l of test solution  
covered with a watch glass. At test initiation,  
approximately 25 daphnids placed in each replicate test  
vessel. The daphnids were fed the unicellular alga  
*Chlorella pyrenoidosa*. Test solutions were renewed  
daily from a stock solution made at test initiation and  
stored in dark at 4°C, at which time the dissolved  
oxygen was measured in both the fresh and spent  
solutions. The pH of the fresh and spent solutions was  
measured 5 days/week. Samples (500 ml) of the fresh  
and spent solutions were collected weekly, preserved

with 0.5% formaldehyde and 5 mg/l of a nonionic surfactant (Dobanol 45/7EO) and analyzed. Adult survival and reproduction was assessed each day and neonates were removed daily. Effect values were based on nominal concentrations.

**Results**

Nominal concentrations (mg/l): 0 (neg. control), 0 (solvent control), 0.0018, 0.0032, 0.0056, 0.010, 0.018, 0.032, 0.056, 0.10, 0.18, 0.32 mg/l  
 Measured concentrations (mg/l): Determined by sponsor; not reported.  
 Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval)  
 Statistical Results:

Elapsed Time (days)	LC <sub>50</sub> (mg/l)	95% Confidence Interval
2	1.0	0.10-8.4 (extrapolated)
4	0.39	0.30-0.49
7	0.25	0.22-0.29
14	0.22	0.19-0.26
21	0.15	0.13-0.17

Additional Results:

Nominal Concentration (mg/l)	Mean % Reproduction <sup>a</sup>
0 (negative control)	100 (by definition)
0 (solvent control)	99
0.0018	99
0.0032	96
0.0056	96
0.01	105
0.018	107
0.032	95
0.056	90
0.1	78
0.18	48
0.32	0.8

<sup>a</sup> Daily average number of young per female divided by the average number of young born in the negative control treatment groups.

Remarks:

The growth and condition of daphnids in the 0.32 mg/l treatment group was very poor (100% mortality by Day 9). The growth and condition of daphnids in the 0.18 mg/l treatment group was poorer than that of the control groups and the mortality averaged 70%. The condition (color) of daphnids in the 0.10 and 0.056 mg/l treatment groups was poorer than that of control groups in the first week, but their growth and condition improved to match that of the control groups and treatment groups at lower concentrations.

Reproduction was significantly lower in the 0.32 and 0.18 mg/l treatment groups, as compared to the controls (0.8% and 48%, respectively). Reproduction in the 0.10 mg/l treatment groups was 78% that of the control groups, while reproduction in the 0.056 mg/l and lower treatment groups was consistently >90% that of the control groups.

The pH of the test solutions ranged from 7.7 to 8.4 during the test. Dissolved oxygen (DO) concentrations generally between 6 and 8 mg/l. In some of the lower concentration test solutions, the DO fell below 6 mg/l on day 17 due to an interruption of air supply; however, this decrease had no effect on mortality, growth or reproduction.

**Conclusions**

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; equivalent to guideline study.

**References**

Adema, M. and H.T. de Oude. 1982. Chronic Toxicity of E8013.01 to *Daphnia magna*. Procter & Gamble European Technical Centre, Belgium. Unpublished report (No. CL 82/28).

**Other Available Reports**

**Other**

Last Changed:

September 18, 2003

Order number for sorting:

340

Remarks:

#### 4.5.2 CHRONIC TOXICITY TO AQUATIC ORGANISMS

##### Test Substance

Identity: Ethomeen HT/12 (CAS No. 61791-31-9;  
Ethanol, 2,2'-iminobis-, N-coco alkyl derives.)  
Purity: 91.6%  
Remarks:

##### Method

Method/guideline followed: ESD VIII H-3, Issue 1, 7/28/77 with modifications.  
Type: Continuous flow  
GLP: Not stated  
Year: 1981  
Species/Strain/Supplier: *Daphnia magna*/Strauss 1820/ex-IRCHA  
Analytical Monitoring: Not reported.  
Exposure Period: 21 days  
Statistical Methods: Standard ETC probit analysis.  
Remarks: The experiment measured the survival and reproduction of *Daphnia magna* over a 21-day exposure to the test and control solutions. Eight treatment groups were tested with four replicates in a continuous flow exposure design: five test concentrations selected on the basis of a range-finding test, two negative controls (for more baseline data) and a solvent control (benzoic acid). The dilution water was the water normally used in the ETC laboratory. Test vessels consisted of 1-l glass beakers each containing 1 l of test solution fitted with stainless steel screen to cover the notch for drainage and a device to insure constant retention time of test solution in beakers. At test initiation, approximately 5 daphnids were placed in each replicate test vessel. The daphnids were fed automatically every 45 minutes (1 ml of a 25% *Daphnia* food solution). Light was provided for 14 h/day at an intensity of 350 +50 footcandles. Test containers were changed once during the first 7 days, and three times per week thereafter. The temperature, pH and dissolved oxygen (DO) was measured in each test chamber on day 0, 1, 3, 6, 8, 10, 13, 15, 17 and 21. Hardness was measured on day 0, 6, 13 and 21, while chlorine was measured on day 0 and 21. Although samples of the test solutions were collected on days 0, 7, 14 and 21, the samples were stored for later analysis and concentrations reported are based on nominal values. Survival of the F<sub>0</sub> was reported on days 1, 2, 3, 6 and three times per week thereafter. The number of F<sub>1</sub> young produced and any behavior such as abnormal

swimming or immobilization were reported three times per week, beginning day 6. The length of surviving F<sub>0</sub> daphnids was measured after day 21.

**Results**

Nominal concentrations (mg/l): 0 (neg. control), 0 (neg. control), 0 (solvent control), 0.036, 0.058, 0.101, 0.195 and 0.477 mg/l  
 Measured concentrations (mg/l): Not reported.  
 Unit: mg/l  
 Element Value: LC<sub>50</sub> (95% Confidence Interval); NOEC  
 Statistical Results:

Elapsed Time (days)	LC <sub>50</sub> (mg/l)	95% Confidence Interval
3	0.35	0.30-0.46
6	0.27	0.22-0.33
21	0.14	0.12-0.17

Additional Results: NOEC = 0.058 mg/l

Nominal Concentration (mg/l)	Offspring/ F <sub>0</sub> Alive	Daily Production/F <sub>0</sub> over 15 days <sup>a</sup>	Mean Length <sup>b</sup> (mm)
(-) control	141.6	9.44	3.9
(-) control	117.8	7.86	3.9
solvent control	121.6	8.11	3.9
0.036	154.1	10.27	3.95
0.058	116.8	7.8	3.85
0.101	92.9	6.19	2.9
0.195	40.9	2.73	2.16
0.477	0	0	NA

NA = not applicable

<sup>a</sup> Test duration after first reproduction occurred (day 6).

<sup>b</sup> F<sub>0</sub> surviving to day 21.

Remarks:

Mortality (F<sub>0</sub>) in the 0.477 mg/l treatment group was 100% by Day 8. Day 21 mortality in the 0.195 and 0.101 mg/l treatment groups was 85 and 20%, respectively. There was only 1 death in the 0.58 mg/l treatment group. No mortality was observed in the lowest, 0.036 mg/l, treatment group. Incidental mortality observed in the solvent and two negative controls was 10, 40 and 15% by Day 21, respectively.

Reproduction started on day 6 for all but the highest, 0.477 mg/l, of the treatment groups. Daily production

(over the 15-day period after first production) in the 0.036 and 0.058 mg/l treatment groups was quite similar to that of the control groups, while both the daily production and the mean length of F<sub>0</sub> survivors in the 0.101 and 0.195 mg/l treatment groups were noticeably lower than that of the control.

Total chloride before and after the test was 0.07 mg/l, the pH was 7.85±0.15 the water harness remained between 195 and 215 mg CaCO<sub>3</sub>/l and the temperature was 23±1°C. Dissolved oxygen (DO) generally varied from 40 to 100% saturation (no correlation with concentration) due to an uneven diluter solution. The study director did not consider the reduced oxygen levels to be significant since only 1 of 4 replicates was affected.

## Conclusions

The end point was adequately characterized. (American Chemistry Council Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline study.

## References

De Boeck, M. and B. Buyle. 1981. Chronic Toxicity of Ethomeen HT/12 (E.8013.01) to *Daphnia magna*. Procter & Gamble European Technical Centre, Belgium. Unpublished report (No. E 8013.01.11/ETS No. 69).

## Other Available Reports

### Other

Last Changed:  
Order number for sorting:  
Remarks:

September 18, 2003  
341

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: PA-14 Acetate (CAS RN 28701-67-9;  
1-Propanamine, 3-(isodecyloxy)-, acetate)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: EPA Guideline Series 81-1  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1993  
Species/Strain: Rat/HSD:SD  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Not used.  
Route of administration: Oral gavage by syringe and stainless steel ball-tipped gavage needle  
Remarks: Groups of rats (five males and five females plus one additional group of 5 females) were administered a single dose of the test substance at dosages of 500 (females only), 1000, 1500, and 2000 mg/kg body weight. Rats weighing 210 to 250 g (males) and 198 to 232 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were young adults at initiation of the study. Food was available *ad libitum*, except for a period of 16 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. LD<sub>50</sub> Analysis was conducted using: Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A Simplified Method of Evaluating Dose-Effect Experiments. *J. Pharm. and Exp. Ther.* 96: 99-115.

#### Results

Value: Male: LD<sub>50</sub> = 1457 mg/kg (95% confidence limits: 1271 to 1670 mg/kg)  
Female: LD<sub>50</sub> = 1033 mg/kg (95% confidence limits: 881 to 1212 mg/kg)  
Combined: LD<sub>50</sub> = 1216 mg/kg (95% confidence limits: 1061 to 1393 mg/kg)  
Number of deaths: 500 mg/kg = 0/5 (females only)  
1000 mg/kg = 0/5 males; 2/5 females  
1500 mg/kg = 3/5 males; 5/5 females

Remarks: 2000 mg/kg = 5/5 males; 5/5 females  
Decreased activity, diarrhea, gasping, piloerection, lacrimation, nasal discharge, polyuria, and salivation were present at all dose levels and generally persisted through Day 7 in surviving animals. Body tremors were also evident and cleared by Day 2. Body weight changes of survivors were generally normal. Gross necropsy findings (including external and internal findings) of the animals that died during the study included: signs of diarrhea, lacrimation, nasal discharge, polyuria and salivation; discolored lungs, discoloration of the contents of the gastrointestinal tract, gastrointestinal tract distended with gas and/or fluid. Necropsy of survivors revealed no observable abnormalities.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A  
Remarks: Reliable without restrictions; guideline study.

**References**

Kuhn, J. O. 1993. Acute Oral Toxicity Study in Rats. Unpublished report (No. 0317-93). Stillmeadow, Inc., Sugar Land, TX, USA.

**Other**

Last changed: July 8, 2002  
Order number for sorting: 137b  
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: 1-Dodecyl amine (CAS RN 124-22-1; Dodecylamine)  
Purity: Not stated

#### Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1953  
Species/Strain: Rat and mouse/Strain not stated  
Sex: Female  
No. of animals per sex per dose: 6  
Vehicle: Propylene glycol  
Route of administration: Oral gavage  
Remarks: Animals were administered 1-dodecylamine dissolved in propylene glycol by gavage (total volume ≤20 ml/kg). Animals were observed for ten days. The LD<sub>50</sub> values and confidence limits were calculated by the method of Litchfield, J.T. Jr. and F. J. Wilcoxon, [*Pharmacol. and Exper. Therap.*, 96:101 (1949)].

#### Results

Value: LD<sub>50</sub> in rats = 1020 mg/kg (confidence intervals 840 to 1240 mg/kg)  
LD<sub>50</sub> in mice = 1160 mg/kg (confidence intervals 1030 to 1310 mg/kg)  
Number of deaths: Not stated  
Remarks: Irritation of the stomach and duodenum were noted.

#### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

#### Data Quality

Reliability (Klimisch): 2D  
Remarks: Reliable with restrictions; basic data provided, with minimal details.

**References**

Anderson, H.H. and G.K. Hurwitz. 1953.  
Dodecylamine and Other Agents Active Against  
Ascaris lumbricoides and Their Toxicity to Mammals.  
Arch. Exper. Path. U. Pharmakol. 219:119-129.

**Other available reports**

**Other**

Last changed:	June 4, 2002
Order number for sorting:	32
Remarks:	

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: 1-Dodecyl amine (CAS RN 124-22-1; Dodecylamine)  
Purity: >99.9%  
**Remarks:**

#### Method

Method/guideline followed: OECD Guideline 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1987  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Sesame oil  
Route of administration: Oral gavage, single dose, 10 ml/kg  
**Remarks:** A group of ten rats (five males and five females) were administered a single gavage dose of the test substance in sesame oil at a dose of 2000 mg/kg and a dose volume of 10 ml/kg. Male rats were 6 weeks of age and weighed 184 to 190 g and female rats were 7 weeks of age and weighed 178 to 186 g. All animals were examined for clinical signs several times on day 1 and daily thereafter for 14 days following dose administration. Body weights were obtained on days 1 and 14. All animals were subjected to a complete necropsy following the 14-day observation period.

#### Results

Value: LD<sub>50</sub> >2000 mg/kg bw  
Number of deaths: None  
**Remarks:** All animals showed diarrhea, piloerection, hunched posture, abnormal gait, reduced activity, flanks drawn in, and irregular breathing. One male rat showed crusted eyelids and crusted snout on day 3. Necropsy findings were normal except one male showed growing together of the stomach with the liver, spleen, pancreas and abdominal wall.

#### Conclusions

**Remarks:** The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restrictions; guideline study.

**References**

Hofmann, Th. and R. Jung. 1988. Genamin 12 R 100 D, Pruefung der akuten oralen Toxizitaet an der Wistar-Ratte. [Genamin 12 R 100 D; Acute oral toxicity study in the Wistar rat] Report No. 88.0146. Hoechst Pharma Forschung Toxikologie und Pathologie.

**Other available reports**

**Other**

Last changed:

August 12, 2002

Order number for sorting:

32a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DM12D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1980  
Species/Strain: Rat/Wistar  
Sex: Male  
No. of animals per sex per dose: 10  
Vehicle: The report does not specify if a vehicle was used; however, the following statement was included: “The vehicle, if any, was chosen because of its lack of known toxicity, lack of physiological effect and because it is relatively unreactive with other chemical substances.”  
Route of administration: Oral gavage  
Remarks: Ten male rats were administered a single dose of the test substance at dosages of 0.60, 0.96, 1.54, 2.47, and 5.0 g/kg bodyweight. Rats were approximately eight weeks old when received and were acclimated to the laboratory for a period at least one week prior to test initiation. Rats weighed 200 to 267 g at test initiation. Food was available *ad libitum*, except for a period of 16 to 20 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity 3 to 4 hours after dosing and once daily for 14 days following test substance administration. Body weights were recorded at 0, 3, 7 and 14 days. A necropsy was performed on all rats. The LD<sub>50</sub> was calculated according to the method of Litchfield, J.T. Jr., and F. Wilcoxon J PET 96:99, 1949.

#### Results

Value: LD<sub>50</sub> = 1.22 g/kg (95% confidence limit of 0.92 to 1.61 g/kg)  
Number of deaths: 0.60 g/kg = 0/10  
0.96 g/kg = 3/10  
1.54 g/kg = 7/10  
2.47 g/kg = 10/10  
5.0 g/kg = 10/10

**Remarks:**

Deaths occurred at the four higher dose levels with 100% mortality at the top two dose levels (2.47 and 4.0 g/kg). The deaths generally occurred by Day 2, with the exception that one rat each in the 1.54 and 0.96 g/kg groups died by day 3 and 7, respectively. Lethargy, diarrhea, ataxia and piloerection were present at all dose levels, generally persisted to day 2 and/or death. Body weight changes and necropsy findings of survivors were generally normal. One survivor in the 1.54 g/kg group had lung abnormalities and below normal weight gain. Animals that died had heart, lung and gastrointestinal abnormalities.

**Conclusions**

**Remarks:**

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

**Reliability (Klimisch):**

2A

**Remarks:**

Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

1980. Test for Oral Toxicity in Rats – Armeen DM12D. Project No. MB 80-4821A. MB Research Laboratories Inc., Spinnerstown, PA, USA.

**Other**

**Last changed:**

July 8, 2002

**Order number for sorting:**

123

**Remarks:**

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: ADMA 2 (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1979  
Species/Strain: Wistar rat  
Sex: Male  
No. of animals per sex per dose: 10  
Vehicle: None or Mazola Oil  
Route of administration: Oral gavage  
Remarks: Wistar rats were at least 9 weeks old and 202-300 g at study initiation. Ten male rats per group were given a single oral dose of 0.072, 0.30, 1.22 and 5.0 g/kg of the test substance. The 0.072 g/kg group was dosed with a 10% w/v mixture of ADMA 2 in Mazola Oil. The rats were observed 3-4 hours after dosing and once daily for 14 days. Mortality, toxicity and pharmacological effects were recorded. Body weights were recorded at pretest and in the survivors at 14 days. At 14 days the survivors were sacrificed. All animals on study were examined for gross pathology. The LD<sub>50</sub> was calculated according to the method of Litchfield, J.T. Jr., & F. Wilcoxon, JPET 96:99, 1949.

#### Results

Value: LD<sub>50</sub> = 0.79 g/kg (95% confidence limits = 0.44 to 1.42 g/kg)  
Number of deaths: 0.072 g/kg = 0/10  
0.30 g/kg = 2/10  
1.22 g/kg = 6/10  
5.0 g/kg = 10/10  
Remarks: All animals in the 5.0 g/kg group died. Predeath clinical observations included lethargy, ataxia, diarrhea, stiff when manipulated, irritable when touched, chromorhinorrhea, piloerection, ptosis and prostration. Six animals died in the 1.22 g/kg group. Predeath clinical observations included prostration, piloerection, ptosis, bulging eyes, diarrhea, ataxia chromorhinorrhea, dyspnea, lethargy, foaming at the

mouth, gasping, oily bodies and tremors. The surviving animals exhibited (from days 1 through 6) isolated instances of the same clinical signs as those exhibited by the animals that died. All surviving animals appeared normal through the remainder of the 14-day observation period. Two animals in the 0.30 g/kg level died (Day 5 and 11). Predeath signs included lethargy, piloerection, dyspnea, chromorhinorrhea, ataxia, ptosis, diarrhea, emaciation and chromodacryorrhea. The surviving animals were normal throughout the testing period. All animals in the 0.072 g/kg dose group survived. Isolated instances of chromorhinorrhea and lethargy were noted 3 to 4 hours post dose. Isolated instances of respiratory rattle and chromorhinorrhea were noted in three animals. Animals were normal at all other time points. All surviving animals in the 0.072, 0.30 and 1.22 g/kg groups gained weight from Day 0 to 14. Significant necropsy findings observed in the animals that died included various intestinal irregularities and dilated hearts.

### Conclusions

Remarks:

The test material is toxic as defined in 16 CFR 1500.3, but not a Class B poison as defined in 49 CFR 173.343. (Author of report)  
The acute oral LD<sub>50</sub> has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

2A  
Reliable with restrictions; acceptable, well-documented publication/study report which meets basic scientific principles.

### References

Test for Oral Toxicity in Rats with ADMA 2. 1979. Project Number: MB 79-3571. MB Research Laboratories, Inc. Spinnerstown, PA, USA.

### Other available reports

#### Other

Last changed:  
Order number for sorting:  
Remarks:

June 7, 2002  
123c

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: N,N-Dimethyldocecylamine (CAS RN 112-18-5;  
N,N-dimethyl-1-Dodecanamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Acute oral toxicity  
GLP: No  
Year: 1976  
Species/Strain: Rat  
Sex: Male  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Oral gavage  
Remarks: Groups of three rats were administered a single dose of the undiluted test substance at concentrations of 0.316, 0.63, 1.26, 2.52 and 5.0 g/kg. Rats were in the weight range of 185 - 232 g. Rats were fasted overnight prior to dosing. Rats were weighed and observed for signs of toxicity at intervals over a two-week post dose period or until any weight loss was regained and the animals appeared healthy. One animal from each group (when available) was evaluated pathologically one day following dosing.

#### Results

Value: LC<sub>50</sub> not determined  
Number of deaths: 0.316 g/kg = 0/2  
0.63 g/kg = 0/2  
1.26 g/kg = 0/2  
2.52 g/kg = 2/2  
5.0 g/kg = 3/3  
Remarks: Clinical signs observed soon after dosing in rats treated with 2.52 and 5.0 g/kg of the test substance included lethargic behavior, urine soaked fur and enlarged eyes. At four hours post dose, one rat was gasping, blue in color, had slight diarrhea and was listless. One day post dose, rats treated with 1.26 and 2.52 g/kg of the test substance were listless and had dark red eye secretions. Clinical signs were not observed in the remaining rats. Rats in the 2.52 and 5.0 g/kg dose groups that died prior to scheduled sacrifice did so by days 3 and 1 post dose, respectively. Rats that

survived the two-week observation period gained weight by study termination. Representative rats (one per group) from the 0.316, 0.63, 1.26 and 2.52 g/kg dose groups were killed 24 hours post dose and a gross macroscopic examination was performed. Examination of the rat from the 0.316 g/kg dose group revealed the stomach to be distended with fluid and submucosal edema of the squamous epithelial portion of the stomach such that the mucosa was separated from the rest of the stomach wall. Examination of the rat from the 0.63 g/kg dose group revealed fluid in the proximal one-half of the small intestines, stomach distended with fluid, and submucosal edema in the squamous epithelial portion of the stomach causing the mucosa to separate from the wall of the stomach. Examination of the rat from the 1.26 g/kg dose group revealed stomach congestion and sloughing of the nonglandular portion of the squamous epithelium from the mucosal surface, and gastric irritation. One rat from the 2.52 g/kg dose group that had died was examined macroscopically, which revealed moistened hair, distended abdomen, small intestines devoid of any normal ingesta, yellowish bile-colored fluid material within the lumen, hyperemia of the mucosal surface of the stomach, possible sloughing of the nonglandular portion of the squamous epithelium from the mucosal surface, and congested liver and kidneys.

### Conclusions

Remarks:

The LD<sub>50</sub> value was not determined; however, this report provided additional information on the acute oral toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

2C

Reliable with restrictions; comparable to guideline study with acceptable restrictions.

### References

Dow Chemical Co. 1988. Initial Submission: Letter from Dow Chem. Co. to US EPA regarding information on N,N-dimethyldodecylamine and Ethanamine, N,N-diethyl with attachments, dated 10/10/88. EPA Doc. No. FYI-OTS-0794-1133, Microfiche No. OTS0001133.

**Other**

Last changed:	June 10, 2002
Order number for sorting:	123d
Remarks:	

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Farmin DM40 (CAS RN 112-75-4;  
1-Tetradecanamine, N,N-dimethyl)  
Purity: 97%  
Remarks:

#### Method

Method/guideline followed: OECD Guidelines for Testing of Chemicals -  
Section 4, Sub-section 401  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1996  
Species/Strain: Rat/CD Strain (remote Sprague-Dawley origin)  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Corn oil  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg bodyweight. The test substance was administered at a constant volume of 10 ml/kg body weight in corn oil. Rats weighing 106 to 134 g (males) and 103 to 129 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The LD<sub>50</sub> value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3<sup>rd</sup> ed; Cambridge University Press).

#### Results

Value: LD<sub>50</sub> = 2116 mg/kg; slope of dose response curve 77°.  
Number of deaths: At 2000 mg/kg, mortality was: 2/5 males and 2/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females.  
Remarks: At 500 mg/kg, animals showed hunched posture on the day of dosing. At 2000 mg/kg, animals showed signs of abnormalities including hypoactivity, staggering gait, hyperpnoea, piloerection, hunched posture,

pigmented orbital secretions, ungroomed appearance, pigmented staining of the snout, hair loss and thin body conformation. With the exception of hair loss, clinical signs had resolved by Day 7. Males in the 2000 mg/kg dose group had lower than expected weight gain. All other groups had normal weight gains. Necropsy of decedents revealed various areas of cannibalization and fur discoloration. Necropsy of the surviving animals revealed no gross lesions, only a single case of hair loss.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restrictions; guideline study.

### References

Rees, P. B. 1996. Farmin DM40: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS165/0652. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. and  
Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 22, 1999.

### Other available reports

#### Other

Last changed:

July 8, 2002

Order number for sorting:

256

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Genamin 14R 302D (CAS RN 112-75-4;  
1-Tetradecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: EG Guideline B.1. Acute Toxicity oral 84/449/EWG;  
OECD Guideline for testing of chemicals, 401 Acute  
Oral Toxicity; Guideline 83/467/EWG  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1989  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: 5 males and 15 females  
Vehicle: Sesame Oil  
Route of administration: Oral gavage  
Remarks: Animals were kept in temperature and humidity  
controlled rooms in groups of five rats per cage.  
Temperature range was  $22 \pm 3^{\circ}\text{C}$ , relative humidity  
was  $50 \pm 20\%$ , and animals received 12 hours of light  
per day. Food was removed about 16 hours before and  
approximately 3 to 4 hours after dosing. The test  
substance was ground in sesame oil with a mortar and  
pestle and then homogenized with a magnetic stirrer.  
The prepared solution was administered via oral  
gavage in the following doses:

Dose (mg/kg)	Concentration (%)	Administered Volume (ml/kg)	Number of Males	Number of Females
1250	12.5	10	-	5
1400	14.0	10	5	5
1600	16.0	10	-	5

Observation time was 14 days after dosing. Symptoms and death were recorded when they occurred. Body weight was determined weekly during this time. Animals that died during the test were dissected and inspected macroscopically. Surviving animals were terminated after the observation time by carbon dioxide asphyxiation, dissected and examined for macroscopically visible changes.

**Results**

Value: LD<sub>50</sub> = 1320 mg/kg body weight (95% confidence limits of 1090 to 1520 mg/kg)

Number of deaths:

Dose (mg/kg)	Mortality			
	Males		Females	
	Absolute	Percent	Absolute	Percent
1250	--	--	1/5	20
1400	0/5	0	4/5	80
1600	--	--	5/5	100

Remarks:

The following clinical symptoms were observed after dosing of Genamin 14R 302D: decreased spontaneous activity, ruffled fur, crouching (cowering), flanks pulled in, uneven breathing, decreased breath frequency, gasping, high-legged gait, uncoordinated gait, blood-colored crusted eye lid rims and diarrhea. In addition, females displayed blood-colored crusted snouts, splayed extremities, narrowed eyelids and staggering gait. The surviving female and male animals were free of symptoms by post dosing days 8 and 5, respectively. In some animals, body weight development was delayed in the first study week. By the end of the study, all animals had gained weight. The macroscopic examination of the dead males and females revealed the following: blood in the small intestine, small intestine filled with whitish yellow masses, distended stomach, bleeding in the stomach lining, blood and test substance remains in the stomach, white colored stomach mucous membrane, strongly reddened gut, reduced liver and pale adrenal glands.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Hofmann, Th. and R. Jung. 1989. Genamin 14R 302D: Study of the Acute Oral Toxicity in the Wistar Rat. Study Number 89.0793. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed:

June 7, 2002

Order number for sorting:

260a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DM16D (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: Albino rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 10% Aqueous Gum Arabic or none  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats.

#### Results

Value: LD<sub>50</sub> = 0.80 ml/kg  
(95% confidence limits = 0.678 to 0.943 ml/kg)  
Number of deaths: 0.50 ml/kg = 1/10  
0.75 ml/kg = 2/10  
1.0 ml/kg = 9/10  
2.0, 4.0 and 8.0 ml/kg = 10/10  
Remarks: LD<sub>0.01</sub> = 0.293 ml/kg  
LD<sub>99.99</sub> = 2.15 ml/kg  
All rats exhibited a generalized lassitude and inactivity within one hour post dose. Also, all rats showed signs of ptosis during the observation period. Severe diarrhea was observed in rats treated with 1.0, 2.0, 4.0

and 8.0 ml/kg of the test substance. Mild diarrhea was observed in rats treated at the lower dose levels. Rats in the four highest dose groups rapidly became moribund and death was preceded by a comatose state. In most cases where death occurred, it was within 19 hours post dose. Rats that survived for 24 to 36 hours usually recovered within the next day or two and no untoward signs or symptoms were observed thereafter. Necropsy examinations revealed intestines distended with fluid and the absence of formed feces in rats that died prior to scheduled sacrifice. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:  
Order number for sorting:  
Remarks:

June 13, 2002  
3

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: C<sub>16</sub>-alkyl dimethylamine (CAS RN 112-69-6; 1-Hexadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1989  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Arachis oil B.P.  
Route of administration: Oral gavage  
Remarks: Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 135-172 g and 125-130 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg  
Number of deaths: 4/10  
Remarks: Three male rats died prior to scheduled sacrifice on days 1, 3 and 8. One female died on day 2. Hunched posture, piloerection, lethargy and decreased respiratory rate were observed in one female at one and four hours post dose. Increased salivation also was observed in this female at one hour post dose. Hunched posture, piloerection and lethargy, and occasional or isolated signs of ptosis, diarrhea, emaciation and red/brown staining around the snout and eyes were observed in surviving rats during the 14-day observation period. All surviving rats appeared normal by day 13. One surviving male and female showed a loss in body weight during the first week of the observation period. All surviving rats showed

body weight gain over the second week of the observation period. Necropsy findings in rats that died prior to scheduled sacrifice included abnormally red lungs, dark liver and kidneys, with hemorrhage of the gastric mucosa and small intestines, and incidents of hemorrhage of the nonglandular epithelium of the stomach and large intestine. No abnormalities were noted at necropsy of the rats that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed:

June 10, 2002

Order number for sorting:

4

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Farmin DM60 (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: 97%  
Remarks:

#### Method

Method/guideline followed: OECD Guidelines for Testing of Chemicals -  
Section 4, Sub-section 401  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1996  
Species/Strain: Rat/CD Strain (remote Sprague-Dawley origin)  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Corn oil  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg. The test substance was administered at constant volume-dosage of 10 ml/kg bodyweight in corn oil. Rats weighing 107 to 139 g (males) and 106 to 129 g (females) were acclimated to the laboratory for a period of at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The LD<sub>50</sub> value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3<sup>rd</sup> ed; Cambridge University Press).

#### Results

Value: LD<sub>50</sub> = 1015 mg/kg; slope of does response curve 84°.  
Number of deaths: At 2000 mg/kg, mortality was: 5/5 males and 5/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females.  
Remarks: At 500 mg/kg, no animals showed signs of abnormalities. At 2000 mg/kg, all animals showed signs of abnormalities including hypoactivity, staggering gait, hyperpnoea, piloerection, pigmented

stain of the snout, pigmented orbital secretion, and hunched posture. No lesions were found at necropsy in the surviving animals of the 500 mg/kg group or the animals that died in the 2000 mg/kg group.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restrictions; guideline study.

**References**

Rees, P. B. 1996. Farmin DM60: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS172/0661. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. and Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 23, 1999.

**Other available reports**

**Other**

Last changed:

July 9, 2002

Order number for sorting:

4d

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: 1-Octadecyl amine (CAS RN 124-30-1;  
Octadecylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1981  
Species/Strain: Rat and mouse/Strain not stated  
Sex: Not stated  
No. of animals per sex per dose: Not stated  
Vehicle: Not stated  
Route of administration: Oral gavage  
Remarks:

#### Results

Value: LD<sub>50</sub>= approximately 1000 mg/kg (rat)  
LD<sub>50</sub>= approximately 1000 mg/kg (mouse)  
Number of deaths: Not stated  
Remarks: Not stated

#### Conclusions

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

#### Data Quality

Reliability (Klimisch): 2D  
Remarks: Reliable with restrictions; data from summary  
document; acceptable because data consistent with  
other data in subcategory.

#### References

Beard, R.R. and J. T. Noe. 1981. Aliphatic and Alicyclic Amines. Cited in: Clayton, G. D. and Clayton, F.E., ed. Patty's Industrial Hygiene and Toxicology, 3rd ed., John Wiley & Sons, New York, 3135-3173. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttgart.

## **Other available reports**

### **Other**

Last changed:	June 5, 2002
Order number for sorting:	40a
Remarks:	

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: 1-Octadecyl amine (CAS RN 124-30-1;  
Octadecylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1988  
Species/Strain: Rat/Strain not stated  
Sex: Male and female  
No. of animals per sex per dose: Not stated  
Vehicle: Sesame oil  
Route of administration: Oral gavage  
Remarks: Male and female rats were dosed with a single oral dose of 2000 mg/kg of the test substance in sesame oil.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg  
Number of deaths: 0  
Remarks: A dose of 2000 mg/kg of 1-octadecylamine in sesame oil was non-lethal; however, for up to 7 hours following treatment, reduced spontaneity, crouching and retracted flanks were observed in the animals.

#### Conclusions

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

#### Data Quality

Reliability (Klimisch): 2D  
Remarks: Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory.

## References

Hoechst. 1988. Genamin SH 100 D. Kurzbericht zur Prüfung der akuten oralen Toxizität an der Wistar-Ratte (Unveröffentlichte untersuchung. Bericht Nr. 88.0969). Hoechst AG, Pharma Forschung Toxikologie, Frankfurt/Main, 1 S. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

## Other available reports

### Other

Last changed:

June 5, 2002

Order number for sorting:

40a2

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Genamin 18 R 100 D (CAS RN 124-30-1;  
Octadecylamine)  
Purity: 100%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401; Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1981  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Sesame oil  
Route of administration: Oral gavage, single dose  
Remarks: Five male and five female rats received a single oral dose of the test substance at a dose level of 2000 mg/kg at a constant dose volume of 10 ml/kg. The test substance was mixed with sesame oil. At the start of the study the males were 7 weeks old and weighed 179 to 208 g and the females were 8 weeks old and weighed 186 to 192 g. All animals were observed several times on day 1 and daily thereafter for a total of 14 days following dosing. Body weights were obtained on days 1, 8 and 15 of the study. A necropsy was performed on all animals at the end of the study (Day 15).

#### Results

Value: LD<sub>50</sub> = >2000 mg/kg bw  
Number of deaths: 1 male died on day 4  
Remarks: All animals showed reduced spontaneous activity, piloerection, hunched posture, abnormal gait, reduced activity, and irregular breathing. One male had a swollen abdomen. All animals recovered by Day 9. The animal that died had a decrease in body weight on day 4. No other effects on body weight were noted. The following observations were noted at necropsy for the animal that died: stomach filled with test substance and gas, flanks drawn in, dark-colored liver, red staining of lungs, intestine and pancreas, intestines filled with gas, and shrunken spleen. All surviving animals had no remarkable findings at necropsy.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1a

Remarks:

Reliable without restrictions; guideline study.

**References**

Hofmann, Th. and R. Jung. 1989. Genamin 18 R 100 D, Pruefung der akuten oralen Toxizitaet an der Wistar-Ratte. [Genamin 18 R 100 D; Acute oral toxicity study in the Wistar rat] Report No. 89.0840. Hoechst Pharma Forschung Toxicologie und Pathologie.

**Other available reports**

**Other**

Last changed:

August 12, 2002

Order number for sorting:

40b

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Oleyl amine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: 97.9%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1987  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Corn oil  
Route of administration: Oral gavage, single dose  
Remarks: Doses: 200, 500, 1000, 2000 mg/kg bw. Dose volume was 10 ml/kg (2.5 ml/kg for dosage group 2000 mg/kg). Animals in groups 200, 500 and 1000 mg/kg were observed for 14 days postdosing. Animals in the 2000 mg/kg group were observed for 29 days postdosing. Body weights were obtained on days 1, 5, 8 and 15. Necropsy was performed on all animals. Data were analyzed by probit analysis.

#### Results

Value: LD<sub>50</sub> = 1689 mg/kg bw  
Female LD<sub>50</sub> = ~2000 mg/kg bw  
Male LD<sub>50</sub> = ~1178 mg/kg bw  
Number of deaths: 200 mg/kg bw: 1/5 male; 0/5 females  
500 mg/kg bw: 0/10 animals  
1000 mg/kg bw: 2/5 males; 0/5 females  
2000 mg/kg bw: 4/5 males, 3/5 females  
Remarks: Clinical signs included: hypokinesia and or sedation, piloerection and dyspnea, abdominal swelling. Decreases in body weight gain were noted between day 1 to 5 at 200 and 500 mg/kg, persisting in one male and one female at 200 mg/kg; and at 1000 mg/kg and returning to normal by day 8. Body weight gain was also decreased at 2000 mg/kg from day 1 to 8, returning to normal by day 15. No abnormalities were noted at necropsy.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restrictions; guideline study.

**References**

Chouteau, J. 1993. NORAM O Determination of  
Acute Oral Toxicity in Rats. Centre International de  
Toxicologie

**Other available reports**

**Other**

Last changed:

August 14, 2002

Order number for sorting:

6b

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Genamin SH 301 (CAS RN 4088-22-6;  
1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: ES Guideline B.1. Acute Toxicity oral 84/449/EWG;  
OECD Guideline for testing of chemicals, 401 Acute  
Oral Toxicity; Guideline 83/467/EWG  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1988  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Sesame Oil (Oleum sesame Ph.Eur.III, Fa. Mainland  
Pharmzeutische Fabrik GmbH, Ffm.)  
Route of administration: Oral gavage  
Remarks: Animals were kept in temperature and humidity  
controlled rooms in groups of 5 rats per cage.  
Temperature range was  $22 \pm 3^{\circ}\text{C}$ , relative humidity  
was  $50 \pm 20\%$ , and animals received 12 hours of light  
per day. Food was removed about 16 hours before and  
approximately 3 to 4 hours after application. The test  
substance was dissolved in sesame oil warmed to  
 $35^{\circ}\text{C}$ . The prepared solution was administered to five  
male and five female rats via oral gavage at  
2000 mg/kg. The dose volume was 10 ml/kg.  
Observation time was 14 days after dosing. Symptoms  
and death were recorded when they occurred. Body  
weight was determined weekly during this time.  
Animals that died during the test were dissected and  
inspected macroscopically. Surviving animals were  
terminated after the observation time by carbon  
dioxide, dissected and examined for macroscopically  
visible changes.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg body weight  
Number of deaths: 0/10  
Remarks: During the 14-day observation period, no deaths were  
observed. In addition, no symptoms of toxicity were  
observed. Body weight gain was not affected. The  
macroscopic examination revealed no visible changes.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Hofmann, Th. and R. Jung. 1988. Genamin SH 301:  
Study of the Acute Oral Toxicity in the Wistar Rat.  
Study Number 88.0225. Pharma Forschung  
Toxikologie und Pathologie, Hoechst  
Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed:

June 7, 2002

Order number for sorting:

77a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: E8220: Ditallowmethylamine (CAS RN 4088-22-6;  
1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1978  
Species/Strain: Sprague-Dawley rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Not stated  
Route of administration: Oral gavage  
Remarks: The test substance was administered to five rats of each sex (190 to 270 g) as a single oral dose at 5 g/kg body weight in a 40% w/v solution (vehicle not identified). Animals were fasted for approximately 18-20 hours prior to dosing. Food was available *ad libitum* immediately following dosing. Animals were observed for mortality and overt signs of toxicity ¼, ½, 1, 2 and 4 hours after treatment and daily thereafter for a total of 14 days. Body weights were measured for each animal just prior to initiation and on Days 7 and 14 of the 14-day observation period. Necropsy was performed on all surviving animals to assess any treatment related gross pathological changes.

#### Results

Value: LD<sub>50</sub> > 5 g/kg (male and female combined)  
Number of deaths: 0/5 males; 0/5 females  
Remarks: All animals survived the study and gained weight during the 14-day observation period. While all animals appeared subdued and lethargic 4 hours after treatment, this observation was only apparent in one female animal at 24 hours. Necropsy of all surviving animals showed no macroscopic abnormalities. The acute oral toxicity of the test substance is in excess of 5 g/kg body weight.

#### Conclusions

Remarks: The endpoint has been adequately characterized.

(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restrictions; comparable to guideline study

**References**

Jones, J.R. 1979. Acute Oral Toxicity in the Rat, ECM BTS 267, E8220: Ditallowmethylamine. Unpublished report (No. 1628-110/179), for Procter and Gamble Ltd., Newcastle-Upon-Tyne, England, from Hazleton Laboratories Europe, Ltd., Harrogate, England.

**Other available reports**

**Other**

Last changed:

March 20, 2003/LAM

Order number for sorting:

311

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DM18D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: Albino rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 10% Aqueous Gum Arabic or none  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance was administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats.

#### Results

Value: LD<sub>50</sub> = 0.78 ml/kg  
(95% confidence limits = 0.636 to 0.956 ml/kg)  
Number of deaths: 0.50 ml/kg = 0/10  
0.75 ml/kg = 5/10  
1.0 ml/kg = 7/10  
2.0, 4.0 and 8.0 ml/kg = 10/10  
Remarks: LD<sub>0.01</sub> = 0.23 ml/kg  
LD<sub>99.99</sub> = 2.65 ml/kg  
Generalized listless behavior was observed in all dose groups shortly after test substance administration. Diarrhea was observed in rats in degrees of severity more or less commensurate with the dose received.

Rats in the higher dose groups became comatose within 4 to 10 hours and succumbed within the next 12 hours. Surviving rats in the lower dose groups showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:

June 13, 2002

Order number for sorting:

37

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Farmin DM80 (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: 97%  
Remarks:

#### Method

Method/guideline followed: OECD Guidelines for Testing of Chemicals - Section 4, Sub-section 401  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1996  
Species/Strain: Rat/CD Strain (remote Sprague-Dawley origin)  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Corn oil  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance into the stomach lumen via a flexible catheter at dosages of 2000 mg/kg and 500 mg/kg bodyweight. The test substance was administered at constant volume of 10 ml/kg body weight in corn oil. Rats weighing 113 to 130 g (males) and 110 to 123 g (females) were acclimated to the laboratory for a period at least five days prior to test initiation. Rats were approximately five weeks old at initiation of the study. Food was available *ad libitum*, except for the overnight period prior to test substance administration and three hours after dosing. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats. The LD<sub>50</sub> value was calculated using probit analysis (Finney, D.J. 1971. Probit Analysis. 3<sup>rd</sup> ed; Cambridge University Press).

#### Results

Value: LD<sub>50</sub> = 2116 mg/kg; slope of dose response curve 77°.  
Number of deaths: At 2000 mg/kg, mortality was: 2/5 males and 2/5 females. At 500 mg/kg, mortality was: 0/5 males and 0/5 females.  
Remarks: At 500 mg/kg, animals showed signs of abnormalities including hypoactivity, piloerection, hunched posture and ungroomed appearance, but all were normal by Day 4. At 2000 mg/kg, all animals showed signs of

abnormalities including lower than expected weight gain, hypoactivity, piloerection, hunched posture, pigmented orbital secretions, ungroomed appearance, eyes closed and hair loss. With the exception of hair loss, surviving animals were overtly normal by Day 8. Necropsy of decedents revealed various areas of cannibalization and fur staining. There were no macroscopic abnormalities noted for the surviving animals in the 2000 and 500 mg/kg dose groups.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1A

Reliable without restrictions; guideline study.

### References

Rees, P. B. 1996. Farmin DM80: Acute Oral Toxicity Study in the Rat. Report No. 96/KAS179/0656. Huntingdon Life Sciences Ltd. Eye, Suffolk, UK. and Letter from High Point Chemical to U.S. Environmental Protection Agency concerning test substance. January 23, 1999.

### Other available reports

#### Other

Last changed:

July 8, 2002

Order number for sorting:

38g

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen C (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1983  
Species/Strain: Wistar rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Oleum arachidis  
Route of administration: Oral gavage  
Remarks: Based on the results of a range-finding test, the test substance was administered to male (170.1 – 190.8 g) and female rats (140.0 – 162.6 g) as a 20% dilution in oleum arachidis at dose levels of 0.5, 1.0, 1.5 and 2.0 g/kg. Animals were fasted 16 hours prior to dosing and were given food ad libitum four hours after dosing. Animals were observed for a total of 14 days. Body weights were measured for each animal at the start and end of the study. A gross necropsy was performed on each animal at the end of the 14-day observation period. The LD<sub>50</sub> was determined by probit analysis.

#### Results

Value: Combined LD<sub>50</sub> = 1.30 g/kg  
Male LD<sub>50</sub> = 1.24 g/kg  
Female LD<sub>50</sub> = 1.39 g/kg  
Number of deaths: 2.0 g/kg = 5/5 males, 5/5 females  
1.5 g/kg = 2/5 males, 2/5 females  
1.0 g/kg = 1/5 males, 1/5 females  
0.5 g/kg = 1/5 males, 0/5 females  
Remarks: The following mortalities were observed:  
Within 48 hours = two males and one female at 2.0 g/kg; one male and one female at 1.5 g/kg; one male at 1.0 g/kg; and one male at 0.5 g/kg;  
Within 5 days = 3 males and 3 females at 2.0 g/kg; one male and one female at 1.5 g/kg; and one female at 1.0 g/kg;  
Within 7-14 days = one female at 2.0 g/kg.  
Clinical signs observed during the observation period included disturbance in consciousness with apathy,

predominant coordination disturbances, clear reduction of reflexes, cyanosis, shortly-persisting massive salivation, predominant piloerection, slightly decreased respiration and hypothermia. These symptoms were evident approximately 20 minutes post-dose and, for the most part, had subsided by day 7. By the end of the 14-day observation period animals that had survived the study appeared normal. Gross necropsy findings noted in animals that died during the study included a reddening discoloration and a small amount of fluid in the stomach and intestinal tract. No gross necropsy findings were noted in animals that survived until study termination.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

2D

Remarks:

Reliable with restrictions; translation of German study report.

### **References**

Sterner, W. and G. Chibanguza. 1983. Akute orale Toxizität an Ratten mit Armeen C. [Acute oral toxicity in the rat with Armeen C] Project No. 1-4-299-83. Akzo Chemie BV, IBR Forschungs GmbH, Hannover, Krumme.

### **Other available reports**

#### **Other**

Last changed:

July 24, 2002

Order number for sorting:

94

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Amines, coco alkyl (CAS RN 61788-46-3)  
Purity: >99%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1994  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: Five  
Vehicle: Not stated  
Route of administration: Oral gavage  
Remarks:

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg (male)  
= 2820 mg/kg (female)  
Number of deaths: Not stated  
Remarks: The animals showed impaired movements and respiration, as well as diarrhea, blood-colored encrusted snouts and eyelid edges, reduced spontaneity, retracted flanks, ruffled fur, and a long-legged, staggering gait. In females, the following symptoms of toxicity also were observed: salivation, splayed attitude of the legs, partially closed eyelids, bloody nasal discharge, prostrate and lateral attitude, uncoordinated gait, forward movement in creeping position, gasping for breath, jerky respiration and tonic cramps. Necropsy of animals that had died revealed discoloring of the liver and spleen, as well as blood in the gastrointestinal tract. Eleven days after treatment, the surviving animals were free of symptoms. Animals sacrificed following termination of the experiment showed no gross changes. Body weight gain among female animals was reduced during the first week of the experiment.

#### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

2D

Remarks:

Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory.

### **References**

Hoechst. 1988. Genamin CC 100 D. Prüfung der akuten oralen Toxizität an der Wistar-Ratte (Unveröffentlichte untersuchung. Bericht Nr. 88.0414). Hoechst AG, Pharma Forschung Toxikologie und Pathologie, Frankfurt/Main, 24S. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

### **Other available reports**

#### **Other**

Last changed:

June 5, 2002

Order number for sorting:

79a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Coconut Primary Amine – Armeen CD  
(CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 99%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1979  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Distilled water  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (190 to 270 g) were administered a 40% w/v aqueous solution of the test substance as a single oral dose at one of four levels (1.80, 2.56, 3.62 or 5.12 g/kg body weight). Additionally, five rats of each sex were treated with the test vehicle (distilled water) at a level equal in volume (12.8 mL/kg) to the highest dose level of the test substance solution administered. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for overt signs of toxicity at ¼, ½, 1, 2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at study initiation and termination (Day 14). Necropsy was performed on all animals to assess any treatment-related gross pathological changes.

#### Results

Value: LD<sub>50</sub> = 2.04 g/kg  
(Male and female combined): 95% confidence limits = 1.51 – 2.76 g/kg  
Number of deaths: 1.80 g/kg dose level = 0/5 males, 0/5 females;  
2.56 g/kg dose level = 1/5 males, 1/5 females;  
3.62 g/kg dose level = 1/5 males, 4/5 females;  
5.12 g/kg dose level = 5/5 males, 4/5 females

Remarks: Mortality in all treatment groups occurred within the first 6 days of the observation period, with one additional death of a male animal from the 1.80 g/kg treatment group on Day 8.

Animals in the 3.62 and 5.12 g/kg treatment groups appeared lethargic within 15 minutes of treatment and throughout Day 1. Clinical observations through the first week of observation included lethargy, chromodacryorrhea, epistaxis with closed eyes and emaciation. All animals in the 2.56 g/kg treatment group appeared subdued and lethargic on Day 1 beginning 1 hour after treatment. Additional clinical signs reported on Day 2 were chromodacryorrhea, and epistaxis with half closed eyes by Day 5 for all animals in this group. One animal in the 1.80 g/kg treatment group appeared lethargic 1 hour after treatment. Lethargy was observed in all animals in the group at Day 2, with epistaxis in two animals at Day 3 and recovery of all animals in group by Day 4. All control animals appeared normal through the observation period.

The one surviving animal in the 5.12 g/kg treatment group and 2 males and 1 female in the 2.56 g/kg treatment group lost weight by the end of the observation period.

The majority of animals necropsied revealed no abnormalities. Abnormalities detected included gaseous distended stomach with fluid filled gastrointestinal tract, congestion of the lungs, intestinal and renal adhesions, and hard and discolored spleen.

The acute oral LD<sub>50</sub> of the test substance for male and female animals combined, calculated by Finney's Probit Methods (1964), was 2.04 g/kg with 95% confidence limits of 1.51 to 2.76 g/kg.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study

## References

Jones, J.R. 1979. Acute Oral LD<sub>50</sub> in the Rat – ECM BTS 278; Test Article: E8286. Unpublished report (No. 1691-110/213), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

## Other available reports

### Other

Last changed:

September 24, 2003

Order number for sorting:

321

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Coconut Primary Amine – Armeen CD  
(CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 99%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1979  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Distilled water  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (190 to 270 g) were administered a 20% w/v aqueous solution of the test substance as a single oral dose at 6.0 g/kg body weight. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for overt signs of toxicity at ¼, ½, 1, 2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights of surviving animals were measured at study initiation and termination (Day 14). Necropsy was performed on all animals to assess any treatment-related gross pathological changes.

#### Results

Value: LD<sub>50</sub> > 6.0 g/kg  
(Male and female combined)  
Number of deaths: 0/5 males; 0/5 females  
Remarks: No mortality was observed through observation period. All animals appeared normal throughout the observation period. Two females showed very small increases in body weight, while weight gain in the remaining animals was normal. Necropsy of surviving animals at the end of the observation period revealed no macroscopic abnormalities.

The acute oral LD<sub>50</sub> of the test substance for male and female animals combined was greater than 6.0 g/kg.

### **Conclusions**

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch): 1B  
Remarks: Reliable without restriction; comparable to guideline  
study.

### **References**

Jones, J.R. 1979. Acute Oral LD<sub>50</sub> in the Rat – ECM  
BTS 278; Test Article: E8296. Unpublished report  
(No. 1703-110/211), for Procter and Gamble Ltd.,  
Newcastle upon Tyne, England; from Hazleton  
Laboratories Europe Ltd., Harrogate, England.

### **Other available reports**

### **Other**

Last changed: September 24, 2003  
Order number for sorting: 322  
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DMMCD (CAS RN 61788-93-0; Amines, coco alkyldimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1984  
Species/Strain: HC/CFY Sprague-Dawley rat  
Sex: Male and female  
No. of animals per sex per dose: Described below  
Vehicle: None  
Route of administration: Oral gavage  
Remarks: The test substance was administered to 4 – 6 week old male and female rats (83 – 128 g) at dose levels of 1.0 (one male and one female), 1.26 (two males and two females), 1.6 (4 males and 4 females), 2.0 (one male and one female) and 2.5 g/kg (one male and one female). First, one male and one female rat were administered the estimated LD<sub>50</sub>. All subsequent dose levels were determined considering each sex individually. If an animal died or was considered moribund the next animal of that sex was dosed at a lower level. If the animal did not die the next animal was dosed at a higher level. Dosing was continued in this manner until a total of six animals per sex had been dosed, after reversal of the initial outcome. The next dose level was not determined until at least the day after the previous dose had been given. The test substance was administered undiluted. Animals were acclimated to the laboratory for at least five days, and were fasted prior to dosing and for approximately four hours after dosing. The animal room was temperature and humidity controlled. Animals were observed soon after dosing and at frequent intervals on the day of dosing and at least twice daily thereafter for a total of eight days. Body weights were measured for each animal on the day of dosing, on Day 8 or at the time of death. A gross necropsy was performed on each animal at the end of the eight-day observation period, or when an animal was found dead.

## Results

Value:	Male LD <sub>50</sub> = 1.5 g/kg (95% confidence limits = 1.1 to 1.9 g/kg) Female LD <sub>50</sub> = 1.3 g/kg (95% confidence limits = 1.0 to 1.7 g/kg)
Number of deaths:	2.5 g/kg = 1/1 male, 1/1 female 2.0 g/kg = 1/1 male, 1/1 female 1.6 g/kg = 3/4 males, 4/4 females 1.26 g/kg = 0/2 males, 0/2 females 1.0 g/kg = 0/1 male, 0/1 female
Remarks:	Mortality was observed in rats treated at 1.6 g/kg and above within one and 3 days of dosing. Animals that survived the study gained weight during the study. Clinical signs observed shortly after dosing in all treated rats included piloerection, abnormal body carriage (hunched posture), abnormal gait (waddling), pallor of the extremities, lethargy and increased salivation. In addition, rats treated at 1.0, 1.6, 2.0 and 2.5 g/kg experienced decreased respiratory rate and ptosis. Diarrhea was observed in rats treated at 1.6 and 2.0 g/kg. Recovery was complete by Day 8 in those animals that survived the study. There were no gross necropsy findings noted in animals that survived the observation period. Gross necropsy findings in animals that died during the observation period included congestion or hemorrhage of the lungs and pallor of the liver, kidneys and spleen. Congestion of the blood vessels of the stomach was observed in two animals at 1.6 g/kg. Body weight loss was observed in all rats that died.

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	1B
Remarks:	Reliable without restriction; comparable to guideline study.

## References

Kynoch, S. R. and D. O. Chanter. 1984. Acute Oral Toxicity to Rats of Armeen DMMCD. Report No. 84015D. Huntingdon Research Centre Plc.

## **Other available reports**

### **Other**

Last changed:	July 25, 2002
Order number for sorting:	129
Remarks:	

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Genamin CS 302 D (CAS RN 61788-93-0; Amines, coco alkyldimethyl)  
Purity: 100%  
Remarks:

#### Method

Method/Guideline followed: ES Guideline B.1. Acute Oral Toxicity 84/449/EWG; OECD Guideline for testing of chemicals, 401 Acute Oral Toxicity; Guideline 83/467/EWG  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1989  
Species/Strain: Rat/Wistar [Hoe: WISKf(SPF71)]  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Sesame Oil (Oleum sesame Ph.Eur.III, Fa. Mainland Pharmzeutische Fabrik GmbH, Ffm.)  
Route of administration: Oral gavage  
Remarks: Animals were kept in temperature and humidity controlled rooms in groups of 5 rats per cage. Temperature range was  $22 \pm 3^{\circ}\text{C}$ , relative humidity was  $50 \pm 20\%$ , and animals received 12 hours of light per day. Food was removed about 16 hours before and approximately 3 to 4 hours after application. The test substance was dissolved in sesame oil in the appropriate concentrations and homogenized using a magnetic stirrer. The prepared solution was administered via oral gavage. It was administered to five female animals per group in the following concentrations: 800, 1000, 1250 and 1600 mg/l. It also was administered to five male and five female animals at 2000 mg/l. Observation time was 14 days after dosing. Symptoms and death were recorded when they occurred. Body weight was determined weekly. Animals that died during the test were dissected and inspected macroscopically. Surviving animals were terminated after the observation time by carbon dioxide, dissected and examined for macroscopically visible changes.

**Results**Value: LD<sub>50</sub> > 1000 and < 1250 mg/kg

Number of deaths

Dose (mg/kg body weight)	Mortality			
	Male animals		Female animals	
	absolute	relative (%)	absolute	relative (%)
800	--	--	0/5	0
1000	--	--	0/5	0
1250	--	--	4/5	80
1600	--	--	5/5	100
2000	4/5	80	5/5	100

Remarks:

The following clinical symptoms were observed in the male and female animals after the application of Genamin CS 202 D: crouching, flanks drawn in, decreased spontaneous activity, ruffled fur, uneven breathing, long-legged and staggering gait, narrowed eyelids, blood-colored crusted lid rims and snouts as well as diarrhea. The symptoms were reversible in the male animals five days post application and in the female animals nine days post application.

The one surviving female rat lost weight by Day 7 but surpassed the initial body weight by Day 14. All other surviving animals in the 1000 and 800 mg/kg dose groups had normal body weight gain throughout the post dosing observation period. The macroscopic examination of the male and female rats that died revealed the following: dark-colored liver, reddened stomach mucous membrane, blood in the stomach and yellow liquid in the small intestine. Animals terminated after the end of the study displayed no unusual macroscopic changes.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

## References

Hofmann, Th. and R. Jung. 1989. Genamin CS 302 D: Study of the Acute Oral Toxicity in the Wistar Rat. Study Number 89.0588. Pharma Forschung Toxikologie und Pathologie, Hoechst Aktiengesellschaft, Frankfurt, Germany.

## Other available reports

### Other

Last changed:

June 7, 2002

Order number for sorting:

228a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DMCD (CAS RN 61788-93-0;  
Amines, coco alkyldimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not Stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: Albino rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 10% Aqueous Gum Arabic or none  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 1.0, 1.5, 1.75, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 1.0, 1.5, 1.75 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats.

#### Results

Value: LD<sub>50</sub> = 1.58 ml/kg  
(95% confidence limits = 1.31 to 1.90 ml/kg)  
Number of deaths: 1.0 ml/kg = 1/10  
1.5 ml/kg = 3/10  
1.75 ml/kg = 7/10  
2.0, 4.0 and 8.0 ml/kg = 10/10  
Remarks: LD<sub>0.01</sub> = 0.52 ml/kg  
LD<sub>99.99</sub> = 4.8 ml/kg (As stated in report; appears inaccurate.)  
Generalized listless behavior was observed in all dose groups shortly after test substance administration.  
Diarrhea was observed in rats in degrees of severity

more or less commensurate with the dose received. Ptosis was observed among the animals in all dose groups. Rats dosed at 1.0 ml/kg and higher that died became comatose within four to ten hours post dose and died within the next 12 hours. Surviving rats showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:

Order number for sorting:

Remarks:

June 13, 2002

228f

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Genamin CS 301 (CAS RN 61788-62-3; Amines, dicoco alkylmethyl)  
Purity: Not stated  
Remarks: The report identifies the product name as “Genamin CS 301”, which corresponds to CAS RN 61788-62-3; however, the chemical name is listed as “methyldistearylamin”. Based on all available information, the test substance evaluated in this study was Genamin CS 301 (CAS RN 61788-62-3) and the chemical name of “methyldistearylamin” was included in the report in error.

#### Method

Method/Guideline followed: EG-Guideline B.1. “Acute Toxicity Oral” of the 84/449/EWG; OECD-Guideline 401 “Acute Oral Toxicity”; Guideline 83/467/EWG  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1990  
Species/Strain: Rat/Wistar [WISKf (SPF71)]  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Sesame oil (Oleum Sesami Ph. Eur. III, Fa. Mainland Pharmaceutical Factory Ltd.  
Route of administration: Oral gavage  
Remarks: The test substance was administered to 5 male and 5 female rats as a 20% (w/v) mixture in sesame oil at a constant volume of 10 ml/kg to yield a dose level of 2000 mg/kg. All animals were observed for 14 days following dosing at which time they were killed by CO<sub>2</sub> inhalation and a necropsy was performed.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg body weight  
Number of deaths: 0/10  
Remarks: No mortality occurred. The animals showed impaired breathing and motion, as well as blood-colored, crusty snouts. The symptoms were reversible by Day 4. The bodyweight gain was not influenced by test substance administration. The necropsy showed no macroscopically visible changes.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability:

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Nölken, G. and R. Jung. 1990. Short Report:  
Genamin CS 301 – Study of the Acute Oral Toxicity  
to the Wistar Rat. Report Number 90.0108. Pharma  
Forschung Toxikologie und Pathologie, Hoechst  
Aktiengesellschaft, Frankfurt, Germany.

**Other available reports**

**Other**

Last changed:

July 25, 2002

Order number for sorting:

126a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Cocodiethanolamide (CAS RN 61791-31-9;  
Ethanol, 2,2'imino bis-,N-coco alkyl derivs.)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Procedure by Hagen, E. D. 1959. Acute Toxicity;  
Appraisal of the Safety of Chemicals in Foods, Drugs  
and Cosmetics, p. 17-25.  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1978  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: Not stated  
Route of administration: Oral gavage  
Remarks: Groups of six rats (three males and three females) were  
administered a single dose of the test substance at  
concentrations of 5.0, 6.3, 7.01, 7.94 and 10.0 g/kg. At  
study initiation males and females weighed 188-300 g  
and 188-244 g, respectively. Rats were acclimated to  
the laboratory for a minimum of seven days. Food and  
water were available *ad libitum*, except overnight prior  
to test substance administration. Rats were observed  
for signs of toxicity one, three, six and 24 hours post  
dose and subsequently daily thereafter for 13 days.  
Individual body weights were recorded at study  
initiation and termination. A gross necropsy was  
performed on all rats.

#### Results

Value: LD<sub>50</sub> > 5 g/kg  
Number of deaths: 5.0 g/kg = 1/6  
6.3 g/kg = 3/6  
7.01 g/kg = 3/6  
7.94 g/kg = 4/6  
10.0 g/kg = 6/6  
Remarks: Slight, moderate and/or severe depression were  
observed in rats in all dose groups during the 14-day  
observation period. These symptoms were observed  
within six hours in rats treated with 5.0 and 7.94 g/kg  
of the test substance. Rats treated with 6.3, 7.01 and  
10.0 g/kg of the test substance exhibited these

symptoms within one hour post dose. Surviving rats in the 5.0, 6.3, 7.01 and 7.94 g/kg dose groups recovered from these symptoms within four, three, three and seven days post-dose, respectively, and gained weight during the study. Deaths occurred between days 2 and 7 post-dose. Necropsy findings for seven of the rats that died prior to scheduled sacrifice in dose groups 6.3 g/kg and above included lobes of lung partially consolidated, fibrous tissue encasing heart and lungs, severely reddened gastric mucosa, and/or pyloric and intestinal mucosa reddened. One of the surviving female rats in the 5.0 g/kg dose group had all lobes of the right lung partially consolidated. No necropsy findings were noted for any other rats that survived until study termination.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

2C

Reliable with restrictions; comparable to guideline study with acceptable restrictions.

**References**

Consumer Product Testing. 1992. Initial Submission: Letter from Rhone-Poulenc Inc. to US EPA regarding toxicity tests of cocodiethanolamide with attachments and cover letter dated 101692. EPA Doc. No. 88-920009652, Microfiche No. OTS0571309.

**Other**

Last changed:

June 12, 2002

Order number for sorting:

109

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Lilamin AC-HBG/P (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1984  
Species/Strain: Rat/HC/CFY remote Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 1% methyl cellulose  
Route of administration: Oral gavage  
Remarks: A group of ten rats (five males and five females) were administered a single gavage dose of the test substance in 1% methyl cellulose at a dose of 5000 mg/kg (limit test) and a dose volume of 10 ml/kg. At study initiation, the animals were 4 to 6 weeks of age and weighed 100 to 128 g. After dosing, the animals were observed for clinical signs several times on day 1 and then once daily thereafter for 14 days. Bodyweights were obtained in day 1, 8, and 15. A necropsy was performed on all animals.

#### Results

Value: LD<sub>50</sub> >5000 mg/kg  
Number of deaths: None  
Remarks: The animals showed diarrhea, piloerection, hunched posture, abnormal gait and pallor of extremities. Complete recovery from these clinical signs was observed by day 5. Body weights were initially reduced but body weight gain was normal by the end of the study (day 15). No treatment-related effects were observed at necropsy.

#### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restrictions; guideline study.

**References**

Kynoch, S.R. 1984. Acute Oral Toxicity to Rats of  
Lilamin AC-HBG/P. Report No. 84592D/KND 1/AC.  
Huntingdon Research Centre.

**Other available reports**

**Other**

Last changed:

September 17, 2002

Order number for sorting:

106d

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

**Identity:** Stearyl Amine (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl)  
**Purity:** Not stated  
**Remarks:** [Stearyl amine is CAS RN 124-30-1 but the European ICCA IUCLID includes this study under CAS RN 61788-45-2]

#### Method

**Method/guideline followed:** Not stated  
**Type:** LD<sub>50</sub>  
**GLP:** No  
**Year:** 1979  
**Species/Strain:** Rat/Sprague-Dawley  
**Sex:** Male  
**No. of animals per sex per dose:** 6  
**Vehicle:** Water  
**Route of administration:** Oral gavage, single dose, 20 ml/kg  
**Remarks:** Groups of six male rats were administered a single gavage dose of the test substance in water at concentrations of 3000, 3900, 5070, 6590 or 8560 mg/kg at a dose volume of 20 ml/kg. At study initiation, the animals weighed 127 to 150 g. The animals were observed for clinical signs for 14 days following dosing. Each animal was subjected to a necropsy at the end of the 14-day postdosing observation period. The LD<sub>50</sub> was calculated using the method of Thompson Moving Average Interpolation.

#### Results

**Value:** LD<sub>50</sub> = 4800 mg/kg  
**Number of deaths:** 0/6 (3000 mg/kg)  
1/6 (3900 mg/kg)  
4/6 (5070 mg/kg)  
5/6 (6590 mg/kg)  
6/6 (8560 mg/kg)  
**Remarks:** All deaths occurred within one to three days following dosing. Clinical observations included: piloerection and hyperkinesia in all dose groups; epistaxis in the 3900 mg/kg group and higher; diarrhea and soiled coat in the 5070 mg/kg group and higher. All animals recovered by day 2 (2300 mg/kg), day 3 (3900 mg/kg) or day 11 (5070 and 6590 mg/kg). Necropsy findings were normal at 3000 mg/kg; gut contents fluid and red stain in gut at 3900 mg/kg; TS in stomach, gut contents

fluid, red stain in gut, lungs patchy, kidneys pale colored at >5070 mg/kg.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study.

**References**

Cuthbert, J.A. 1979. Safety Tests on Commercial Stearyl Amine. Report No. 1375. Berol Kemi AB, Inveresk Research International.

**Other available reports**

**Other**

Last changed:

September 17, 2002

Order number for sorting:

106e

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Farmin TH (CAS RN 61788-45-2; Amines, hydrogenated tallow alkyl)  
Purity: >98%  
Remarks:

#### Method

Method/guideline followed: 92/69/EEC, Annex, Part B, method B.1. bis – fixed dose method  
Type: Acute oral toxicity  
GLP: Yes  
Year: 1995  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 5% Tween 80 in bidistilled water  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five male and five female) were administered a single gavage dose of the test substance in 5% Tween 80 at doses of 500 or 2000 mg/kg in a dose volume of 10 ml/kg. The animals were four weeks of age at arrival and weighed 90-100g (500 mg/kg) and 141 to 169 g (2000 mg/kg) at study initiation. All animals were observed for clinical signs at least twice daily for 14 days postdosing. Body weights were obtained on days 1, 2, 3, 7, 14 and at the time of necropsy. All animals were subjected to a necropsy at the end of the 14-day observation period. The body weight range of the animals at the beginning of the experiment was too large (90-159 g; OECD requires  $\pm 20\%$  from mean body weight); however, the body weight range within treatment groups was acceptable.

#### Results

Value:  $LD_0 = 500$  mg/kg  
 $LD_{50} >2000$  mg/kg  
Number of deaths: 0/10 at 500 mg/kg and 1/10 at 2000 mg/kg.  
Remarks: The following clinical signs were observed in the animals dosed at 2000 mg/kg: hunched back, soft feces, rattling in throat, salivation during the first two hours; some females also showed decreased motor activity and muscle tone, ataxia, dispnea, swollen abdomen and traces of blood in the snout. At 500 mg/kg the following clinical signs were observed:

hunched back, soft feces rattling in the throat, piloerection, ataxia, decreased motor activity and muscle tone, pallor and traces of blood in the shout. Weight gain was normal at 500 mg/kg but two females lost weight at 2000 mg/kg in second week of treatment. Necropsy findings were normal.

### Conclusions

Remarks:

According to the results obtained and the guidelines set for by the test method, the test substance is free of any significant toxicity (Author or report). The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1A

Reliable without restrictions; guideline study.

### References

Tortajada, A. 1995. Acute Oral Toxicity Test in Rats, Fixed Dose Method, Farmin TH. Report No. CD-95/4308T. KAO Corporation S.A., Centro de Investigacion y Desarrollo aplicado.

### Other available reports

#### Other

Last changed:

Order number for sorting:

Remarks:

September 17, 2002

106f

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Hydrogenated tallow alkyl dimethylamine  
[CAS RN 61788-95-2; Amines, (hydrogenated tallow  
alkyl)dimethyl]

Purity: Not stated

Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 401, Acute Oral Toxicity

Type: LD<sub>50</sub>

GLP: Yes

Year: 1989

Species/Strain: Rat/Sprague-Dawley

Sex: Male and female

No. of animals per sex per dose: 5

Vehicle: Arachis oil B.P.

Route of administration: Oral gavage

Remarks: Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 130-143 g and 122-140 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg

Number of deaths: 2/10

Remarks: One male and one female rat died prior to scheduled sacrifice on days 3 and 1, respectively. Hunched posture, piloerection and red/brown staining around the snout, and occasional or isolated signs of lethargy, ptosis, emaciation and increased salivation were observed in rats during the first six days of the 14-day observation period. All surviving rats appeared normal five to seven days post dose. A loss in body weight or reduced body weight gain during the first week of the observation period was commonly noted. All surviving rats showed body weight gain over the second week of the observation period. Necropsy findings in rats that died prior to scheduled sacrifice

included abnormally red lungs, dark liver and kidneys, and hemorrhage of the gastric mucosa and small intestines. No abnormalities were noted at necropsy of the rats that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed:

June 10, 2002

Order number for sorting:

107

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen 2HT (CAS RN 61789-79-5; Amines, bis (hydrogenated tallow alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Regulations for the Enforcement of the Federal Hazardous Substances Act, 1964  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1971  
Species/Strain: Albino rat  
Sex: Male  
No. of animals per sex per dose: 5  
Vehicle: Corn oil  
Route of administration: Oral gavage  
Remarks: The test substance was administered to male rats (222 to 252 g) as a 25% w/v suspension in corn oil at dose levels of 0.464, 1.0, 2.15, 4.64 and 10.0 g/kg body weight. Since the 10.0 g/kg dose level would have exceeded the capacity of the rat's stomach, this level was administered as a split-dose, i.e. one-half the dose was administered in the morning and the second half within 4 or 5 hours. Animals were fasted for approximately 18 hours prior to dosing. Food was available *ad libitum* following dosing. Animals were observed for gross signs of systemic toxicity and mortality at frequent intervals on the day of dosing and at least once daily thereafter for a total of 14 days. Body weights were measured for each animal on the day of dosing and at the end of the 14-day observation period. A gross necropsy was performed on each animal at the end of the 14-day observation period.

#### Results

Value: LD<sub>50</sub> > 10.0 g/kg body weight  
Number of deaths: 0/5 males in all dose groups  
Remarks: All animals survived the study and gained weight during the study. Clinical signs observed in two rats treated at the 2.15 g/kg dose level included slight diarrhea stains, seen on the first and/or second day post-dose. Signs of toxicity noted at the 10.0 g/kg dose level included depression, depressed righting and placement reflexes, ataxia, rapid or shallow respiration,

excessive salivation, mucoid diarrhea and oily, unkempt hair coats. These signs were observed several hours following dosage or on the first day post-dose. All animals appeared normal from the fifth or sixth day post-dose through study termination. There were no gross necropsy findings noted in any animal.

### **Conclusions**

Remarks:

Based on these results, Armeen 2HT is classified as non-toxic by ingestion as these terms are defined in the above-cited regulations. (Author of study report)  
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):  
Remarks:

2A  
Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

### **References**

Daniels, C. L. 1971. Acute Oral Administration of Armeen 2HT to Rats. Report No. V-833. Hill Top Research, Inc., USA.

### **Other available reports**

#### **Other**

Last changed:  
Order number for sorting:  
Remarks:

July 25, 2002  
131

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen M2HT (CAS RN 61788-63-4;  
dihydrogenated tallow methylamine)  
Purity: 95%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1983  
Species/Strain: Rat/HC/CFY (Sprague-Dawley)  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 1% Methyl cellulose  
Route of administration: Oral gavage  
Remarks: Ten rats (five males and five females) were administered a single dose of the test substance via a syringe and plastic catheter at a concentration of 5.0 g/kg. The test substance was prepared as a 50% w/v suspension in the vehicle and administered at a volume not exceeding 10.0 ml/kg. Rats were in the weight range of 90 - 115 g and were approximately four to six weeks of age. All rats were acclimated to the laboratory for a minimum period of five days prior to the start of the study. Food was available *ad libitum*, except for overnight prior to administration and approximately four hours post dose. Water was available *ad libitum*. Temperature and humidity were monitored during the study. Rats were observed for signs of toxicity soon after dosing; then at frequent intervals on day 1 (day of dosing). Subsequent observations were made twice daily. Rats were observed for 14 days following test substance administration. Individual body weights were recorded on days 1, 8 and 15. A necropsy was performed on all rats on study day 15.

#### Results

Value: LD<sub>50</sub> > 5.0 g/kg  
Number of deaths: 0/10

Remarks: Piloerection and hunched posture were observed shortly after dosing in all treated rats. These signs were accompanied by pallor of the extremities and abnormal gait in three male and three female rats. All rats recovered from these symptoms by day 4 and gained weight over the observation period. No findings were noted at necropsy.

**Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 1A  
Remarks: Reliable without restriction; guideline study.

**References**

Kynoch, S. R. 1984. Acute Oral Toxicity to Rats of Armeen M2HT. Report No. 8464D/AKZ 162/AC. Huntingdon Research Centre Plc., Huntingdon, Cambridgeshire, U.K.

**Other**

Last changed: June 10, 2002  
Order number for sorting: 102  
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: B0390-01: Adogen 343 (CAS RN 61788-63-4;  
Dihydrogenated tallow methylamine)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1978  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Mineral oil  
Route of administration: Oral gavage  
Remarks: The test substance was administered to five rats of each sex (206 to 251 g) as a single oral 20 mL/kg dose of a 75% w/v suspension of the test substance in mineral oil. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* prior to and immediately following dosing. Animals were observed for mortality and pharmacotoxic signs at ½2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at initiation and again on Days 7 and 14. Necropsy was performed on all surviving animals and abnormalities were recorded.

#### Results

Value: Estimated oral LD<sub>50</sub> > 15.0 g/kg of body weight (male and female combined)  
Number of deaths: 0/5 males; 0/5 females  
Remarks: All animals survived the study and gained weight during the 14-day observation period, although female body weight gain generally stabilized after Day 7. Clinical signs observed during the first 7 days post-dosing included diarrhea, hypoactivity, oily hair and urine-stained anal-genital area. All animals appeared normal after Day 7. Necropsy of all animals showed no visible lesions. The oral LD<sub>50</sub> was 15.0 g/kg based upon a 75% w/v suspension of the test substance in mineral oil.

### **Conclusions**

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch): 2A  
Remarks: Reliable with restrictions; acceptable, well-  
documented study report which meets basic scientific  
principles.

### **References**

Thompson, G.W. 1982. Acute Oral Toxicity (LD<sub>50</sub> in  
Rats) of B0390-1 and B0020-01. Unpublished report  
(No. 943445 & 943446), for The Proctor & Gamble  
Company, Cincinnati, OH, USA, from Hazleton  
Raltech, Inc., Madison, WI, USA.

### **Other available reports**

#### **Other**

Last changed: September 24, 2003  
Order number for sorting: 313  
Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Tallow alkyl amine (CAS RN 61790-33-8)  
Purity: >99%  
Remarks:

#### Method

Method/guideline followed: OECD Guideline 401 “Acute Oral Toxicity”  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1987  
Species/Strain: Rat/Wistar  
Sex: Male and female  
No. of animals per sex per dose: Five  
Vehicle: Sesame oil  
Route of administration: Oral gavage  
Remarks: Male rats (7 weeks old, 167 to 189 g) and female rats (8 weeks old, 171 to 181 g) received a single oral dose of 2000 mg/kg (males and females) or 2500 mg/kg (males only). Animals were observed for 14 days postdosing.

#### Results

Value: LD<sub>50</sub> = >2500 mg/kg (male)  
= >2000 mg/kg (female)  
Number of deaths: 1 male per dose group. No females died.  
Remarks: One in five males per group died within six days of treatment. The following clinical signs were observed following dosing: hunched posture, flanks drawn in, pilo-erection, irregular breathing, abnormal gait, diarrhea, crusted eyelids and snout (both males and females); decreased spontaneous activity, uncontrolled movements, crawling-like movements, emaciation, drowsiness, gasping (males). All symptoms disappeared by day 11 or 12. Decreased body weight gain was observed the first week postdosing. Necropsy of animals that had died revealed stained liver, pale-colored lungs and gastro-intestinal tract swollen with gasses. Animals sacrificed following termination of the experiment showed no gross changes.

### Conclusions

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

2D

Remarks:

Reliable with restrictions; data from summary  
document; acceptable because data consistent with  
other data in subcategory.

### References

1988. Genamin TA 100 D. Prüfung der akuten oralen  
Toxizität an der Wistar-Ratte [Genamin TA 100 D  
Acute oral toxicity study in the Wistar rat]  
(Unveröffentlichte untersuchung. Bericht Nr.  
88.0358). Hoechst AG, Hoechst Pharma Forschung  
Toxikologie und Pathologie, Frankfurt/Main, 18 S.

### Other available reports

#### Other

Last changed:

June 5, 2002

Order number for sorting:

1 and 218a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen T (CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1983  
Species/Strain: Rat/WISW – SPF TNO  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Not stated  
Route of administration: Oral gavage  
Remarks: Groups of 5 male and 5 female rats were dosed with the test substance by oral gavage at the following concentrations: 1.5, 2.5, 3.5, and 5.0 ml/kg. Animals had access to food *ad libitum* except for a period of 16 hours prior to dosing. Food was returned approximately 4 hour following dosing. Animals were observed for signs of toxicity at approximately 30 minutes; 1, 2, 3, 6, 24 and 48 hours; and Days 4, 6, 7 and 14 following dosing. Body weights were obtained on Day 0 and 14 for all surviving animals. The LD<sub>50</sub> value was determined by probit analysis (Finney, D.Y. 1971. Probit Analysis, 3. Auflage, Cambridge).

#### Results

Value: Males: LD<sub>50</sub> = 2.23 ml/kg bodyweight  
Females: LD<sub>50</sub> = 2.61 ml/kg bodyweight  
Combined LD<sub>50</sub> = 2.40 ml/kg bodyweight  
Number of deaths: Mortality at 14 days following dosing:

Dose (ml/kg)	Males	Females
1.5	1/5	1/5
2.5	3/5	2/5
13.5	4/5	3/5
5.0	5/5	5/5

Remarks: Clinical observations included: incoordination, cyanosis, excessive salivation, piloerection, reduced respiration, and hypothermia. The surviving animals

appeared normal at the end of the 14-day post dosing observation period. Surviving animals showed a normal body weight gain.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

2C

Remarks:

Reliable with restrictions; comparable to guideline study with acceptable restrictions.

### **References**

Sterner, W. and G. Chibanguza. 1983. Akute Orale Toxizität an Ratten mit Armeen T. [Acute oral toxicity study in the rat with Armeen T] Unpublished report (1-4-298-83). IBR Forschungs GmbH.

### **Other available reports**

#### **Other**

Last changed:

July 25, 2002

Order number for sorting:

132

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Tallow alkyl trimethylene diamine  
(CAS RN 61791-55-7; Amines, N-tallow  
alkyltrimethylenedi-)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1989  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Arachis oil B.P.  
Route of administration: Oral gavage  
Remarks: Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 5000 mg/kg. At study initiation males and females weighed 124-152 g and 120-140 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study.

#### Results

Value: LD<sub>50</sub> > 5000 mg/kg  
Number of deaths: 2/10  
Remarks: One male and one female rat died prior to scheduled sacrifice on days 5 and 2, respectively. Hunched posture and piloerection were noted one to ten days after treatment. Red/brown staining around the snout was also commonly noted three to five days after treatment. An isolated incident of pallor of the extremities was noted in one male on day five. Surviving animals appeared normal eight to eleven days after treatment. Body weight loss was commonly noted at the end of the first week. All surviving animals showed expected weight gain during the second week post-dosing. The necropsy of the dead animals revealed abnormally red lungs, dark or patchy

pallor of liver and hemorrhage of the gastric mucosa.  
No abnormalities were noted at necropsy of the rats  
that survived the 14-day, post-dose observation period.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and  
Derivatives. Acute Oral Toxicity Studies in the Rat.  
Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed:

June 10, 2002

Order number for sorting:

283a

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Ethomeen T/12 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: 95%  
Remarks:

#### Method

Method/guideline followed: Acute Oral Toxicity, Up and Down Method  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1984  
Species/Strain: Rat/HC/CFY (Sprague-Dawley)  
Sex: Male and female  
No. of animals per sex per dose: See Remarks below  
Vehicle: 1% Methyl cellulose  
Route of administration: Oral gavage  
Remarks: One male and one female were administered a single dose of the test substance via a syringe and plastic catheter at the estimated LD<sub>50</sub>. All subsequent decisions on dose levels were taken considering each sex individually. If an animal died or was considered moribund the next animal of that sex was dosed at a lower level. If the animal did not die the next animal was dosed at a higher level. The decision for the next dose level was not taken until at least the day after the previous dose had been given. Following are the dose levels administered for each sex:  
Males: 1.0, 1.26, 1.6, 2.0, 2.5, 4.0 and 5.0 g/kg  
Females: 0.8, 1.0, 1.26, 1.6, 2.0, 2.5, 4.0 and 5.0 g/kg  
The test substance was prepared as various w/v suspensions in the vehicle and administered at a volume not exceeding 10.0 ml/kg. Rats were in the weight range of 81-132 g and were approximately four to six weeks of age. All rats were acclimated to the laboratory for a minimum period of five days prior to the start of the study. Food was available *ad libitum*, except for overnight prior to administration and approximately four hours post dose. Water was available *ad libitum*. Temperature and humidity were monitored during the study. Rats were observed for signs of toxicity soon after dosing; then at frequent intervals on day 1 (day of dosing). Subsequent observations were made twice daily. Rats were observed for seven days following test substance administration. Individual body weights were recorded

on days 1, 8 and at death. A necropsy was performed on all rats. The LD<sub>50</sub> values were estimated by probit analysis, using a slope estimated from background data. Approximate confidence intervals (95% level) were derived by adding and subtracting 1.96 times the standard error of the (log.) LD<sub>50</sub> estimate.

## Results

Value:	Male LD <sub>50</sub> = 1.5 g/kg (95% confidence interval = 1.1 to 2.0 g/kg) Female LD <sub>50</sub> = 1.2 g/kg (95% confidence interval = 0.9 to 1.6 g/kg)
Number of deaths:	Males: 1.0 g/kg = 0/2 1.26 g/kg = 0/3 1.6 g/kg = 2/2 2.0, 2.5, 4.0 and 5.0 g/kg = 1/1 Females: 0.8 g/kg = 0/1 1.0 g/kg = 0/3 1.26 g/kg = 1/1 1.6 and 2.0 g/kg = 2/2 2.5, 4.0 and 5.0 g/kg = 1/1
Remarks:	Piloerection and hunched posture were observed shortly after dosing in all treated animals. These signs were accompanied by pallor of the extremities, lethargy and abnormal gait in the majority of rats in all treatment groups. Incidences of ptosis, diarrhea and increase salivation were seen at dose levels of 1.0 g/kg and above. These signs were accompanied by a decreased respiratory rate in rats dosed at 1.26 g/kg and above. Deaths occurred amongst rats treated at 1.26 g/kg and above from within two and four days of dosing. All surviving rats appeared to recover between days 5 and 8, and gained weight over the observation period. Piloerection was still observed in one male rat dosed at 1.26 g/kg and one female rat dosed at 1.0 g/kg on day 8. This finding was not considered to be of toxicological importance and the observation period was not extended. Necropsy findings in the majority of rats that died prior to scheduled sacrifice included hemorrhage or congestion of the lungs. These findings were usually accompanied by pallor of the liver, kidneys and spleen. Congestion of the blood vessels of the stomach was observed in one female rat treated at 1.6 g/kg and congestion of the blood vessels of the intestine in one female rat treated at 5.0 g/kg. All rats that died showed a loss in body weight. No necropsy findings were noted in rats that survived the

observation period.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline  
study.

**References**

Kynoch, S. R. 1984. Acute Oral Toxicity to Rats of  
Ethomeen T/12. Report No. 84119D/AKZ 163/AC-3.  
Huntingdon Research Centre Plc., Huntingdon,  
Cambridgeshire, U.K.

**Other**

Last changed:  
Order number for sorting:  
Remarks:

June 13, 2002  
112

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Amines, tallow alkyl ethoxylates, 2EO  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: OECD Guideline No. 401, Acute Oral Toxicity  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1989  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Arachis oil B.P.  
Route of administration: Oral gavage  
Remarks: Ten rats (five males and five females) were administered a single dose of the test substance in Arachis oil B.P. by oral gavage at a concentration of 2000 mg/kg. At study initiation males and females weighed 131-145 g and 120-142 g, respectively. Rats were observed for signs of toxicity one and four hours post dose and subsequently once daily for 14 days. Individual body weights were recorded on the day of treatment and on days 7 and 14. A gross necropsy was performed on all rats. Temperature and humidity were monitored throughout the study.

#### Results

Value: LD<sub>50</sub> > 2000 mg/kg  
Number of deaths: 0/10  
Remarks: Hunched posture and piloerection were observed in all rats one hour post dose. All rats appeared normal within four hours post dose. All rats showed body weight gain over the 14-day observation period. No necropsy findings were noted in any rat.

#### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Jones, J.R. 1991. Cesio Study: Fatty Amines and Derivatives. Acute Oral Toxicity Studies in the Rat. Safepharm Laboratories Limited, Derby, U.K.

**Other**

Last changed:

June 10, 2002

Order number for sorting:

113

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,  
N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1979  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: None  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (192 to 310 g) were administered the undiluted test substance as a single oral dose at one of four levels: 0.547, 0.765, 0.918, 1.071 g/kg body weight. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for mortality and pharmacotoxic signs at ½2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at initiation and again on Days 7 and 14 for surviving animals. Necropsy was performed on all surviving animals and abnormalities were recorded.

#### Results

Value LD<sub>50</sub> = 0.89 g/kg of body weight  
(Male and female combined): (95% Confidence intervals = 0.78 to 1.01 g/kg)  
Number of deaths  
(Male and females combined): 0.547 g/kg dose level = 0/10  
0.765 g/kg dose level = 4/10  
0.918 g/kg dose level = 5/10  
1.071 g/kg dose level = 8/10  
Remarks: All animals in the lowest treatment group, 0.547 g/kg, appeared normal through the observation period. Four and five of the animals in the 0.765 and 0.918 g/kg treatment groups, respectively, died by Day 4 of the observational period. While most of the surviving animals in the group did not develop visible lesions or other treatment-related signs of toxicity, the stomach mucosa of one female in the 0.765 g/kg group was

noted to have mild, diffuse, 1-mm, white raised areas, for which the etiology was unknown. Three females in the 0.918 g/kg treatment group developed diarrhea prior to death. All but 2 animals in the highest treatment group, 1.071 g/kg, died. Of the 8 animals in this group that died, 4 had external signs of diarrhea, 2 others had blood stains around the nose and mouth and 1 other had dark brown fluid in its stomach. The eighth animal had no visible lesions.

Body weights of all but one (a female in the 0.547 g/kg treatment group) of the surviving animals increased through the observation period. The defined LD<sub>50</sub>, for males and females combined, was calculated to be 0.80 g/kg body weight (95% C.I. = 0.78 to 1.01 g/kg) with a slope in the dose response curve of 2.17.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study

### **References**

Thompson, G.W. 1982. Acute Oral Toxicity (LD<sub>50</sub> in Rats) of B0235-01. Unpublished report (No. 748982), for The Proctor & Gamble Company, Cincinnati, OH, USA, from Raltech Scientific Services, Madison, WI, USA.

### **Other available reports**

#### **Other**

Last changed:

September 24, 2003

Order number for sorting:

314

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Polyethoxylated Tallowamine; Varonic T-220  
(Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.; CAS  
RN 61791-44-4)  
Purity: Not stated  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1979  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: None  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (195 to 275 g) were administered the undiluted test substance as a single oral dose at one of five levels: 160, 400, 1000, 2500 and 6250 mg/kg body weight, or 0.150, 0.374, 0.935, 2.336 and 5.841 mL/kg based on specific gravity, respectively. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for mortality and pharmacotoxic signs at ½, 1, 2-½ and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at initiation and again on Days 7 and 14 for surviving animals. Necropsy was performed on all animals and abnormalities were recorded.

#### Results

Value LD<sub>50</sub> = 0.63 g/kg of body weight  
(Male and female combined): (95% Confidence intervals = 0.45 to 0.89 g/kg)  
Number of deaths: 160 mg/kg dose level = 0/5 males, 0/5 females;  
400 mg/kg dose level = 1/5 males, 1/5 females;  
1000 mg/kg dose level = 3/5 males, 5/5 females;  
2500 mg/kg dose level = 5/5 males, 5/5 females;  
6250 mg/kg dose level = 5/5 males, 5/5 females;  
Remarks: While all animals in the 160 mg/kg treatment group survived through the study, several animals in the group showed mild signs of toxicity (piloerection, ataxia, decreased activity, discharge around the eyes, nose, and mouth, and diarrhea) during the first few

days of the observation period and appeared normal again by Day 4. Pharmacotoxic signs observed in animals in the 400, 1000, 2500 and 6250 mg/kg treatment groups were similar to those observed in the low dose group, but also included stained abdomen and anogenitals, emaciation, excess salivation, red crusty material around the nose, decreased activity and/or subsequent death. Mortality in these groups ranged from 20 to 100%. One male animal in the 400 mg/kg treatment group was reported to have clonic convulsions in the first 1/4 hour of the observation period. The surviving animals in the 1000 mg/kg treatment group exhibited additional signs including red crusty material on face, soft stools, decreased limb tone, prolapsed penis and hypothermia.

Body weights of surviving animals generally increased through the observation period, although weight gain in females was reduced.

Necropsy observations were most pronounced in the stomach and lower g.i. tract showing a dose-related incidence of lesions associated with irritation and fluid accumulation. Other effects included congestion of the lungs and thymus.

Based upon the data obtained, the acute oral (LD50) value (with 95% confidence limits) calculated for males and female combined was 0.63 (0.45 to 0.89) g/kg.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study

### **References**

Dean, W.P. 1979. Acute Oral Toxicity (LD<sub>50</sub>) Study in Rats. Unpublished report (No. 191-490), for The Proctor and Gamble Company, Cincinnati, OH, USA, from International Research and Development Corporation, Mattawan, MI, USA.

## **Other available reports**

### **Other**

Last changed:	September 24, 2003
Order number for sorting:	316
Remarks:	

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine T-220D (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: 96.7%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1980  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: None  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (212 to 317 g) were administered the undiluted test substance as a single oral dose at one of four levels: 0.69, 0.97, 1.17 and 1.36 g/kg body weight. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for mortality and pharmacotoxic signs at ½2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at initiation and again on Days 7 and 14 for surviving animals. Necropsy was performed on all animals and abnormalities were recorded.

#### Results

Value (Male and female combined): LD<sub>50</sub> = 1.15 g/kg of body weight  
(95% confidence limits = 1.04 to 1.26 g/kg)  
Number of deaths: 0.69 g/kg dose level = 0/5 males, 0/5 females;  
0.97 g/kg dose level = 1/5 males, 1/5 females;  
1.17 g/kg dose level = 1/5 males, 4/5 females;  
1.36 g/kg dose level = 5/5 males, 4/5 females  
Remarks: Pharmacotoxic signs seen during the first 9 days following test material administration included hypoactivity, diarrhea, soft stools, ataxia, urine or reddish-brown stained abdomen, decreased limb tone, hypersensitivity to touch, lacrimation, bradypnea, red stain around nose and eyes, high carriage, increased limb tone and tremors. All animals in the 0.69 g/kg treatment group were normal by Day 2. Surviving animals in the 0.97 and 1.17 g/kg treatment groups had

returned to normal by Days 6 and 10, respectively. The one surviving animal in the 1.36 g/kg treatment group returned to normal on Day 8. Average weight gain in animals across treatment groups was normal.

Based upon the data obtained, the acute oral (LD<sub>50</sub>) value (with 95% confidence limits) calculated for males and females combined was 1.15 g/kg (95% confidence limits = 1.04 to 1.26 g/kg).

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study

### References

Thompson, G.W. 1980. Acute Oral Toxicity (LD<sub>50</sub> in Rats) of B0254-01. Unpublished report (No. 778965), for The Proctor and Gamble Company, Cincinnati, OH, USA, from Raltech Scientific Services, Madison, WI, USA.

### Other available reports

### Other

Last changed:

Order number for sorting:

Remarks:

September 24, 2003

318

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Ethomeen 18/60 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs.)  
Purity: Polyoxyethylene Octadecylamine = 99%  
Remarks:

#### Method

Method/Guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1980  
Species/Strain: Rat/Sprague-Dawley, albino  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: Distilled water  
Route of administration: Oral gavage  
Remarks: Five rats of each sex (221 to 299 g) were administered a single oral dose of a 75% w/v suspension of the test substance at a volume of 20.0 mL/kg (15.0 g/kg) of body weight. Animals were fasted for approximately 18-20 hours prior to dosing. Food and water were available *ad libitum* immediately following dosing. Animals were observed for mortality and pharmacotoxic signs at ½2 and 4 hours after dosing and daily thereafter for a total of 14 days. Individual body weights were measured at initiation (before and after fasting) and again on Days 7 and 14 for surviving animals. Necropsy was performed on all animals and abnormalities were recorded.

#### Results

Value: LD<sub>50</sub> > 15.0 g/kg of body weight  
(Male and female combined)  
Number of deaths: 1/5 males, 1/5 females  
Remarks: One female and one male died on Day 1 and 2 of the observation period, respectively. Body weight increased, on average, during the study period. Pharmacotoxic signs observed during the study period included hypoactivity, diarrhea, ataxia, brown-stained anal region, red-stained nose and mouth, and death. All surviving animals returned to normal within five days of test substance administration, with the exception of one male which exhibited a brown-stained anal region from Day 5 to 9. All gross observations recorded at necropsy were considered incidental and

not treatment related.

The estimated oral LD<sub>50</sub>, calculated in g/kg of active ingredient based upon a 75% w/v mixture of the test substance in distilled water, was greater than 15.0 g/kg of body weight for male and female rabbits combined.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restrictions; comparable to guideline study.

### References

Wayne, W.A. 1983. Acute Oral Toxicity (LD<sub>50</sub> in Rats) of B0590-01. Unpublished report (No. 769135), for The Procter & Gamble Company, Cincinnati, OH, USA, Hazleton Raltech, Inc., Madison WI, USA.

### Other available reports

#### Other

Last changed:

September 24, 2003

Order number for sorting:

320

Remarks:

### 5.1.1 ACUTE ORAL TOXICITY

#### Test Substance

Identity: Armeen DMSD (CAS RN 61788-91-8;  
Amines, dimethylsoya alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not Stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: Albino rat  
Sex: Male and female  
No. of animals per sex per dose: 5  
Vehicle: 10% Aqueous Gum Arabic or none  
Route of administration: Oral gavage  
Remarks: Groups of ten rats (five males and five females) were administered a single dose of the test substance via a polyethylene stomach tube at concentrations of 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 ml/kg. The test substance administered at concentrations of 0.50, 0.75, 1.0 and 2.0 ml/kg was diluted in 10% aqueous Gum Arabic. The test substance administered at concentrations of 4.0 and 8.0 ml/kg was undiluted. Rats weighing approximately 95 g were acclimated to the laboratory for a period of 14 days prior to test initiation. Food was available *ad libitum*, except for a period of 24 hours prior to test substance administration. Water was available *ad libitum*. Rats were observed for signs of toxicity for 14 days following test substance administration. A necropsy was performed on all rats.

#### Results

Value: LD<sub>50</sub> = 0.835 ml/kg  
(95% confidence limits = 0.745 to 0.935 ml/kg)  
Number of deaths: 0.50 ml/kg = 0/10  
0.75 ml/kg = 3/10  
1.0 ml/kg = 8/10  
2.0, 4.0 and 8.0 ml/kg = 10/10  
Remarks: LD<sub>0.01</sub> = 0.41 ml/kg  
LD<sub>99.99</sub> = 1.68 ml/kg  
Generalized listless behavior was observed in all dose groups shortly after test substance administration. Diarrhea was observed in rats in degrees of severity more or less commensurate with the dose received.

Ptoxis was observed among the animals in all dose groups. Rats dosed at 1.0 ml/kg and higher that died became comatose within four to ten hours post dose and died within the next 12 hours. Surviving rats showed signs of recovery within 24 to 48 hours post dose. Necropsy examinations of those animals that died prior to scheduled sacrifice revealed intestines distended with fluid. All other tissues and organs examined appeared normal.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:

June 13, 2002

Order number for sorting:

104

Remarks:

### 5.1.2 ACUTE INHALATION TOXICITY

#### Test Substance

Identity: Armeen C (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: EPA TSCA, Federal Register 44: No. 145, 1979  
Type: Range finding  
GLP: No  
Year: 1975  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male  
No. of animals per sex per dose: 10  
Vehicle: Air  
Route of administration: Inhalation (whole-body)  
Remarks: The object of this study was to determine the minimum lethal level of the test substance vapor when administered to albino rats via inhalation for one hour. Groups of ten male rats, initially weighing between 180 and 200 grams, were exposed to the test substance at mean analytical concentrations of 0.063 and 0.099 mg/l for one hour. Food and water were withheld during exposure. Chamber concentrations were monitored during the entire one-hour exposure period at a rate of 0.52 l/min. Rats were observed for mortality and signs of toxicity and/or abnormal behavior throughout the exposure and daily for 14 days after the termination of exposure. Body weights were recorded prior to exposure (day 1) and on day 14. All surviving rats were subjected to a gross necropsy, and the following tissues excised and preserved in 10% neutral buffer formalin: brain, liver, kidney, heart, pancreas, stomach, lungs, spleen and testes. The tissues from the animals in the 0.099 mg/l group were examined under a light microscope by a veterinarian.

#### Results

Value: One hour  $LC_{50} > 0.099$  mg/l  
Number of deaths: 0.063 mg/l = 0/10  
0.099 mg/l = 0/10  
Remarks: After five minutes of exposure several rats in the 0.063 mg/l dose group were preening and inactive. All animals were hypoactive after ten minutes. After 40 minutes, several animals exhibited a slight irritation around the muzzle. This latter condition, as well as

hypoactivity in all rats, continued for the remainder of the exposure period. After ten minutes of exposure all rats in the 0.099 mg/l dose group were hypoactive. After 30 minutes, several animals showed signs of irritation, were preening, and exhibited a nasal discharge. At the end of the one-hour exposure, all rats showed mild to severe irritation around the muzzle and had reddish areas of discoloration on the fur. All rats in both groups exhibited normal appearance and behavior throughout the 14-day postexposure observation period. A mean body weight gain in both dose groups was noted at the end of the observation period. No necropsy findings were noted in any rats from both dose groups. Microscopic evaluation of selected tissues from the rats in the 0.099 mg/l dose group included minimal to slight peribronchial lymphoid hyperplasia present in the lung, as well as minimal focal interstitial nephritis in seven of the ten rats, but these findings were believed not to reveal compound-related histomorphologic alterations. All other tissues were within normal histologic limits.

## Conclusions

Remarks:

The inhalation exposure of male albino rats to the test substance up to 0.1 mg/l for one hour would not appear to be toxic since no rats died and no serious pharmacotoxic signs were indicated. The effects observed were all reversed within 24 hours (Author of report).

The acute inhalation LC<sub>50</sub> was not provided. This study is included to provide additional information on the acute inhalation toxicity of this test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

Remarks:

2D

Reliable with restrictions; exposure period was one hour.

## References

Coate, W. B. 1975. Range Finding Acute Inhalation Toxicity Study in Albino Rats. Armeen C and Armeen T. Project No. M931-100. Hazleton Laboratories America, Inc., Vienna, VA, USA.

**Other**

Last changed:	July 24, 2002
Order number for sorting:	95
Remarks:	

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: ADMA 2 (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated.  
Type: LD<sub>50</sub>  
GLP: Not stated.  
Year: 1979  
Species/Strain: Rabbit/New Zealand White  
Sex: Male and female  
No. of animals per sex per dose: 4 rabbits per group, the ratio of males and females was not stated.  
Vehicle: None  
Route of administration: Dermal  
Remarks: Twelve male and four female rabbits were approximately 9 weeks old and weighed 2.0 to 3.0 kg at study initiation. Immediately prior to dosing the fur was clipped from the abdomen of the animals. Abrasions were made in one half of the rabbits. The abrasions extended the length of the exposure site, scratched the stratum corneum but did not reach the derma or produce bleeding. Four rabbits per dose group were dosed at 20.0, 10.2, 5.20 and 2.68 g/kg. The test material was applied once dermally to the prepared site under a gauze patch and occluded. The test material was kept in contact with the skin for 24 hours, at which time the wrapping was removed. The exposure site was wiped, but not washed, to remove excess material. Dermal reactions were scored at 24 hours by the Draize scoring system. The rabbits were observed daily for 14 days for signs of toxicity, pharmacological effects and mortality. Body weights were recorded pretest and in the survivors at 14 days. All animals that died during the study and all surviving animals in the 2.68 g/kg group were examined for gross pathology.

## Results

Value: LD<sub>50</sub> approximately 5.0 g/kg  
Number of deaths: 20.0 g/kg = 4/4  
10.2 g/kg = 4/4  
5.20 g/kg = 1/4  
2.68 g/kg = 2/4

Remarks: Deaths occurred at all dose levels. All animals in the 10.2 and 20.0 g/kg group died. Significant predeath toxic signs included lethargy, ptosis, anorexia, adipisia, diarrhea, mucus in feces and ataxia. Toxic signs noted in the surviving animals in the 2.68 and 5.20 g/kg groups included lethargy and diarrhea and mucus in stool, ataxia, ptosis, and yellow nasal discharge. Additional signs of toxicity observed in the 5.20 g/kg surviving animals included isolated instances of vocalization post dose, blood-shot eyes and difficulty in mobility of rear legs, possibly due to severe skin reaction. Dermal reactions were moderate to severe at all dose levels. Minimal weight gains or weight loss were noted in all surviving animals. Necropsy observations revealed dilated hearts and gastrointestinal irregularities.

## Conclusions

Remarks: The test material is not toxic as defined in 16 CFR 1500.3, nor is it a Class B Poison as defined in 49 CFR 173.343 (Author of report)  
The acute dermal LD<sub>50</sub> has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 2A  
Remarks: Reliable with restrictions; acceptable, well-documented publication/study report which meets basic scientific principles.

## References

Test for Acute Dermal/LD<sub>50</sub> in Albino Rabbits with ADMA 2. 1979. Project Number: MB 79-3571. MB Research Laboratories, Inc. Spinnerstown, PA, USA.

## Other available reports

### Other

Last changed: June 6, 2002  
Order number for sorting: 123c  
Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Armeen DM16D (CAS RN 112-69-6;  
1-Hexadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Range-finding LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: New Zealand White rabbit  
Sex: Not stated  
No. of animals per sex per dose: 4 (sex not stated)  
Vehicle: None  
Route of administration: Dermal  
Remarks: Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and gently, but thoroughly, rubbed into the exposure site and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the LD<sub>0.01</sub> and LD<sub>99.99</sub>

#### Results

Value: LD<sub>50</sub> = 4.29 ml/kg  
(95% confidence limits = 3.01 to 6.10 ml/kg)  
Number of deaths: 4.0 ml/kg = 2/4  
6.0 ml/kg = 3/4  
8.0 ml/kg = 4/4  
Remarks: LD<sub>0.01</sub> = 1.63 ml/kg  
LD<sub>99.99</sub> = 11.25 ml/kg  
No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Rabbits in all dose groups showed signs of generalized weakness and lassitude, and did

not eat or drink 24 hours post dose. Between 24 and 48 hours post dose, the rabbits in the 8.0 ml/kg dose group became extremely weak, lethargic and in a moribund state. These rabbits died within the next few hours. Rabbits in the 4.0 and 6.0 ml/kg dose groups showed signs of increasing listlessness and extreme inactivity, with deaths occurring between four and five days post dose. Rabbits in the 4.0 and 6.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. The skin at the application site in all dose groups showed signs of slight transient erythema, and appeared dried, leathery and wrinkly, which was most pronounced in animals in the 8.0 ml/kg dose group. There were no significant necropsy findings in any rabbit.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:

June 13, 2002

Order number for sorting:

3

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: E8220: Ditallowmethylamine (CAS RN 4088-22-6;  
1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1977  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Dermal  
Remarks: Three rabbits of each sex, weighing 2.2 to 3.0 kg, were percutaneously administered a single dose of the test substance at 2 g/kg body weight. The test substance was administered as supplied, a wax-like solid. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. The skin of 3 animals (2 males, 1 female) was left intact and the skin of the other 3 was abraded by penetration of the horny layer of the epidermis without causing bleeding. The test substance was applied to the exposure site of each rabbit and the exposure site was occluded with a gauze pad, rubber dam, and adhesive strapping for 24 hours. Rabbits were observed daily for mortality and signs of toxicity for 14 days following removal of the bandage and excess test substance. A necropsy was performed on all rabbits.

#### Results

Value: LD<sub>50</sub> > 2.0 g/kg  
(male and female combined)  
Number of deaths: 1/3 males; 1/3 females  
Remarks: Three animals developed diarrhea during the observation period. By Day 4 and 7 following treatment, the condition of two of these animals (one abraded female and one intact male, respectively) deteriorated further and death occurred. The third animal recovered and survived through the observation period. The other three animals appeared normal throughout the observation period.

Slight to moderate erythema and edema were observed in all animals during the observation period. Slight atonia with slight desquamation was noted in some of the animals.

Two of the four surviving animals showed normal body weight gain, while the body weights of the other two animals decreased by the end of the observation period.

Necropsy of the animals identified a slight degree of crusting and fissuring of the epidermis, not extending to the dermis, in the skin of 2 abraded and 1 intact animals. Necropsy of the male animal that died on Day 7 determined that the stomach was impacted with dry food and the gastrointestinal tract was filled with fluid. No significant treatment effects were identified in major organs of the other animals and no tissues were retained.

The LD<sub>50</sub> value was determined to be greater than 2 g/kg when the test substance is administered according to this procedure.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study

### References

Jones, J.R. 1978. Acute Percutaneous Toxicity in the Rabbit, ECM BTS 267, E8220: Ditallowmethylamine. Unpublished report (No. 1601-110/182), for Procter and Gamble Ltd., Newcastle-Upon-Tyne, England, from Hazleton Laboratories Europe, Ltd., Harrogate, England.

### Other

Last changed/Initials:

Order number for sorting:

Remarks:

September 24, 2003

312

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Armeen DM18D (CAS RN 124-28-7; 1-Octadecanamine, N,N-dimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Range-finding LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: New Zealand White rabbit  
Sex: Not stated  
No. of animals per sex per dose: 4 (sex not stated)  
Vehicle: None  
Route of administration: Dermal  
Remarks: Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the LD<sub>0.01</sub> and LD<sub>99.99</sub>

#### Results

Value: LD<sub>50</sub> = 4.29 ml/kg  
(95% confidence limits = 3.01 to 6.10 ml/kg)  
Number of deaths: 4.0 ml/kg = 2/4  
6.0 ml/kg = 3/4  
8.0 ml/kg = 4/4  
Remarks: LD<sub>0.01</sub> = 1.63 ml/kg  
LD<sub>99.99</sub> = 11.25 ml/kg  
No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Signs of mild to moderate erythema and slight drying and wrinkling at the application site were observed 24 hours post dose. Rabbits in all dose

groups were markedly inactive, and did not eat or drink. Between 24 and 48 hours post dose, the rabbits in the 8.0 ml/kg dose group died. Rabbits in the 4.0 and 6.0 ml/kg dose groups showed signs of increasing listlessness and extreme inactivity, with deaths occurring between three and four days post dose. Rabbits in the 4.0 and 6.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. A slight injection of the blood vessels directly underneath the skin of the application sites was the only necropsy finding.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

**References**

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

**Other**

Last changed:

June 13, 2002

Order number for sorting:

37

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Amine KK (CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated.  
Type: LD<sub>50</sub>  
GLP: No  
Year: 1985  
Species/Strain: Rat/Sprague-Dawley  
Sex: Male and female  
No. of animals per sex per dose: 2  
Vehicle: Distilled water (used only in the 2000 mg/kg dose group)  
Route of administration: Dermal  
Remarks: Four animals per group were treated with a single application of the test substance at doses of 500 or 2000 mg/kg. The 500 mg/kg dose group received the neat test substance at a dose volume of 0.63 ml/kg and the 2000 mg/kg dose group received the test substance in distilled water (40% w/v) at a dose volume of 5.0 ml/kg. The animals were approximately 6 to 8 weeks of age and weighed 200 to 245 g at the start of the study. Each treatment site remained occluded for the entire 24-hour exposure period. At the end of the exposure period the dose site was washed with warm (30 to 40°C) water to remove any residual test substance. During the 14-day post exposure observation period, animals were observed at least twice daily and clinical observations were recorded. The treated skin was examined daily for signs of dermal irritation with erythema and edema scores recorded at each observation. Body weights were obtained on days 1, 4, 8 and 15. A post-mortem examination was performed on all animals on day 15.

#### Results

Value: LD<sub>50</sub>  
Number of deaths: No animals died.  
Remarks: Shortly after dosing, rats at 2000 mg/kg showed hunched posture, abnormal gait, lethargy and decreases respiration. Observation of the treated skin revealed edema until Day 4 or 5, scabs from days 4 to 5 and

necrosis of the skin at 500 mg/kg. Treated animals initially lost body weight followed by recovery and normal weight gain. Necropsy findings included slight bruising in the subcutaneous tissue of one male and one female at 500 mg/kg; scab formation with or without ulceration in all rats in the 2000 mg/kg group and minimal congestion of the stomach in one female in the 2000 mg/kg group.

### Conclusions

Remarks:

The study provides evidence of irritation of the test material. Since the alkyl amines are not water soluble, it is possible that the 2000 mg/kg dose did not adequately represent exposure to this dose. The study provides limited information on acute dermal toxicity. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

2D

Reliable with restrictions; the study provides limited information on the acute dermal toxicity.

### References

Kynoch, S.R. 1985. Acute Dermal Toxicity to Rats of Amine KK. HRC Report No. 851001D/KND 10/AC. Huntingdon Research Centre. Huntingdon, England

### Other available reports

#### Other

Last changed:

August 15, 2002

Order number for sorting:

95a

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Coconut Primary Amine – Armeen CD  
(CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 99%  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1979  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Dermal  
Remarks: Three rabbits of each sex (2.2 to 3.0 kg) were administered a single dermal dose the undiluted test substance at a volume of 2.0 mL/kg of body weight. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. Abraded areas of one male and two female rabbits in each treatment group were prepared by penetrating the horny layer of the epidermis without causing bleeding. The treatment was applied to the intact or abraded exposure site of each rabbit and the exposure site was occluded with a gauze pads and adhesive strapping for 24 hours. Rabbits were observed daily for mortality and signs of toxicity for a period of 14 days. Individual body weights of surviving animals were measured at study initiation and termination (Day 14). Necropsy was performed on all rabbits and all abnormalities were recorded.

#### Results

Value: LD<sub>50</sub> > 2.0 mL/kg  
(male and female combined)  
Number of deaths: Skin intact = 0/2 males, 0/1 female;  
Skin abraded = 0/1 male, 0/2 females  
Remarks: One male animal with intact exposure site died by Day 3. Upon necropsy, caused of death was concluded to be non-treatment related. This animal was replaced and no further animals died during the study. All animals showed small to moderate body weight gains by the end of the observation period. Skin irritation reactions were produced in all animals following

treatment. Necrosis and eschar formations were reported for all animals. Moderate to severe edema during Day 1 to 4 was replaced by hard dry skin with marked atonia. Some exfoliation was noted at the end of the observation period revealing the presence of beet red lesions.

Necropsy revealed the presence of hard necrotic treated skin with thickened new skin or normal to beet red color underneath. No marked abnormalities were noted in any other organs.

The estimated dermal LD<sub>50</sub> was greater than 2 mL/kg of body weight for male and female rabbits combined.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Jones, J.R. 1979. Acute Percutaneous Toxicity in the Rabbit; Test Article: E8286; ECM BTS 278. Unpublished report (No. 1665-110/214), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

### Other

Last changed/Initials:

September 24, 2003

Order number for sorting:

323

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Coconut Primary Amine – Armeen CD  
(CAS RN 61788-46-3; Amines, coco alkyl)  
Purity: 99%  
Remarks:

#### Method

Method/guideline followed: Not stated.  
Type: LD<sub>50</sub>  
GLP: Not stated  
Year: 1979  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Dermal  
Remarks: Three rabbits of each sex (2.2 to 3.0 kg) were administered a single dermal dose the undiluted test substance at a volume of 2.0 mL/kg of body weight. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. Abraded areas of one male and two female rabbits in each treatment group were prepared by penetrating the horny layer of the epidermis without causing bleeding. The treatment was applied to the intact or abraded exposure site of each rabbit and the exposure site was occluded with a gauze pads and adhesive strapping for 24 hours. Rabbits were observed daily for mortality and signs of toxicity for a period of 14 days. Individual body weights of surviving animals were measured at study initiation and termination (Day 14). Necropsy was performed on all rabbits and all abnormalities were recorded.

#### Results

Value: LD<sub>50</sub> > 2.0 mL/kg  
(male and female combined)  
Number of deaths: Skin intact = 1/2 males, 0/1 female;  
Skin abraded = 0/1 male, 0/2 females  
Remarks: One male animal with intact exposure site died by Day 7. Neither the labored breathing noted on Day 6, the severely consolidated lungs noted upon necropsy of this animal, nor death were concluded treatment related. Slight diarrhea was noted in one female animal on Day 3. All other animals appeared normal throughout the observation period. One female animal

with abraded skin showed a small weight loss; all other surviving animals showed small to moderate body weight gain. Skin irritation reactions included slight to moderate erythema upon removal of adhesive dressing, developing into severe erythema in one female animal by Day 7, slight and moderate desquamation, and slight edema and eschar formation.

Necropsy of surviving animals revealed no macroscopic abnormalities.

The estimated dermal LD<sub>50</sub> was greater than 2 mL/kg of body weight for male and female rabbits combined.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Jones, J.R. 1979. Acute Percutaneous Toxicity in the Rabbit; Test Article: E8296; ECM BTS 278. Unpublished report (No. 1664-110/212), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

### Other

Last changed/Initials:

September 24, 2003

Order number for sorting:

324

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Armeen DMCD (CAS RN 61788-93-0;  
Amines, coco alkyldimethyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Range-finding LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: New Zealand White rabbit  
Sex: Not stated  
No. of animals per sex per dose: 4 (sex not stated)  
Vehicle: None  
Route of administration: Dermal  
Remarks: Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 4.0, 6.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and gently, but thoroughly, rubbed into the exposure site and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the LD<sub>0.01</sub> and LD<sub>99.99</sub>

#### Results

Value: LD<sub>50</sub> = 4.29 ml/kg  
(95% confidence limits = 3.01 to 6.10 ml/kg)  
Number of deaths: 4.0 ml/kg = 2/4  
6.0 ml/kg = 3/4  
8.0 ml/kg = 4/4  
Remarks: LD<sub>0.01</sub> = 1.63 ml/kg  
LD<sub>99.99</sub> = 11.25 ml/kg (As stated in report; appears inaccurate.  
Subdermal hemorrhages were noted at the application sites within the first six hours following test substance administration. No other reactions were observed at

this time. Rabbits in all dose groups were listless and inactive and the skin at the dose site was acutely inflamed 24 hours after dose administration, with subdermal hemorrhages present (most severe in the 8.0 ml/kg dose group). During the next 24 hours the rabbits in the 8.0 ml/kg dose group became moribund (pronounced weakness and inactivity) and died. Deaths that occurred in the 4.0 and 6.0 ml/kg groups three to four days post dose. The observations of these animals preceding death were similar to those animals that died in the 8.0 ml/kg dose group. Necropsy of the dead rabbits in all dose groups revealed diffuse subdermal hemorrhages about the entire trunk of the animals, ventral as well as dorsal, which extended well beyond the limits of the application sites. The skin at the dose site was indurated and leathery. Sloughing had begun prior to death and loss of sensitivity at the application site had been noted among the animals. All other organs and tissues appeared normal. The three surviving animals lost weight during the study and did not show any regrowth of hair at the application site; at the end of the 14-day observation period, they were still underweight.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

### Other

Last changed:

June 13, 2002

Order number for sorting:

228f

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine T-220D; Varonic T-220D  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow  
alkyl derivs)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Not Stated  
Year: 1980  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Dermal  
Remarks: Three rabbits of each sex were dermally administered a single dose of the liquid test substance at a concentration of 2.0 mL/kg. The test substance was administered undiluted. The hair on the backs of 14-week old rabbits, weighing 2089 to 2412 g, was clipped twenty-four hours prior to test substance administration. Abraded areas of two male and one female rabbits were prepared by making crisscross epidermal abrasions over the exposure site, penetrating the stratum corneum while not deep enough to cause bleeding from the dermal layer. The test substance was applied to the exposure site of each rabbit and the exposure site was occluded with a gauze bandage, dental dam, and tape for 24 hours. Rabbits were observed twice daily for signs of dermal irritation for 14 days following removal of the bandage and excess test substance. A necropsy was performed on all rabbits.

#### Results

Value: LD<sub>50</sub> > 2.0 mL/kg  
(male and female combined)  
Number of deaths: 0/3 males; 0/3 females  
Remarks: One female exhibited signs of respiratory congestion from Day 3 to 14, while another female exhibited dehydration from Day 10 to 14. The remaining four animals appeared normal for the duration of the study. Two of the males and one female were found to have

no visible lesions. The lungs in the third male were reported to be dark red with small, multifocal, raised areas. One lobe of the liver in the second female was reported to have pinpoint-size white foci. The third female had several, small tan areas throughout its liver. The right anterior lung of this animal was reportedly adhered to the thoracic wall and contained a 2 x 1 cm abscess. All lesions noted in these animals, particularly the lung lesions in two animals, were considered to be incidental and possibly indicative of a latent *Pasteurella* infection common in this species. The etiology of the liver lesion is unknown.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline study.

### References

Thompson, G. W. 1980. Acute Percutaneous Toxicity (LD<sub>50</sub> in Rabbits) of B0254-01. Unpublished report (No. 778970), for Proctor and Gamble Company, Cincinnati, OH, USA; from Raltech Scientific Services, Madison, WI.

### Other

Last changed/Initials:  
Order number for sorting:  
Remarks:

September 23, 2003  
298

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Polyethoxylated, or (POE)<sub>20</sub>, Tallowamine (Varonic T-220); (Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.; CAS RN 61791-44-4)  
Purity: 98%  
Remarks:

#### Method

Method/guideline followed: Procter and Gamble Standard Procedure No. C10 – Acute Percutaneous Toxicity (5/1/1979) Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1979  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: Distilled water (group II only)  
Route of administration: Dermal  
Remarks: Three rabbits of each sex (2.31 to 3.06 kg) were administered a single dermal dose of either undiluted (group I) or 50% (w/v, group II) test substance at a volume of 2.0 mL/kg of body weight. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. Abraded areas of two male and one female rabbits in each treatment group were prepared by making crisscross epidermal abrasions over the exposure site, penetrating the stratum corneum while not deep enough to cause bleeding from the dermal layer. The respective treatment was applied to the intact or abraded exposure site of each rabbit and the exposure site was occluded with a gauze bandage, rubber dams, and Elastoplast tape for 24 hours. Rabbits were first observed for dermal irritation 30 minutes after bandage removal, then daily for dermal irritation and twice daily for mortality and pharmacotoxic signs for a period of 14 days. Body weights were measured at test initiation and again at Days 7 and 14. Necropsy was performed on all rabbits and all abnormalities were recorded.

#### Results

Value: Estimated LD<sub>50</sub> > 2.0 g/kg (male and female combined)  
Number of deaths: Group I: Undiluted, intact = 0/1 male, 0/2 females;  
Undiluted, abraded = 0/2 males, 0/1 female;  
Group II: 50% w/v, intact = 0/1 male, 0/2 females;

**Remarks:**

50% w/v, abraded = 0/2 males, 0/1 female  
All 12 animals survived through the 14-day observation period. Gross lesions on the lungs, liver and kidneys were noted upon necropsy of four of the animals in Group I, none of which were considered test related. Gross lesions were noted on the liver of one Group II animal and on the liver and kidneys of another, again neither of which was considered test related. One female animal (Group II) was noted to have pinworms in the colon.

On average all animals in both treatment groups showed normal body weight gain during the observation period. A male animal with intact skin at exposure site in Group I and all males in Group II lost weight at various times during the observation period, although the minor weight loss was not attributed to the treatment.

The LD<sub>50</sub> value, for males and females combined, was estimated to be greater than 2.0 mL/kg when the test substance is administered according to this procedure.

**Conclusions**

**Remarks:**

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

**Reliability (Klimisch):**

**Remarks:**

1B

Reliable without restriction; comparable to guideline study.

**References**

Thompson, G.W. 1978. Acute Percutaneous Toxicity (LD<sub>50</sub> in Rabbits) of B0235-01. Unpublished report (No. 748981), for The Proctor & Gamble Company, Cincinnati, OH, USA, from Raltech Scientific Services, Inc., Madison, WI, USA.

**Other**

**Last changed/Initials:**

**Order number for sorting:**

**Remarks:**

March 21, 2003/LAMSeptember 24, 2003

315

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Polyethoxylated Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: 95%  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Acute Dermal  
GLP: Yes  
Year: 1979  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: None  
Route of administration: Dermal  
Remarks: Three rabbits of each sex (2.65 to 2.86 kg) were administered a single dermal dose the undiluted test substance at a volume of 2.0 mL/kg of body weight. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. Abraded areas of one male and two female rabbits in each treatment group were prepared by making 10-cm long epidermal abrasions every 2 to 3 cm longitudinally over the area of the exposure site, penetrating the stratum corneum while not deep enough to cause bleeding from the dermal layer. The respective treatment was applied to the intact or abraded exposure site of each rabbit and the exposure site was occluded with a gauze bandage, dental dam, and Elastoplast tape for 24 hours. Rabbits were first observed for pharmacotoxic signs 24 hours after bandage and test substance were removed, then daily for pharmacotoxic signs and dermal irritation and twice daily for mortality for a period of 14 days. Body weights were measured at test initiation and again at Days 7 and 14. Necropsy was performed on all rabbits and all abnormalities were recorded.

#### Results

Value:  $LD_{50} < 2.0 \text{ mL/kg}$   
(male and female combined)  
Number of deaths: Skin intact = 1/2 males, 1/1 female;  
Skin abraded = 1/1 male, 1/2 females  
Remarks: Overall mortality was 60% in this study. Signs of skin

irritation observed on animals with intact exposure site included slight to marked erythema, atonia, and coriaceousness; slight to moderate edema, desquamation and fissuring; eschar; exfoliation; subcutaneous hemorrhage and hyperthermia. Signs of skin irritation observed on animals with abraded exposure sites included moderate to marked erythema; slight to marked atonia and desquamation; slight to moderate edema, coriaceousness and fissuring; subcutaneous hemorrhage and hyperthermia. All animals surviving through observation period exhibited normal body weight gain. Changes in the lungs, heart, intestines, and colon identified by gross necropsy of all 6 animals were concluded to be non-specific or agonal in nature and were not considered to be related to administration of the test substance.

Based upon the data obtained, the minimum lethal dose for the test substance was found to be less than 2.0 mL/kg.

### Conclusions

Remarks:

An LD<sub>50</sub> was not established; the study provides additional information to evaluate the overall toxicity of the test chemical. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

2A

Reliable with restriction; well documented study report; an LD<sub>50</sub> was not established.

### References

Dean, W.P. 1979. Acute Percutaneous Toxicity Study in the Albino Rabbit. Unpublished report (No. 191-489, for The Proctor & Gamble Company, Cincinnati, OH, USA, from International Research and Development Corporation, Mattawan, MI, USA.

### Other

Last changed/Initials:

Order number for sorting:

Remarks:

September 24, 2003

317

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Ethomeen 18/60 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: Polyoxyethylene Octadecylamine = 99%  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: LD<sub>50</sub>  
GLP: Yes  
Year: 1983  
Species/Strain: New Zealand White rabbit  
Sex: Male and female  
No. of animals per sex per dose: 3  
Vehicle: Distilled water  
Route of administration: Dermal  
Remarks: Three rabbits of each sex (2.72 to 2.98 kg) were administered a single dermal dose of a 75% w/v mixture of the test substance at a volume of 2.0 mL/kg of body weight. The hair on the backs of the rabbits was clipped twenty-four hours prior to test substance administration. Abraded areas of one male and two female rabbits in each treatment group were prepared by making longitudinal epidermal abrasions over the area of exposure, penetrating the stratum corneum while not deep enough to cause bleeding from the dermal layer. The treatment was applied to the intact or abraded exposure site of each rabbit and the exposure site was occluded with a gauze bandage, rubber dam, and Elastoplast tape for 24 hours. Rabbits were first observed for dermal irritation 30 minutes after bandage and test substance were removed, then daily for dermal irritation and twice daily for pharmacotoxic signs and mortality for a period of 14 days. Body weights were measured at test initiation and again at Days 7 and 14. Necropsy was performed on all rabbits and all abnormalities were recorded.

#### Results

Value: LD<sub>50</sub> > 1.5 g/kg  
(male and female combined)  
Number of deaths: Skin intact = 0/2 males, 0/1 female;  
Skin abraded = 0/1 male, 0/2 females  
Remarks: All animals appeared normal, except for dermal irritation, throughout the study period. Dermal irritation observed during the study included slight to

moderate erythema and desquamation with slight fissuring and edema. No mortality was observed during the study. Average body weights increased normally throughout the observation period. No visible lesions were observed at necropsy.

The estimated dermal LD<sub>50</sub>, calculated in g/kg of active ingredient based upon a 75% w/v mixture of the test substance in distilled water, was greater than 1.5 g/kg of body weight for male and female rabbits combined.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Wayne, W.A. 1983. Acute Percutaneous Toxicity Study in Rabbits of B0590-01. Unpublished report (No. 769138), for The Procter & Gamble Company, Cincinnati, OH, USA, Hazleton Raltech, Inc., Madison WI, USA.

### Other

Last changed/Initials:

September 24, 2003

Order number for sorting:

319

Remarks:

### 5.1.3 ACUTE DERMAL TOXICITY

#### Test Substance

Identity: Armeen DMSD (CAS RN 61788-91-8;  
Amines, dimethylsoya alkyl)  
Purity: Not stated  
Remarks:

#### Method

Method/guideline followed: Not stated  
Type: Range-finding LD<sub>50</sub>  
GLP: No  
Year: 1957  
Species/Strain: New Zealand White rabbit  
Sex: Not stated  
No. of animals per sex per dose: 4 (sex not stated)  
Vehicle: None  
Route of administration: Dermal  
Remarks: Groups of four rabbits were administered a single dose of the test substance dermally at concentrations of 2.0, 4.0 or 8.0 ml/kg. The test substance was administered undiluted. The hair on the backs of young, adult rabbits, averaging 2.5 kg in body weight, was clipped twenty-four hours prior to test substance administration. The test substance was applied to the back of each rabbit and the site occluded with impervious plastic sheeting for 24 hours. Rabbits were observed for signs of toxicity for 14 days following removal of the plastic sheeting and excess test substance. A necropsy was performed on all rabbits. The method of Litchfield and Wilcoxon was used to determine the range-finding acute percutaneous mean lethal dose together with the LD<sub>0.01</sub> and LD<sub>99.99</sub>

#### Results

Value: LD<sub>50</sub> = 3.0 ml/kg  
(95% confidence limits = 1.96 to 4.57 ml/kg)  
Number of deaths: 2.0 ml/kg = 0/4  
4.0 ml/kg = 3/4  
8.0 ml/kg = 4/4  
Remarks: LD<sub>0.01</sub> = 0.93 ml/kg  
LD<sub>99.99</sub> = 9.50 ml/kg  
No signs of toxicity were observed in the rabbits during the first six hours following test substance administration. Rabbits in all dose groups showed signs of generalized weakness and lassitude, and did not eat or drink 24 hours post dose. Rabbits in the 4.0

and 8.0 ml/kg dose groups that died prior to scheduled sacrifice did so within three to five days post dose. Rabbits in the 2.0 and 4.0 ml/kg dose groups that survived until study termination eventually showed signs of recovery, although all lost considerable weight and hair regrowth was not observed. The skin at the application site of rabbits in all dose groups showed signs of moderate erythema and edema at the time of removal of the plastic sheeting and persisted for several days. There were no significant necropsy findings in any rabbit.

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Calandra, J. C. 1957. Range-Finding Toxicity Studies on Armeens. Industrial Bio-Test Laboratories, Inc., Northbrook, IL, USA.

### Other

Last changed:

June 13, 2002

Order number for sorting:

104

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not stated

Remarks: Description is a brown premix, containing approximately 5% compound (amine fluorides 335/242)

### Method

Method/Guideline followed: Not stated

Test type: Oral

GLP: No

Year: 1973-1975

Species: Rat

Strain: Long-Evans

Route of administration: Oral feed

Duration of test: 24 months

Doses/concentration levels: 1.2, 6.0 and 30.0 mg/kg/day

Sex: Male and female

Exposure period: 24 months

Frequency of treatment: Continuous

Control group and treatment: Yes, laboratory diet alone

Postexposure observation period: None

Statistical methods: Yes

Remarks: Seventy rats/sex/group were administered the test substance prepared in laboratory diet at doses of 1.2, 6.0 and 30.0 mg/kg/day for 24 months. Males (104 – 159 g) and females (98 – 148 g) of weanling age when received were used on study. The diet without test substance was administered to two control groups (70 rats/sex/group). Diets were prepared weekly and adjusted to the most recent body weight and food consumption data. Animals were observed daily for physical appearance, signs of local or systemic toxicity, pharmacologic effects or mortality. Observations for tissue masses were performed weekly. Eye examinations were performed pretest, and at months 3, 6, 12, 18 and 24. Body weights were measured once during pretest, weekly during treatment and at study termination, after fasting. Food consumption was recorded once during pretest and weekly during treatment. Compound consumption was calculated from food consumption data. Hematology (at 3, 6, 12, 18, 19 and 24 months), clinical chemistry

(at 6, 12 and 24 months) and urinalysis (at 6, 12 and 24 months) were evaluated from 10 control animals/sex (5 from each control group) and from 10 treated animals/sex/group. A gross necropsy was performed on all animals. From those animals that died prior to study termination, any tissue masses present or organs abnormal in size were weighed. Adrenals, kidneys and liver were weighed. From 5 control animals/sex/group and 10 animals/sex in the 30 mg/kg treatment group, the following tissues were fixed and examined histopathologically at 6 and 24 months: adrenals, bone, bone marrow, brain, eye, heart, intestine, kidneys, liver, lung, lymph node, mammary gland, ovaries, pancreas, pituitary, prostate, skeletal muscle, stomach, testes, thyroid, tongue, urinary bladder, uterus and gross lesions. For 10 animals/sex in the 1.2 and 6.0 mg/kg treatment groups, the liver, kidney and/or mesenteric lymph nodes were fixed and examined histopathologically at 6 and 24 months.

## Results

NOAEL (NOEL):	NOEL = 6.0 mg/kg/day
LOAEL (LOEL):	Not stated
Actual dose received:	Males: 0.98 to 1.36, 5.6 to 8.49 and 25.28 to 33.99 mg/kg/day Females: 0.75 to 1.38, 3.72 to 6.90 and 17.46 to 37.14 mg/kg/day
Toxic response/effects:	Described below
Statistical results:	30 mg/kg group compared to controls: Significantly lower body weights for males and females throughout treatment except for 1 or 2 weeks. Significant reductions in food consumption periodically throughout the treatment period for both males and females. Decreased clinical chemistry values: serum glutamic pyruvic transaminase (female 12 mo.), alkaline phosphatase (female 24 mo., also in 6.0 mg/kg group), total protein (female 24 mo.), calcium (male 6 mo., female 12 mo.), cholesterol (male 12 mo.), triglycerides (male 12 mo., female 24 mo.). Absolute liver and kidney weights significantly reduced, and adrenal weights relative to body weight significantly increased in males at 6 months. Absolute liver weight significantly reduced and relative kidney weight significantly increased in females at 6 months. Relative liver weight in males at 24 months significantly increased. No treatment-related significant differences from

Remarks:

control group were noted in the 6.0 and 1.2 mg/kg groups.

Compound intake was generally within 15% of the desired dose level throughout the study. Mortality rates were comparable among all treated and control groups. Effects noted in the 30 mg/kg group, when compared to controls, included consistently lower body weights and lower cholesterol and triglyceride levels in the males at 12 months and lower triglyceride levels in the females at 24 months. The nature of histologic changes observed in the intestinal mucosa suggest a possible malabsorption of lipids, which may have been responsible for the reduction in serum triglyceride levels. Ankylosis was observed in a few animals in all compound-treated groups. Evaluations of mortality, tissue masses, ocular changes, food and compound consumption, hematology, urine and organ/body weight ratios revealed no effects at any dose level considered to be of toxicologic significance. Histopathological examination revealed enlarged mesenteric lymph nodes and yellow discoloration of the small intestine. The incidence appeared to be dependent on dose level of the test substance. Histologically, the gross manifestations in these two organs were adjudged to be the result of reticuloendothelial (RE) cell hypertrophy and/or hyperplasia. Although foreign material was not detected in the RE cells, these gross and microscopic changes were considered to represent a phagocytic response to the compound at a site of absorption as well as by the lymphatic system related to this site. Many of the lymph nodes examined histologically also had sinusoidal dilation with congestion and fibroplasia. These latter changes were considered indicative of a chronic lymphadenopathy and representative of an exacerbation of the lymph node response to the compound after 2 years of continued administration. RE cell changes of the mesenteric lymph nodes were observed after 6 months of test substance administration, but there was no evidence of chronic, irreversible change at that time. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

2A

Remarks:

Reliable with restrictions; acceptable, well-  
documented study report which meets basic scientific  
principles.

**References**

Killeen, J.C. and W.R. Rapp. 1975. A Two Year Oral  
Toxicity Study of Amine Fluorides 335/242 in Rats.  
Project No. 72R-816. Bio/dynamics Inc.

**Other**

Last changed:

November 19, 2002

Order number for sorting:

74

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; and 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not stated

Remarks:

### Method

Method/Guideline followed: Not stated

Test type: Oral

GLP: No

Year: 1975

Species: Dog

Strain:

Route of administration: Oral gavage

Duration of test: 2 years

Doses/concentration levels: 1.2, 6.0 and 12.0 mg/kg/day

Sex: Male and female

Exposure period: 2 years

Frequency of treatment: Once daily

Control group and treatment: Yes, not stated

Postexposure observation period: None

Statistical methods: Body weights, hematology and clinical chemistry parameters were analyzed using F-test and Student's t-test.  
Organ weights and organ to body weight ratios were analyzed using Dunnett's test.

Remarks: Six Beagle dogs/sex/group were administered the test substance orally at doses of 1.2, 6.0 and 12.0 mg/kg/day for 2 years. The highest dose initially was 30.0 mg/kg (for the first five weeks of the study). Dosing at 12.0 mg/kg was initiated at the eighth week, following one week of nondosing and one week of dosing with a placebo (vehicle) in an attempt to decondition dogs from salivating in anticipation of dosing. Males (8.7 – 11.8 kg) and females (7.2 – 12.2 kg) 5 to 6 months old when received were used on study. The test substance was suspended in 0.25% Methocel 90<sup>®</sup> HG Premium 15000 CPS and these suspensions were prepared weekly. A group of 6 dogs/sex also was used as a control. Animals were acclimated to the testing facility for approximately seven weeks prior to test substance administration. Animals were observed daily for physical appearance, signs of local or systemic toxicity, pharmacologic

effects or mortality. Eye examinations were performed pretest, and at months 6, 12 and 24. Body weights were measured pretest, weekly during treatment and at study termination, after fasting. Food consumption was estimated visually at pretest and 4 times weekly thereafter. Hematology, clinical chemistry and urinalysis were evaluated twice pretest, and at months 1, 3, 6, 9, 12, 20 and/or 24 for all animals. A necropsy was performed on all animals. An interim necropsy was performed at 6 months on 16 animals (2/sex/group). From all animals, adrenals, kidneys, thyroid and liver were weighed. Also, the following tissues were fixed and examined histopathologically: adrenals, bone, bone marrow, brain, eye, gall bladder, heart, intestine, kidneys, liver, lungs, lymph nodes, mammary gland, peripheral nerve, ovaries, pancreas, parathyroid, pituitary, prostate, salivary gland, skeletal muscle, spleen, stomach, testes, thyroid, urinary bladder, uterus, gross lesions and tissue masses.

## Results

NOAEL (NOEL):

NOEL = 6.0 mg/kg/day

LOAEL (LOEL):

LOEL = 12.0 mg/kg/day

Actual dose received:

1.2, 6.0 and 12.0 mg/kg/day

Toxic response/effects:

Described below

Statistical results:

Statistically significant differences were noted in some of the hematology and clinical chemistry parameters. However, they were transient and/or did not occur in a dose-related pattern.

Remarks:

Two accidental deaths occurred during the study; one mid-dose male and one high-dose male. The death of the mid-dose male resulted from complications arising from the accidental fracture of the os penis and the death of the high-dose male was attributed to an intratracheal dosing accident. There were no effects of the test substance evident at dose levels of 1.2, 6.0 and 12.0 mg/kg/day. At the original high-dose level of 30.0 mg/kg/day (administered for the first 5 weeks of the test), a decrease in body weight and food consumption was evident with slight decreases in the mean serum total protein and glucose values recorded at one month in the males. This dose level also resulted in excessive salivation before and after dosing, and increased incidences of diarrhea and emesis in both sexes. These effects disappeared after the high-dose was reduced from 30.0 to 12.0 mg/kg/day. No differences from the control group in mortality,

ophthalmology, hematology, urinalysis, absolute or relative (to body weight) organ weight or pathology data were considered related to administration of the test substance. Total protein levels were consistently lower than controls in the high-dose females throughout the two years of the test. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

Remarks:

2A

Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Killeen, J.C. and W.R. Rapp. 1975. A Chronic Oral Toxicity Study of Amine Fluorides 335/242 in Dogs. Project No. 72R-815. Bio/dynamics Inc.

**Other**

Last changed:

November 19, 2002

Order number for sorting:

75

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Commercial grade containing 20% hexadecylamine  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1957  
Species: Rat  
Strain: Sprague Dawley  
Route of administration: Oral (feed)  
Duration of test: Two years  
Doses/concentration levels: 20, 100, 200 and 500 ppm  
Sex: Male and female  
Exposure period: Two years  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; untreated diet  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Five groups of 24 weanling rats (12 males and 12 females) were fed diets containing the test substance at concentrations of 0, 20, 100, 200 and 500 ppm daily for two years. Diets contained Purina Laboratory Chow supplemented with cod liver oil. The test substance was added to experimental diets as solutions in corn oil. A record was kept of food consumed by each animal. Individual body weights were determined at weekly intervals throughout the study. Complete blood counts, including red cell count, white cell count, hemoglobin concentration and differential white cell count, were carried out at varying intervals throughout the study on rats picked at random from all groups. These tests were conducted after 4, 8, 13, 16, 20, 25, 28, 43, 55, 66, 86 and 96 weeks of feeding. Organs and tissues of 30 rats fed 20, 100, 200 and 500 ppm of the test substance were examined. There were five to seven rats in each group. The organs examined microscopically consisted of the heart, lungs, liver, spleen, pancreas, kidneys, gastrointestinal tract, lymph nodes, brain, pituitary, adrenals and bone marrow. [The publication of this report (Deichmann, W.B., et.al. 1957, Arch. Ind. Health 18:483-487.) indicates that the ovaries and testes were also examined.]

## Results

NOAEL (NOEL)	NOEL = 500 ppm
LOAEL (LOEL)	Not stated
Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Described below
Remarks:	<p>There were no significant differences between the rats fed the test substance and the controls in either the percentage of deaths or the mean survival time throughout the two years. In both control and treated rats there was a higher than expected rate of mortality due to acute respiratory infections. There was no significant difference between the average diet consumption of the male and female rats fed the test substance and the control rats. There were no treatment-related effects on body weight gains or growth curves in any treatment group when compared to the controls. There was no discernable effect of the test substance on hemoglobin. There was a slight, but significant, decrease in the number of red blood cells in all rats in the treatment and control groups. This change was combined with an upward trend in the total number of white blood cells and total neutrophil counts. These effects probably were a reflection of the prevalence of respiratory disease in the experimental colony. There was no significant pathologic difference in organs examined between the control group and the treatment groups. Lesions encountered in all experimental and the control groups included pyelonephritis, hyaline casts in the renal tubules, occasional renal abscesses, and bronchitis or pneumonia. One rat in the control group showed a mild endocarditis and valvulitis; one rat in the 100 ppm dose group developed a brain abscess, and one rat receiving 500 ppm of the test substance showed histocytic hyperplasia of the mesenteric lymph node. The changes were not considered significant or treatment-related. Results were confirmed with a supplemental study reported in 1962 (article/report no. 66).</p>

## Conclusions

Remarks:	<p>The test substance produced no toxic effects when fed to rats in the diet up to concentrations of 500 ppm for two years. No significant pathological changes were observed during the microscopic examination of the tissues of these rats. (Author of report)</p>
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Although the study does not meet typical standards (primarily since the high dose group showed no effects) it provides a NOAEL of 50 mg/kg/day for chronic exposure. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

2A

Remarks:

Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Deichmann, W. B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA.

and

Deichmann, W.B., J.L. Radomski, W.E. McDonald, R.L. Kascht and R.L. Erdmann. 1957. The Chronic Toxicity of Octadecylamine. Arch. Ind. Health 18:483-487.

**Other**

Last changed:

July 18, 2002

Order number for sorting:

63

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Contained 20% hexadecylamine  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1961  
Species: Rat  
Strain: Holzman Sprague Dawley  
Route of administration: Oral (feed)  
Duration of test: Two years  
Doses/concentration levels: 200 and 500 ppm  
Sex: Male and female  
Exposure period: Two years  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; untreated diet  
Post exposure observation period: None  
Statistical methods: Not stated  
Remarks: This supplemental study was conducted in order to confirm the results of a two-year chronic study conducted in 1957 (article/report no. 63). Groups of 20 weanling rats (10 males and 10 females) were fed diets containing the test substance at concentrations of 0, 200 and 500 ppm daily for two years. Diets contained Purina Laboratory Chow supplemented with dried meat meal and cod liver oil, and corn oil. Test substance was added to experimental diets. A record was kept of food consumed by each animal. Individual body weights were determined at monthly intervals. All surviving animals were sacrificed after two years of treatment and postmortem examinations were performed. Organ weights were determined for the heart, liver, spleen, kidneys and testes. Micropathologic examinations were conducted on tissues of the heart, lungs, liver, spleen, kidneys, stomach, small and large intestine, lymph nodes, and gonads of seven rats from each group. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

## Results

NOAEL (NOEL)	NOEL = 500 ppm
LOAEL (LOEL)	Not stated
Actual dose received:	Not determined
Toxic response/effects:	Described below
Statistical results:	Described below
Remarks:	There were no significant differences observed between the rats fed the test substance and the controls in regard to: mean daily food consumption, mean weight gain and mean survival. Pathologic changes were observed to the same extent in both control and experimental rats. They included chronic murine pneumonia with the associated changes in other organs such as an occasional myocarditis, hepatitis, or nephritis; lesions of chronic arteriolar nephrosclerosis with resulting tubular atrophy and fibrosis; and panarteritis of the mesenteric arteries. No lesions were seen, either grossly or microscopically, which could be considered as having been caused by the long-term feeding of the test substance. These results confirmed the conclusions of the previous experiment.

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2D
Remarks:	Reliable with restrictions; supplemental work done in support of previous study.

## References

W. E. MacDonald, W. B. Deichmann, J. L. Radomski and B. S. Ausin. 1962. The Chronic Toxicity of Octadecylamine in the Rat – A Supplemental Report. Toxicol Appl. Pharmacol. 4:610-612.

## Other

Last changed:	July 18, 2002
Order number for sorting:	66
Remarks:	

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Commercial grade containing 20% hexadecylamine  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1957  
Species: Dog  
Strain: Mongrel  
Route of administration: Oral (capsule)  
Duration of test: One year  
Doses/concentration levels: 0.6, 3.0 and 15.0 mg/kg/day  
Sex: Male and female  
Exposure period: One year  
Frequency of treatment: Once daily, 5 days/week  
Control group and treatment: Yes; does not specify if controls received capsules of corn oil only or if they were untreated.  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Groups of three dogs received the test substance via capsule in corn oil solution at concentrations of 0.6, 3.0 and 15.0 mg/kg once a day, five days per week for one year. The per kilogram dose was adjusted based on the most recent body weight. The sexes were divided as evenly as the odd number of dogs in a group permitted. Dogs were wormed prior to testing and fed once a day during the study. The dogs were fed once per day and dog biscuits were available *ad libitum*. Individual body weights were determined once a month throughout the study. Complete blood counts were taken on all dogs at the start of the experiment and 1, 2, 3, 6, 8, 11 and 12 months thereafter. Organs and tissues from all dogs were examined. The organs examined microscopically consisted of the heart, lungs, liver, spleen, pancreas, kidneys, gastrointestinal tract, pancreas, lymph nodes, brain, pituitary, adrenals, ovary/testis, and bone marrow. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

## Results

NOAEL (NOEL)	NOEL = 3.0 mg/kg day
LOAEL (LOEL)	LOEL = 15.0 mg/kg
Actual dose received:	0.6, 3.0 and 15.0 mg/kg/day
Toxic response/effects:	Described below
Statistical results:	Described below
Remarks:	<p>One dog treated with 15.0 mg/kg of the test substance died after 22 weeks of treatment. During the last three weeks of life, signs of anorexia were observed, and bloody diarrhea during the last three days was observed. The dog did not exhibit a severe loss in weight. It was proposed that the dog was suffering from gastroenteric irritation. All other dogs appeared in good health at the end of the study. The average weight gain of the dogs in the 15 mg/kg dose group was less than the weight gain of the controls and the dogs fed lower levels of the test substance. The average weight gain of the dogs in the 0.6 and 3.0 mg/kg dose groups was essentially the same as that of the control group. No significant hematological effects considered to be treatment-related were observed. Microscopic examination of the organs found no definite lesion of the intestinal tract. However, in two dogs treated with 15.0 mg/kg/day of the test substance, the tips of the villi of the small intestinal mucosa were pale staining. This appeared in the superficial substantia propria. No foam cells or deposits of lipid material were identified although the intestines of these dogs had a different appearance from the intestines of the other dogs. This suggested the possibility of some absorption of a non-staining material into the small intestine mucosa. Also, in both of these dogs, the sinuses of the mesenteric lymph nodes were filled with pale “foamy” histiocytes. There was, however, no granuloma formation, and no necrosis or giant cell reaction occurred. No other changes in other organs considered to be treatment-related were observed.</p>

## Conclusions

Remarks:	<p>It was concluded that the test substance is likely to be toxic if ingested at 15 mg/kg/day for one year. (Author of report)</p> <p>The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)</p>
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**Data Quality**

Reliability (Klimisch):

2A

Remarks:

Reliable with restrictions; acceptable, well-documented study report which meets basic scientific principles.

**References**

Deichmann, W. B. 1957. The Chronic Toxicity of Octadecylamine. Department of Pharmacology, School of Medicine, University of Miami, Coral Gables, FL, USA.

**Other**

Last changed:

July 18, 2002

Order number for sorting:

63

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Oleylamine (9-octadecenylamine, (Z)-;  
(CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: 89.11% and 90.4% (two samples received)  
Remarks:

### Method

Method/guideline followed: EPA TSCA, Health Effects Test Guideline and  
Pesticide Assessment Guidelines – Subdivision F –  
Hazard Evaluation

Test type: Dermal  
GLP: Yes  
Year: 1985  
Species: Rat  
Strain: Sprague Dawley  
Route of administration: Dermal  
Duration of test: 14 days  
Doses/concentration levels: 0.5, 1.5 and 3.0% v/v  
Sex: Male and female  
Exposure period: 10 days  
Frequency of treatment: Two 5-day dosing periods with intermediate 2-day  
non-dosing period

Control group and treatment: Yes; mineral oil  
Post exposure observation  
period: None  
Statistical methods: Non-parametric analysis of variance; post hoc  
Wilcoxon's 2-sample test

Remarks: Based on the results of a pilot study, groups of young  
adult rats (4 males and 4 females) were treated  
dermally with the test substance at concentrations of 0,  
0.5, 1.5 and 3.0%. Rats were treated for two five-day  
dosing periods with an intermediate two-day non-  
dosing period in order to more closely reproduce  
conditions of human exposure to the test substance.  
The first day of dosing was designated as Day 1. Due  
to excessive tissue destruction indicated by sloughing,  
scores of moderate to severe erythema, scabbing,  
hardening of the skin, and sensitivity to touch, the  
dosing at the intermediate and high dose levels (1.5  
and 3.0%) was discontinued on Day 9. These animals  
were subsequently sacrificed on Day 10.  
At initiation of dosing the rats' body weights ranged  
from 205.7 to 321.3 g. Rats were acclimated to the  
laboratory for seven days prior to test substance  
application. Water and food were provided *ad libitum*.

Approximately 24 hours prior to test substance application, the fur was clipped from the dorsal area of each animal. Shaving was repeated one week later. The test substance was applied at a volume dosage of 5 ml/kg. The application site was covered by a porous gauze dressing that was held in place with tape, and covered with a taped elastic bandage. Each day, wrappings were removed approximately six hours after test substance application and the test sites were washed with warm water to remove excess test substance. Observations of signs of toxicity were made once each day. Body weights were recorded during acclimation, weekly during the study and at sacrifice. Food consumption was recorded weekly during the study. Morbidity/mortality checks were made twice each day. The skin of each rat was examined prior to test substance administration on days 2, 4, 6, 8, 10, 12 and 14 for signs of erythema and edema. No animals died on study therefore, no necropsies were performed. Animals were killed and discarded three days following the completion of dosing.

## Results

NOAEL (NOEL)	Not defined
LOAEL (LOEL)	Not defined
Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Described below
Remarks:	All rats survived until scheduled sacrifice. Concentrations of 1.5 and 3.0% produced moderate to severe irritation (erythema scores 2-4), which in some instances progressed to hardening and sloughing of the skin. A number of rats were sensitive to touch. In the 0.5% group, erythema scores of 1 to 2 were observed, indicating mild to moderate irritation, and flaking of the outer layers of the epidermis was observed. An increased sensitivity in females to the irritant effects of the test substance as compared to males was observed. In the control group, one male showed an erythema score of 1 at one observation. All rats in the 1.5 and 3.0% v/v groups were sacrificed on day 9 of the study due to the irritant/corrosive effects of the test substance. No other treatment-related irritant effects or clinical signs were observed. A significant treatment-related effect on body weight was observed for males at day 7. Individual group comparisons

revealed that body weights in both the 1.5 and 3.0% groups were significantly lower than controls. Females in the 3.0% group showed a mean weight loss during the first week of the study, although this finding was not significant. Food consumption during the first week of study was reduced significantly in the 1.5% group males when expressed as total food consumed. No significant difference was noted when expressed on a per weight basis.

### Conclusions

Remarks:

This endpoint has not been adequately characterized; however, the study provides additional data on the toxicity of repeated dermal dosing, including severe irritation, of this test substance at concentrations of 0.5, 1.5 and 3.0%. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

2C  
Reliable with restrictions; comparable to guideline study with acceptable restrictions.

### References

Chem MFGS Assn. 1985. 14-Day Dermal Toxicity Range-Finding Study of Oleylamine in Rats (Final Report) with cover letter dated 041185. EPA Doc. No. 40-8584196, Microfiche No. OTS0525400.

### Other

Last changed:  
Order number for sorting:  
Remarks:

July 17, 2002  
18

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: N-methyl-N-octadecyl-1-octadecanamine  
(CAS RN 4088-22-6; 1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1981  
Species: Rat  
Strain: CD Sprague Dawley  
Route of administration: Oral (feed)  
Duration of test: 13 weeks  
Doses/concentration levels: 0, 0.15, 0.5 and 1.5% w/w (through week 4);  
0, 0.15, 0.4 and 1.0% w/w (through week 13)  
Sex: Male and female  
Exposure period: 13 weeks  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; untreated diet  
Post exposure observation period: None  
Statistical methods: Group mean values and standard deviations, where appropriate; analysis of variance, Student's t-test; and  $\log_{10}$  transformed data  
Remarks: Groups of 40 rats (20 male and 20 female) were fed diets containing the test substance at concentrations of 0.15, 0.5 and 1.5% w/w daily. Due to marked depression of body weight gain at the highest concentration, from week 5 until termination (week 13) the dietary concentrations were changed to 0.15, 0.4 and 1.0% w/w daily (approximately 130, 375 and 1000 mg/kg/day). Diets were prepared at the laboratory and contained basic rat diet and corn oil or corn oil/test substance mixtures. Stability of the test substance in the diet was not performed. Water was available *ad libitum*. Rats were acclimated to the laboratory for 21 days prior to test substance administration. All rats were examined once daily for signs of ill-health, overt toxicity or behavioral changes. Individual body weights were recorded prior to treatment on the first day of the study, at weekly intervals throughout the study and at necropsy. Food consumption was measured weekly

throughout the study. The blood samples obtained from all rats during week 12 were evaluated for the following: hemoglobin concentration, mean cell volume, red blood cell count and derived indices (packed cell volume, mean cell hemoglobin and mean cell hemoglobin concentration), and total and differential white blood cell count. A necropsy was conducted on all rats. The following organs were weighed: adrenals, heart, kidneys, liver, lung, and ovaries/testes. Samples of the following tissues and organs were fixed: adrenals, aorta, bone marrow smear, bladder, brain, cecum, colon, duodenum, epididymides, gross lesions, heart, ileum, jejunum, kidneys, liver, lungs, mandibular salivary gland and lymph node, esophagus, ovary/testis, pancreas, pituitary, psoas muscle, sciatic nerve, seminal vesicle, skin, spleen, stomach, thymus, tongue, trachea and uterus/prostate. All tissues from the 0 and 1.5 (1.0)% dose groups were stained and examined microscopically. Subsequently sections of jejunum, mesenteric lymph nodes and ovaries from rats in the remaining two groups were prepared and examined.

## Results

NOAEL (NOEL)

None determined due to foamy macrophage accumulation in multiple organs and enlarged lymph nodes found in the 0.15 % group.

LOAEL (LOEL)

0.15%

Actual dose received:

<i>Mean Test Substance Intake (mg/kg/day) for Weeks 1-13</i>			
<b>Dose group:</b>	<b>0.15%</b>	<b>0.5 (0.4)%</b>	<b>1.0 (1.5)%</b>
Males	117	343	936
Females	139	406	1076

Toxic response/effects:

Described below

Statistical results:

Described below

Remarks:

All rats survived the treatment period. Alopecia was observed in 12 male and 13 female rats in the high dose group. The overall body weight gains for rats in the mid and high dose groups were significantly lower than the controls ( $p \leq 0.01$ ). There also was a significant decrease in overall body weight gain in females in the low dose group. Food consumption in the high dose group was moderately lower (20 to 25%) than the controls and there were slight reductions

(approximately 10%) in the mid dose group. Food conversion efficiencies of the high dose group were markedly lower than the controls throughout the study. Significant increases in total leukocyte count in all treated groups was observed when compared to the controls. Also, there were significant reductions in hemoglobin concentration in all treated groups and significant reductions in packed cell volume in the medium and high dose groups. The absolute weights of most weighed organs were lower in the high dose group male and female rats and in the mid dose group males than in the controls. Relative weights of the liver, testes, kidneys and lungs were higher in treated rats than the controls. Accumulation of histiocytes with foamy cytoplasm were found in the lamina propria of the jejunum, in the mesenteric lymph nodes, and to a lesser extent in other tissues. Focal degenerative changes were found in some of the histiocyte aggregates in the mesenteric lymph node of high dose rats, and a few animals had peritonitis. This histiocytosis was present in all treated groups and was sufficiently marked even in the low dose group rats to cause a visible enlargement of the mesenteric node at necropsy, thereby precluding this as the “no-effect” level. Effects in organs remote from the gastrointestinal tract and associated tissues were foamy interstitial cells (undetermined origin) in the ovary and alopecia in the skin. The ovarian changes were detected in all treated groups, but alopecia was restricted largely to rats in the high dose group. The histiocytosis in the jejunum and mesenteric lymph nodes indicated uptake of dietary lipid material by the local reticuloendothelial system, and the changes in the ovary and skin suggested possible systemic disturbances in lipid metabolism. Reproductive organs were examined, meeting the requirements of SIDS/HPV reproductive screening.

## Conclusions

### Remarks:

The study fulfills the requirement of the HPV screening program although a NOAEL was not determined. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; Comparable to guideline study.

**References**

Procter & Gamble Co. 1981. Initial Submission: 13 Week Oral (Dietary Administration) Toxicity Study of N-methyl-n-octadecyl-1-octadecanamine in Rats with cover letter dated 081292. EPA Doc. No. 88-9200007039, Microfiche No. OTS0537649.

**Other**

Last changed:

June 14, 2002

Order number for sorting:

76

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl-  
(CAS RN 4088-22-6)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: Yes  
Year: 1980  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Oral gavage  
Duration of test: 23 days  
Doses/concentration levels: 100, 250, 500, 750 and 1000 mg/kg  
Sex: Non-pregnant females  
Exposure period: 13 days  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; corn oil  
Postexposure observation period: 10 days  
Statistical methods: Not stated  
Remarks: Groups of 4 non-pregnant female rabbits were administered the test substance by gavage at one of five levels (100, 250, 500, 750 and 1000 mg/kg), at a volume of 2 mL/kg, daily for 13 days. The sexually mature rabbits, weighing 3.50 to 4.11 kg, were acclimated to the laboratory for 14 days prior to test initiation. Food and water were available *ad libitum*. Animals were examined at least once daily during the 13-day treatment and 10-day observation periods for signs of ill-health, toxicity or behavioral change. Individual body weights and food consumption were recorded on days 1, 4, 7, 10 and 13 of the treatment period, and on days 18 and 23 during the observation period. The “no effect” dose level was to be determined on the basis of evidence of systemic toxicity at the respective dosage levels.

### Results

NOAEL (NOEL) NOEL could not be determined.  
Actual dose received: Not stated  
Toxic response/effects: Described below  
Statistical results: Not applicable  
Number of deaths: Control = 0/4;  
100 mg/kg dose level = 0/4;

250 mg/kg dose level = 0/4;  
500 mg/kg dose level = 0/4;  
750 mg/kg dose level = 0/4;  
1000 mg/kg dose level = 0/4

Remarks: No mortalities occurred during the study. Clinical signs included respiratory distress in one animal from the 100 mg/kg/day treatment group from Days 3 through 23 and one animal from the 250 mg/kg/day treatment group on Day 23. These clinical signs were concluded to be non-treatment related.

Control animals showed a very slight mean weight loss from Day 1 to Day 7; thereafter, a weight gain was observed. All treated animals showed fluctuations in body weight resulting in slight non-treatment related weight losses over the treatment period.

Mean daily food intake during the treatment period for animals in the 100, 250, 500 and 750 mg/kg/day treatment groups was lower than in the control group. However, daily food intake by animals in the 1000 mg/kg/day treatment group was similar to that of the control group. An increase in mean food intake was reported during the observation period for animals in all but the 250 mg/kg/day treatment group. The reduction in mean food intake observed for this group was mainly due to one animal.

A no effect level was not established because the minimal suppression of weight gain and food intake at all dose levels was not dose related but was considered treatment related. Therefore, the lowest dose level recommended for the subsequent teratology study was less than 100 mg/kg/day.

### Conclusions

Remarks: This study is useful in overall evaluation of the repeat dose toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1D  
Remarks: Reliable without restrictions; range-finding study for developmental toxicity

**References**

Armitage, A.K. 1980. E0016: Oral (Gavage) Dose Ranging Study in the New Zealand White Rabbit: ECM BTS 294. Unpublished report (No. 2538-110/333), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

**Other**

Last changed/Initials:

September 21, 2003

Order number for sorting:

289

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl-  
(CAS RN 4088-22-6)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: 7-Day Percutaneous Dose Sighting  
GLP: Yes  
Year: 1980  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Dermal  
Duration of test: 7 days  
Doses/concentration levels: 50, 100, 200 or 500 mg/kg /day  
Sex: Male and female  
Exposure period: 5 days  
Frequency of treatment: Daily  
Control group and treatment: Yes; polyethylene glycol 600  
Postexposure observation period: 2 days  
Statistical methods: Not stated  
Remarks: One young adult rabbit of each sex, weighing 2.78 to 4.64 kg, were administered one of four test substance concentrations (50, 100, 200 or 500 mg/kg) at a dosage volume of 2.0 mL/kg/day for 5 consecutive days and then maintained untreated for an additional 2 days. The control animals (one of each sex) were administered 2.0 mL/kg/day polyethylene glycol 600. The test substance (or polyethylene glycol 600) was applied to a non-abraded, shaved dorso-lumbar region of each animal through a syringe and left for 7 hours before removal by washing. Animals were examined at least once daily for signs of overt toxicity. Individual body weights were measured at initiation and on Day 7. Skin irritation was assessed daily prior to dosing.

### Results

NOAEL (NOEL) Not stated  
Actual dose received: Not stated  
Toxic response/effects: Described below  
Statistical results: Not applicable  
Number of deaths Control group: 0/2;  
(male and female combined): 50 mg/kg/day dose level: 0/2  
100 mg/kg/day dose level: 0/2

Remarks: 250 mg/kg/day dose level: 1/2 (sacrificed)  
500 mg/kg/day dose level: 2/2 (sacrificed)  
The female from the 250 mg/kg/day treatment group and both the male and female from the 500 mg/kg/day treatment group were killed after 3 days of treatment due to severe local irritation at the test site. There were no treatment-related clinical changes other than local irritation at the exposure sites in any of the other treatment groups.

There was no consistent treatment-related effect on overall weight gain.

Skin irritation was characterized as moderate to severe erythema and edema with fissuring in both males and females in the 200 and 500 mg/kg/day treatment groups. Mild to severe reactions of erythema and edema in the 50 and 100 mg/kg/day treatment groups remained constant from Day 3 through termination. Slight atonia and wrinkling was exhibited by animals in treatment groups. Both control animals showed slight transient erythema on a single occasion.

### Conclusions

Remarks: Based on the results of this study, a high dose level of 50 mg/kg/day was suggested for use in the subsequent 13-week percutaneous toxicity study, with a low concentration as one-tenth of the high concentration.

This study is useful in overall evaluation of the repeat dose toxicity of the test substance.. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1D

Remarks:

Reliable without restrictions; range-finding study for a subchronic toxicity study

### References

Armitage, A.K. 1980. 7 Day Percutaneous Dose Sighting Study in Rabbits: ECM BTS 294, E0016. Unpublished report (No. 2510-110/314), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

**Other**

Last changed/Initials: September 21, 2003

Order number for sorting: 290

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl-  
(CAS RN 4088-22-6)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: 13-Week Dermal Toxicity  
GLP: Yes  
Year: 1980  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Dermal  
Duration of test: 13 weeks  
Doses/concentration levels: 5 or 50 mg/kg/day  
Sex: Male and female  
Exposure period: 13 weeks  
Frequency of treatment: 5 consecutive days/week  
Control group and treatment: Yes; polyethylene glycol 600  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Five young adult rabbits of each sex, weighing 2.16 to 2.94 kg, were administered one of two test substance concentrations (5 or 50 mg/kg) at a dosage volume of 2.0 mL/kg for 5 consecutive days per week for 13 weeks. The control animals (five per sex) were administered 2.0 mL/kg polyethylene glycol 600 according to the same treatment schedule. The test substance (or polyethylene glycol 600) was applied to a non-abraded, shaved dorso-lumbar region of each animal through a syringe and left for 7 hours before removal by washing. Exposure sites were shaved twice weekly. Skin irritation was assessed daily prior to dosing throughout the study. Animals were examined at least once daily for signs of overt toxicity. Individual body weights were measured at initiation, then weekly throughout the study, and at necropsy. Hematology was performed using samples collected from the marginal ear vein of each animal at initiation and during final week of study. Terminal studies included necropsy of all animals, organ weights (adrenals, heart, liver, ovaries/testes, lungs, and kidneys) and histology, including reproductive organs.

## Results

NOAEL (NOEL)	Not stated
LOAEL (LOEL)	Not stated
Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Not applicable
Number of deaths:	Control: 1/5 males, 1/5 females; 5 mg/kg/day dose level: 0/5 males, 1/5 females; 50 mg/kg/day dose level: 1/5 males, 0/5 females
Remarks:	One male and one female from the control group, one female from the 5 mg/kg/day treatment group and one male from the 50 mg/kg/day treatment group were killed for humane reasons after 46, 22, 52 and 36 days of treatment, respectively. Clinical and pathological findings in the sacrificed animal from 50 mg/kg/day treatment group revealed multiple abscesses resulting in poor body condition characterized by body weight loss, swelling around the mouth and a yellow discoloration of the fur. All other incidental mortalities presented a similar picture of enteric discharge, lethargy and body weight loss. The findings at necropsy suggested gastrointestinal disease as the cause of death.

Clinical observations included skin sensitivity to touch, raised vesicles at the exposure site. Additional clinical observations considered incidental to treatment included enteric discharge, perianal staining, nasal exudates, ocular exudates and alopecia.

Group mean body weight gain was slightly reduced in animals in the 50 mg/kg/day treatment group during the latter 7 weeks of treatment, as compared to that of control animals, thought to be attributed to a reduced food consumption during Week 10. Body weight gain in the 5 mg/kg/day treatment group was considered to be similar to or greater than that of the control animals.

Skin irritation characterized for the 50 mg/kg/day treatment group included moderate reactions of erythema, edema, desquamation and atonia throughout the treatment period. Atonia became severe in 3 rabbits in this group and was usually associated wrinkling of the skin. Animals in the 5 mg/kg/day treatment group exhibited slight erythema and edema during the first 8 weeks of treatment which developed into moderate reactions for all males and one female in

the group from Week 9 to termination. Additionally, mild transient desquamation and slight to moderate atonia with wrinkling were recorded for the majority of these animals throughout the treatment period. Slight erythema, edema and atonia with wrinkling were recorded for several control animals, suggesting that the nature of the vehicle may have exacerbated the dermal response seen in the treatment groups.

Hemoglobin concentration, red blood cell count and packed cell volume were unusually low for two female rabbits in the 50 mg/kg/day treatment group. Hematology values for all other animals were within the range considered normal for this species.

No treatment-related trends were identified in the absolute or relative organ weights of the treated rabbits. The macroscopic findings were infrequent and generally minor. Microscopic examination of the skin revealed a moderate to marked epidermal response in the 50 mg/kg/day treatment group, typified by moderate to marked hyperkeratosis, acanthosis and hypergranulosis accompanied by low grade congestion and leukocyte infiltration in the superficial dermis. A minimal degree of acanthosis and/or hyperkeratosis was identified in animals from the 5 mg/kg/day treatment group. There was a notably higher incidence of intralobular leukocyte foci (lymphoid cells, macrophages and heterophils) in the liver and epithelioid cells the mesenteric lymph nodes of animals in the 50 mg/kg/day treatment group, as compared to the control animals. Since the dermal reactions observed in the 5 mg/kg/day treatment group were predominantly mild, skin histology was considered unnecessary. The only systemic finding was the leukocyte foci in the liver. The NOAEL for systemic toxicity was 50 mg/kg/day; mild skin irritation was noted at the low dose. There were no effects on reproductive organ weights or histopathology.

## Conclusions

Remarks:

This test substance appeared to be a moderate irritant at 50 mg/kg/day and a mild irritant at 5 mg/kg/day. The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1D

Remarks:

Reliable without restrictions; only two test substance-treated groups

**References**

Armitage, A.K. 1980. 13 Week Percutaneous Toxicity Study in the Rabbit: ECM BTS 294, E0016. Unpublished report (No. 2655-110/315), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

**Other**

Last changed/Initials:

September 21, 2003

Order number for sorting:

292

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Genamin TA 100 D(CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: >96%  
Remarks:

### Method

Method/guideline followed: OECD Guideline 407 “Repeated Dose Oral Toxicity – Rodent: 28-day or 14-day Study”  
Test type: Oral  
GLP: Yes  
Year: 1995  
Species: Rat  
Strain: Sprague Dawley  
Route of administration: Oral gavage  
Duration of test: 28 days  
Doses/concentration levels: 0, 12.5, 50 and 150 mg/kg/day  
Sex: Male and female  
Exposure period: 28 days  
Frequency of treatment: Daily  
Control group and treatment: Yes; concurrent vehicle  
Post exposure observation period: None  
Statistical methods: Bartlett’s test, ANOVA, Dunnet’s test, Kruskal-Wallis and Mann Whitney’s “U” test  
Remarks: Five male and five female rats per group were dosed for a period of 28 days to the test substance at concentrations of 0, 12.5, 50 and 150 mg/kg/day. At the start of dosing, the animals were approximately 7 weeks of age and weighed 214 to 240 g (males) and 157 to 182 g (females). Animals were observed for clinical signs daily and mortality twice daily. Body weights were obtained on Day 0 and weekly thereafter. Food consumption was measured weekly. Ophthalmoscopic examination was performed prior to study start and during week 4. Behavioral effects including, flexion reflex, grasping reflex, righting reflex, placing reactions, equilibrium tests, corneal reflex, pupillary reflex, auditory startle, toe spreading and head shaking, were measured during week 4. Hematology/biochemistry evaluation of the blood (according to OECD 407) was obtained for Day 29. Urinalysis was also evaluated on Day 29 (on Day 28, animals received 10 ml/kg tap water over a 16 hour period as per OECD 407). Organ weights were

obtained for the following tissues: testes, epididymides, spleen, liver, kidneys, adrenals, heart, thymus, brain and pituitary. Macroscopic evaluation was performed according to OECD 407. The following tissues were examined microscopically from the animal in the control and high dose groups: urinary bladder, prostate, testes, epididymides, uterus, ovaries, spleen, stomach, intestine, lymph nodes (mesenteric and mandibular), liver, kidneys, adrenals, sternum (with bone marrow), heart, thymus, lungs, trachea, thyroids, brain, pituitary, skeletal muscle, sciatic nerve, spinal cord, gross lesions. From the mid and low dose groups the following tissues were examined microscopically: liver, spleen, mesenteric lymph nodes, thymus, lungs, adrenals, duodenum, jejunum and ileum and gross lesions. Dose formulations were analyzed for accuracy of preparation by HPLC/UV in weeks 1 and 3. Twenty-four hour stability analysis was performed on the 1 and 36 mg/ml dose formulations.

## Results

NOAEL (NOEL)	12.5 mg/kg/day
LOAEL (LOEL)	50 mg/kg/day
Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Significant decrease of body weights on Days 14 and 28, of body weight gain at 50 and 150 mg/kg/day. Most effects reported for hematology and clinical chemistry reached the level of significance.
Remarks:	Dose concentrations were within 90 to 110% of nominal. Dose preparations were stable of the 24 hour period (>96% of initial concentration).

<b>Mortality</b>		
<b>Dose group (mg/kg/day)</b>	<b>Male</b>	<b>Female</b>
12.5	0/5	0/5
50	0/5	1/5 (wk 2)
150	2/5 (wks 2 and 3)	3/5 (wks 3 and 4)

Clinical signs: Salivation was observed in all animals at 50 and 150 mg/kg/day, and piloerection was observed at 50 mg/kg/day (females only) and at 150 mg/kg/day (all animals). Hunched posture, fur loss, soft stool, dyspnea were reported among high

dose animals.

Body weight: Decreased in males at 50 mg/kg/day on Day 28 and in both sexes at 150 mg/kg/day on Days 14 to 28.

Body weight gain: At 50 mg/kg/day decreased in males on Days 21-28 and on Days 0-7 in females. At 150 mg/kg/day, decreased in males Day 7-14 and 21-28 and females Day 0-7.

Food consumption: Decreased at 50 and 150 mg/kg/day

Ophthalmoscopic examination: no treatment related effects.

Hematology: At 150 mg/kg/day, RBC increased in both sexes; white blood cells increased in males (more neutrophils and less lymphocytes compared to control values); MCV decreased in both sexes; platelets increased in both sexes; and prothrombine time increased in males. At 50 mg/kg/day, white blood cells increased in males (more neutrophils and less lymphocytes compared to control values); MCV decreased in both sexes; platelets increased in females; and prothrombine time increased in males. At 12.5 mg/kg/day, MCV decreased in females.

Clinical chemistry: At 150 mg/kg/day, ASAT and ALAT increased in both sexes and gamma glutamyl transpeptidase increased in females; ratio albumin/globulin decreased in both sexes; creatinine, total protein and cholesterol decreased in females; glucose and bilirubin decreased in males; and blood urea nitrogen increased in males. At 50 mg/kg/day, ALAT increased in both sexes; total protein and ratio albumin/globulin decreased in females; and potassium and bilirubin decreased in males. At 12.5 mg/kg/day, ALAT increased in males; and potassium and bilirubin decreased in males. Effects on ALAT, total protein and albumin/globulin ratio showed a relationship with dose.

Urinalysis: No treatment related effects.

Organ weights: At 150 mg/kg/day, absolute liver, kidney, heart and thymus weight were decreased in males and females (heart and thymus only); relative weight of brain and adrenals was increased in both sexes; testes and epididymides weight (rel.) was increased; rel. liver weight was increased in both sexes and relative kidney weight was increased in females only. At 50 mg/kg/day, absolute liver and kidney weight was decreased in males; and relative kidney

weight was increased in females. The decrease in liver, kidney and heart weight was related to dose. The relative increase of brain weight was related to dose.

Gross pathology: At 150 mg/kg/day, dilation of the intestine and the stomach; congestion of the lungs; emaciation and increased size of lymph nodes noted in both sexes. At 50 mg/kg/day, dilation of the intestine in both sexes; congestion of the lungs and increased size of lymph nodes in females. Incidental in the highest dose levels; fur loss, dark areas on the lungs, increased size of the adrenals, and/or decreased size of the thymus.

Histopathology: At 150 mg/kg/day, histiocytosis (with vacuolization of histiocytes) of the lamina propria of the small intestine and mucosal hyperplasia in both sexes; decreased vacuolization of liver cells; necrosis with lymphocyte infiltration in the liver of both sexes; inflammation of the lungs (increased number of leukocytes) in females; histiocytosis (with vacuolization of histiocytes) of the lymph nodes in both sexes; depletion of lymphocytes in the thymus in both sexes; and spleen atrophy with leukocyte infiltration in both sexes. At 50 mg/kg/day, histiocytosis (with vacuolization of histiocytes) and mucosal hyperplasia in the small intestine in both sexes; liver necrosis in females; bronchial histiocytosis, fibrosis and inflammation in females; histiocytosis (with vacuolization of histiocytes) of the lymph nodes in both sexes; and depletion of lymphocytes in the thymus in both sexes. At 12.5 mg/kg/day, histiocytosis (with vacuolization of histiocytes) of the intestines in both sexes; and histiocytosis (with vacuolization of hystocytes) of the lymph nodes in both sexes. A relationship with dose was established for the effects on lymph nodes and thymus.

The NOEL of 12.5 mg/kg/day was based on the local effects on gastro-intestinal tract and lungs (related to the irritating properties of the test substance), body weight loss and the presence of liver effects (both histopathological and biochemical) at the two highest dose levels. Other effects seen were related to the poor condition of the animals.

## Conclusions

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen

Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1

Remarks:

Reliable without restriction

**References**

Oberto, G. 2000. Genamin TA100 "4-Week Toxicity Study in Rats by Oral Route". APAG, Istituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A.

**Other**

Last changed:

August 8, 2002

Order number for sorting:

221a

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Ethomeen T/12 (CAS RN 61791-44-4;  
Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1965  
Species: Rat  
Strain: SPF Wistar  
Route of administration: Oral (feed)  
Duration of test: 90 days  
Doses/concentration levels: 0, 170, 500, 1500 and 4500 ppm  
Sex: Male and female  
Exposure period: 90 days  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; concurrent, untreated diet  
Post exposure observation period: None  
Statistical methods: None  
Remarks: Groups of 25 young adult male and female rats were fed diets containing the test substance at concentrations of 0, 170, 500 and 1500 ppm (approximately 15, 50 and 150 mg/kg/day). A group of ten male and ten female rats were fed a diet containing test substance at a concentration of 4500 ppm. In addition, a further group of seven male and seven female rats were fed a diet containing 4500 ppm of the test substance and killed at intervals up to six weeks from the beginning of the experiment. Tissues from these animals were examined for sudanophilic material. Diets were prepared at the laboratory and contained powdered stock diet, malt extract and corn. Test substance was added to experimental diets via corn oil, in which it was dissolved by gentle heating at 40°C. The ingredients were mixed mechanically and water added to produce a dough, which was then formed into pellets and dried at a temperature of not more than 40°C. Food and water were available *ad libitum*. Body weights were recorded at study initiation and weekly during the treatment period. Hemoglobin concentrations, packed-cell volumes, white-cell counts

and differential white-cell counts were measured prior to treatment and immediately prior to sacrifice at the end of the 90-day test period. These hematologic parameters were evaluated on individual samples from five male and five female rats from each group except that blood was examined from all animals fed diet containing 4500 ppm of the test substance. At the time of sacrifice, the liver, heart, lung, adrenals, kidneys and spleen were weighed and organ/body weight ratios calculated from random selection of animals in each group. Tissues and organs from the remaining animals were fixed and examined microscopically. The following tissues and organs were examined: liver, kidney, spleen, heart, lung, adrenals, gonads, thymus, thyroid, pancreas, stomach, duodenum, jejunum, ileum, caecum, colon, salivary gland, mesenteric lymph nodes, spinal cord and brain (cerebrum, cerebellum and medulla).

## Results

NOAEL (NOEL)

NOEL = 500 ppm (approximately 50 mg/kg/day)

LOAEL (LOEL)

LOEL = 1500 ppm

Actual dose received:

Not determined

Toxic response/effects:

Described below

Statistical results:

None

Remarks:

No unscheduled deaths occurred and males and females responded similarly. Rats fed diet containing 4500 ppm of the test substance lost hair and generally were lethargic throughout the study. No clinical observations were noted in rats at any other dietary level. Body weight gain was inhibited at the 4500 ppm dietary level and partly inhibited in the 1500 ppm dietary level. There was no apparent affect on body weight for rats in the 1500 ppm or 700 ppm groups. The palatability of the diet was decreased by the addition of 4500 and 1500 ppm of the test substance. No definite hematological abnormality was detected at any dose level of the test substance. No significant differences were seen between test and control group organ weights. Gross macroscopic observations at necropsy were seen only in the 4500 ppm group and comprised of yellow coloration of the stomach and bowel contents, and thickening and yellow coloration of the mucosa of the small intestine and the regional mesenteric nodes. Microscopic findings, which were documented in rats treated at dietary levels of 1500 and 4500 ppm, were confined to the small intestine and

regional mesenteric nodes. All rats in the 4500 ppm group showed engorgement of the villi and lamina propria of the small intestine with swollen foamy macrophages. Similar macrophages occasionally were seen to a lesser degree in Peyer's patches and in the regional lymph nodes. Changes were most pronounced in the jejunum and upper ileum but were detected throughout the small intestine. The macrophages were sudanophilic and were presumed to contain deposits of the test substance. Similar findings were present to a lesser degree in 31 of the 40 rats fed 1500 ppm of the test substance. No findings were noted at any other dietary level. Reproductive organs were examined, meeting the requirements of SIDS/HPV reproductive screening.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline study.

### **References**

Goater, T. O., D. Griffiths and T. F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 - Albino Rats. Report No. IHR/173. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire.

### **Other available reports**

Goater, T.O., D. Griffiths, T.F. McElligott and A.A.B. Swan. 1970. Summary of Toxicology Data - Acute Oral Toxicity and Short-Term Feeding Studies on Polyoxyethylene Tallow Amine in Rats and Dogs. Food & Cosmetics Toxicol. 8:249-252.

### **Other**

Last changed:  
Order number for sorting:  
Remarks:

June 7, 2002  
115 and 134d

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Ethomeen T/12 (Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.; CAS RN 61791-44-4)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: No  
Year: 1965  
Species: Dog  
Strain: Beagle  
Route of administration: Oral (feed)  
Duration of test: 90 days  
Doses/concentration levels: 0, 13, 40 and 120 mg/kg  
Sex: Male and female  
Exposure period: 90 days  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; concurrent, untreated diet  
Post exposure observation period: None  
Statistical methods: None  
Remarks: Groups of four male and female dogs were fed diets containing the test substance at concentrations to yield doses of 0, 13, 40 and 120 mg/kg. Diets were prepared at the laboratory and contained a meat preparation, dry pelleted diet and corn oil. Test substance was added to experimental diets. The main meal was offered to each dog daily at noon and a dog biscuit was offered late each afternoon. Water was available *ad libitum*. Body weights were recorded at study initiation and weekly during the treatment period. Hemoglobin concentrations, packed-cell volumes, white-cell counts and differential white-cell counts were measured in all animals prior to treatment and immediately prior to sacrifice. Blood urea, serum alkaline phosphatase, liver function and urine analysis also were tested. At the end of the test period, dogs were sacrificed, and the following organ weights were recorded: heart, liver, kidneys, adrenals, spleen, thyroid, testes, epididymes, brain and pituitary. For microscopic examination, representative sections were taken from the following organs: brain (cerebrum, cerebellum and medulla), spinal cord, pituitary, submaxillary gland, thyroid,

thymus, heart, lung, aorta, stomach, duodenum, jejunum, ileum, colon, liver, spleen, kidney, bladder, adrenal, ovary and uterus or testes and epididymis, and sciatic nerve.

## Results

NOAEL (NOEL)

NOEL = 13 mg/kg/day

LOAEL (LOEL)

LOEL = 50 mg/kg/day

Actual dose received:

Not determined

Toxic response/effects:

Described below

Statistical results:

None

Remarks:

No deaths occurred in any group. Dogs given the dietary concentration of 120 mg/kg/day frequently vomited the meal, despite attempts to condition the dogs to the meal either by gradual dose increment or by offering the food in small quantities throughout the day. Treatment in this group was terminated after five to six weeks due to the general poor health of these dogs and the loss of approximately 20% of their initial body weight. Dogs in the 40 mg/kg dose group vomited sporadically and showed signs of anorexia daily. On occasion dogs refused part of the meal when offered. However, no specific signs were observed other than subdued physical activity with the occasional vomiting. A decrease in body weight was observed in male dogs in this dose group at study termination. Vomiting did not occur in dogs given 13 mg/kg of the test substance or in the control group, and no clinical signs were observed in the dogs in either group. Dogs in both of these groups showed increases in body weight at study termination. At week 5, hematology results revealed a degree of simple hypochromic anemia in females in the 120 mg/kg dose group. Clinical blood chemistry showed a slight elevation in the blood urea and serum alkaline phosphate levels at week 6 in male dogs treated with 120 mg/kg of the test substance. In addition, the liver function test showed some retention of bromsulphalein in male dogs fed 120 mg/kg of the test substance. There were no urine analysis findings. No gross pathological variations or gross lesions were observed in the any dogs that were considered to be treatment-related. Histologic evaluations revealed an increase in the incidence of foamy macrophages in the small intestine and regional lymph nodes of dogs in the 40 and 120 mg/kg/day groups. The incidence of these foamy macrophages in the 13-mg/kg/day group was

comparable with the control group suggesting that the increased incidence at higher dose levels was an accentuation of a normal response. Reproductive organs were examined, meeting the requirements for SIDS/HPV reproductive screening.

### **Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### **References**

Goater, T. O., D. Griffiths and T. F. McElligott. 1965. Ninety-Day Oral Toxicity of Ethomeen T/12 – Beagle Dogs. Report No. IHR/175. Industrial Hygiene Research Laboratories, Macclesfield, Cheshire.

### **Other available reports**

Goater, T.O., D. Griffiths, T.F. McElligott and A.A.B. Swan. 1970. Summary of Toxicology Data - Acute Oral Toxicity and Short-Term Feeding Studies on Polyoxyethylene Tallow Amine in Rats and Dogs. Food & Cosmetics Toxicol. 8:249-252.

### **Other**

Last changed:

June 10, 2002

Order number for sorting:

116 and 134d

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Test article E1095.01 (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derives.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: Oral  
GLP: Yes  
Year: 1981  
Species: Rat  
Strain: CrI:CD(SD)BR  
Route of administration: Oral (feed)  
Duration of test: 13 weeks  
Doses/concentration levels: 0.001, 0.015 and 0.5% w/w (approximately 0.8, 12, and 400 mg/kg/day)  
Sex: Male and female  
Exposure period: 13 weeks  
Frequency of treatment: *ad libitum*  
Control group and treatment: Yes; untreated powdered diet  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Four groups of 40 rats (20 males and 20 females) were fed diets containing the test substance at concentrations of 0, 0.001, 0.015 and 0.5% w/w for 13 weeks, or until necropsy. The test substance was added to experimental diets as solutions in corn oil (1%). Rats at approximately 6-1/2 weeks of age, weighing 136 to 188 g (males) and 119 to 165 g (females), were acclimated to the laboratory for 19 days prior to test initiation. With the exception of an overnight fasting period before necropsy, food and water were available *ad libitum*. All animals were examined at least once daily for signs of ill health, overt toxicity or behavioral changes. Individual body weights and group food consumption were recorded weekly throughout the study. Hematology analyses and necropsy were performed on all rats. Organ weights (adrenals, kidneys, lungs, testes, heart, liver and ovaries) were determined at necropsy. Histopathology, including reproductive organs, was conducted for all animals in the control and high dose groups. In addition, jejunum and mesenteric lymph nodes were examined for animals in Groups 2 and 3. The “no effect” dose level

was determined on the basis of evidence of systemic toxicity at the respective dosage levels.

## Results

NOAEL (NOEL)	0.015% (approximately 12 mg/kg/day)
LOAEL (LOEL)	Not stated
Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Not applicable
Number of deaths:	Control = 0/20 males; 1/20 females (during blood sampling) 0.001% w/w = 0/20 males; 0/20 females 0.015% w/w = 0/20 males; 0/20 females 0.5% w/w = 0/20 males; 0/20 females
Remarks:	A high incidence of hair loss observed across all groups within each sex (70-90% males; 35-70% females) was not considered to be treatment related. Body weight gain was slightly reduced in the 0.5% w/w treatment group and the 0.015% male treatment group. Food consumption was similar among all groups relative to the control. There were no biologically significant differences in hematology or organ weights between treatment and control groups during Week 13. Histiocytosis, characterized by aggregations of macrophages with foamy cytoplasm, in the jejunum and mesenteric lymph nodes in the 0.5% w/w treatment group was the only treatment related histopathological finding in this study. Histiocytosis was not observed in these organs of the lower dose groups. No treatment-related effects on organ weights or histopathology of the reproductive organs were seen.

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	1B
Remarks:	Reliable without restrictions; comparable to guideline study.

**References**

Sheppard, D.B. 1982. 13 Week Oral (Dietary) Toxicity Study in the Rat: ECM BTS 306, E1095.01. Unpublished report (No. 2913-110/369), for Proctor and Gamble, Ltd., Longbenton, Newcastle-upon-Tyne, England; from Hazleton Laboratories Europe, Ltd., Harrogate, England.

**Other**

Last changed/Initials:

September 21, 2003

Order number for sorting:

297

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: Polyethoxylated Tallowamine; Varonic T-220  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derives.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: 28-Day Percutaneous Toxicity  
GLP: Yes  
Year: 1979  
Species: Rabbit  
Strain: New Zealand Albino (Dutchland)  
Route of administration: Dermal  
Duration of test: 28 days  
Doses/concentration levels: 2 mL/kg; 10% w/v aqueous; reduced to 2% w/v aqueous after 2 treatments (200 mg/kg/day reduced to 40 mg/kg/day)  
Sex: Male and female  
Exposure period: 28 days  
Frequency of treatment: Daily, 5 days/week, 4 weeks  
Control group and treatment: Yes; distilled water  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Five rabbits of each sex were initially administered 2 doses of 10% w/v aqueous test substance on abraded exposure sites. The dose concentration was reduced to 2% w/v aqueous and abrasion was discontinued for the remaining 18 treatments due to severe reaction to the 10% w/v aqueous doses. The control group (also 5 rabbits/sex) was administered distilled water to abraded exposure sites for the full 20 treatments. Individual body weights were measured weekly for the 28-day study period. Hematology analyses and a full necropsy were performed at termination. Organ weights (liver and kidney) were collected at necropsy. Histopathology on several tissues, including treated skin, was conducted on all rabbits.

### Results

NOAEL (NOEL) Not stated  
LOAEL (LOEL) Not stated  
Actual dose received: Not stated  
Toxic response/effects: Described below  
Statistical results: Not applicable

Number of deaths: Control group: 0/5 males, 0/5 females;  
Treatment group: 0/5 males, 0/5 females  
0.5% w/w = 0/20 males; 0/20 females

Remarks: The test substance produced severe erythema to severe edema, severe atonia, mild to severe desquamation and mild and a high sheen appearance following the sloughing of eschar tissue during the course of the study. The severe skin reactions initially observed on treatment animals required the dose reduction to 2% w/v aqueous and termination of the abrasion to exposure site after 2 treatments. Skin conditions of these animals improved on Day 13 and remained relatively constant throughout the remainder of the study. No test related effects were reported on test sites of water control animals for which abrasion was continued throughout the study period.

Body weight losses were reported for 6 of the 10 treated animals by the end of week one, after which a steady weight gain was reported. One animal remained below its initial weight by the end of the study. A normal weight gain pattern was reported for the control animals.

Anorexia was reported in 3 animals which, along with 2 other animals, also displayed signs of rales. No biologically significant, treatment related effects on hematology were observed in the treated animals. Additionally, necropsy confirmed treatment related adaptive, cutaneous morphological alterations, likely associated with occurrence of focal inflammatory respiratory tract disease. Skin lesions were characterized microscopically as epidermal and keratin layer thickening. Liver, kidney and body weights were comparable in treatment and control groups. A decreased kidney weight in treated females, relative to control females, was not considered to be biologically significant.

### Conclusions

Remarks: This study is useful in the overall evaluation of repeated dose toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 2B

Remarks:

Reliable with restrictions; complete study details were not provided.

**References**

Nixon, G.A. 1980. Subchronic Percutaneous Toxicity Study (28-Day). Unpublished report (No. BSBTS 593S; YE-252-B), Miami Valley Laboratories, H&ES Division, Proctor and Gamble Company, Cincinnati, OH, USA.

**Other**

Last changed/Initials:

September 21, 2003

Order number for sorting:

299

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine T-220D; Varonic T-220D  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: Not stated

Remarks:

### Method

Method/guideline followed: Not stated

Test type: 28-Day Dermal Toxicity

GLP: Yes

Year: 1980

Species: Rabbit

Strain: New Zealand White

Route of administration: Dermal

Duration of test: 28 days

Doses/concentration levels: 2.0 mL/kg; 2% w/v aqueous (40 mg/kg/day)

Sex: Male and female

Exposure period: 28 days

Frequency of treatment: Daily, 5 days/week, 4 weeks

Control group and treatment: Yes; distilled water

Postexposure observation period: None

Statistical methods: Not stated

Remarks: Five young adult rabbits of each sex, weighing 2.0 to 3.0 kg, were administered distilled water (control) or the liquid test substance as a 2% w/v aqueous suspension at a dosage volume of 2.0 mL/kg daily, 5 days per week for 4 weeks. The exposure sites were prepared, just prior to study initiation and every 3 to 4 days throughout the study before application of test suspension, by clipping the back of each animal and abrading the horny layer of the epidermis without causing bleeding. Skin abrasion was discontinued if the skin became fissured. The test substance (or distilled water) was applied through a syringe, with gentle inunction using a glass rod, spread evenly over the test site and left for 7 hours of exposure. All rabbits were examined daily for gross pharmacotoxic signs and mortality. Skin irritation was recorded daily according to the method of Draize. Individual body weights were measured at initiation and weekly for the 28-day study period. Hematology analyses and a complete necropsy was performed at termination. Liver and kidneys were weighed at necropsy. Histopathology, including treated skin and

reproductive organs, was performed for all rabbits.

## Results

NOAEL (NOEL)

Not stated

LOAEL (LOEL)

Not stated

Actual dose received:

Not stated

Toxic response/effects:

Described below

Statistical results:

Not applicable

Number of deaths:

Control group: 0/5 males, 0/5 females;

Treatment group: 0/5 males, 0/5 females

Remarks:

No dermal irritation was observed in the first three days of the study. Signs of irritation were observed by the end of Week 1. Dermal irritation was most severe in Week 2, during which all animals exhibited moderate to severe erythema and edema, slight to moderate atonia, slight to marked desquamation, moderate coriaceousness and slight to severe fissuring of the exposure sites. The degree of dermal irritation was reduced slightly during the third week and then increased slightly during the fourth week. No dermal irritation was observed in the control group.

Significant differences in individual body or organ weights of treated rabbits relative to the control rabbits were not observed. Statistically significant and treatment related changes in hematological values were not observed in treated animals, relative to the control group. Histologically, mild to moderate hyperplasia of the epidermis and mild inflammatory changes of the outer dermis were observed at the exposure sites of treated animals. Cholangitis was observed in treated and control animals, probably due to a prestudy hepatic coccidial infection endemic to the test animals.

## Conclusions

Remarks:

This study is useful in the overall evaluation of repeated dose toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

1D

Remarks:

Reliable without restrictions; only one dose group was used in the study.

**References**

Thompson, G.W. 1980. Subchronic 28-Day Dermal Toxicity Study of B0254-01 in Rabbits. Unpublished report no. 277723 (Study 80513), for The Proctor and Gamble Company, Cincinnati, OH, USA from Raltech Scientific Services, Madison, WI, USA.

**Other**

Last changed/Initials: September 21, 2003

Order number for sorting: 300

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: ECM BTS 306, E1069.02 (CAS RN 61791-44-4;  
Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: 4-Week Percutaneous Toxicity  
GLP: Yes  
Year: 1980  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Dermal  
Duration of test: 4 weeks  
Doses/concentration levels: 2.0 mL/kg; 0.1 or 0.5% w/v aqueous dispersions (2 and 10 mg/kg/day)  
Sex: Male and female  
Exposure period: 4 weeks  
Frequency of treatment: Daily, 5 days/week  
Control group and treatment: Yes; distilled water  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Five young adult rabbits of each sex, weighing 2.5 to 3.3 kg, were administered distilled water (control) or the liquid test substance as 0.1 or 0.5% w/v aqueous dispersions at a dosage volume of 2.0 mL/kg daily, 5 days per week for 4 weeks. The test dispersion (or distilled water) was applied to the shaved dorso-lumbar region of each animal through a syringe and left for 7 hours before removal by washing. All rabbits were examined at least once daily for signs of ill-health or overt toxicity. Skin irritation was assessed daily using a Draize scoring procedure. Individual body weights were measured at initiation and weekly through the study period. Hematology analyses and a complete necropsy were conducted at termination. Organ weights (adrenals, heart, liver, kidneys, lungs, and ovaries/testes) were weighed at necropsy. Histopathology was performed for tissues, including treated skin and reproductive organs, of all rabbits in the control and high dose groups.

### Results

NOAEL (NOEL) Not stated  
LOAEL (LOEL) Not stated

Actual dose received:	Not stated
Toxic response/effects:	Described below
Statistical results:	Not applicable
Number of deaths:	Control group: 1/5 males, 0/5 females; 0.1% w/v aqueous dispersion: 2/5 males, 2/5 females; 0.5% w/v aqueous dispersion: 0/5 males, 1/5 females
Remarks:	Three animals of each sex died or were killed because of illness before study termination, none of which were deemed treatment related. Skin irritation developed in all rabbits of the 0.5% w/v treatment group within 24 hours and persisted throughout the study. Slight erythema and edema developed into moderate erythema in most rabbits in this group after the second treatment. Slight to moderate fissuring and atonia with wrinkled skin and slight desquamation also developed during the first half of the study, although the presence of a thick layer of skin prevented assessment of edema and atonia in one rabbit in this group. Skin irritation in the lower concentration, 0.1% w/v, treatment group was characterized by slight erythema 2 days after treatment, which developed into moderate erythema 2 days later. Slight edema, desquamation and wrinkled skin also developed in most animals in this group. No reaction to treatment was observed in the control group.

There were no treatment-related effects on body weights, organ weights or hematology. The skin reaction found in all rabbits in the 0.5% w/v treatment group was assessed histologically as slight to moderate and was characterized by slight to moderate acanthosis, hypergranulosis and hyperkeratosis accompanied by slight congestion, edema and leucocyte infiltration in the superficial dermis. One rabbit in this group had an acute inflammatory reaction at the exposure site and died during the study. A few rabbits in the control group had a few minor changes in the treated skin site. While infrequent, minor pathological findings were noted in surviving rabbits in both treatment groups, there was no evidence of systemic toxicity.

## Conclusions

Remarks:	Repeated topical application of the test substance at 0.1 and 0.5% w/v to the non-abraded skin of rabbits elicited overt slight and moderate irritation, respectively. There was no evidence of systemic
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toxicity from mortalities, clinical changes, hematological measurements, body and organ weights or pathological findings.

This study is useful in the overall evaluation of repeated dose toxicity of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1D

Remarks:

Reliable without restrictions; only two dose groups were examined.

**References**

Shaw, D.C. 1982. E1069.02: A 4 Week Percutaneous Toxicity Study in the Rabbit, ECM BTS 306. Unpublished report no. 2827-110/366, for The Procter and Gamble Limited, Longbenton, Newcastle-Upon-Tyne, England, from Hazleton Laboratories Europe, Ltd., Harrogate, North Yorkshire, England.

**Other**

Last changed/Initials:

September 21, 2003

Order number for sorting:

301

Remarks:

## 5.4 REPEATED DOSE TOXICITY

### Test Substance

Identity: ECM BTS 306, E1069.02 (CAS RN 61791-44-4;  
Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Test type: 13-Week Dermal Toxicity  
GLP: Yes  
Year: 1981  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Dermal  
Duration of test: 13 weeks, treatment discontinued at Day 17  
Doses/concentration levels: 2.0 mL/kg; 0.1 or 0.5% w/v aqueous dispersions (2 or 10 mg/kg/day)  
Sex: Male and female  
Exposure period: 17 days  
Frequency of treatment: Daily, 5 days/week  
Control group and treatment: Yes; distilled water  
Postexposure observation period: None  
Statistical methods: Not stated  
Remarks: Five young adult rabbits of each sex, weighing 2.25 to 2.85 kg, were administered distilled water (control) or the liquid test substance as 0.1 or 0.5% w/v aqueous dispersions at a dosage volume of 2.0 mL/kg/day, 5 days per week through the 1x7-day period. The test dispersion (or distilled water) was applied to the non-abraded, shaved dorso-lumbar region of each animal through a syringe and left for 7 hours before removal by washing. Individual body weights were measured at initiation and weekly through the study period. Hematology was performed only at study initiation. No necropsy or histopathology was conducted.

### Results

NOAEL (NOEL) Not stated  
LOAEL (LOEL) Not stated  
Actual dose received: Not stated  
Toxic response/effects: Described below  
Statistical results: Not applicable  
Number of deaths: Control group: 0/5 males, 1/5 females;  
0.1% w/v aqueous dispersion: 1/5 males, 0/5 females;  
0.5% w/v aqueous dispersion: 3/5 males, 1/5 females  
Remarks: The proposed 13-week study period was terminated at

Day 17, as assessment of systemic toxicity became precluded by moderate/marked skin irritation. One male rabbit from the high concentration, 0.5% w/v, treatment group was killed on Day 8 because of open ulceration and bleeding at the exposure site. Five other animals across the three groups died or were killed during the study, for which cause of death was not determined.

Body weight in two male rabbits in the high concentration treatment group decreased, while most other animals gained weight.

Skin irritation characterized as slight erythema in 8 rabbits of the 0.5% w/v treatment group within 24 hours developed into moderate erythema and edema with slight desquamation, fissuring and atonia with wrinkled skin by Day 5. The exposure site on male animals in this group developed a thickening of the epidermis, which precluded assessment of edema and atonia in some animals. Skin irritation in the lower concentration, 0.1% w/v, treatment group was characterized by slight to moderate erythema and slight edema, desquamation and atonia with wrinkled skin. No reaction to treatment was observed in the control group.

## Conclusions

Remarks:

Repeated topical application of the test substance at 0.1 and 0.5% w/v to the non-abraded skin of rabbits elicited overt slight and moderate/marked irritation, respectively. The skin reaction was considered likely to affect absorption of the test article at the test site if treatment was continued for the intended 13 weeks, in which case systemic toxicity could have been questioned. For this reason and because the treatment concentrations used in this study could not be reduced, the study was terminated early.

This study is useful in evaluating the skin irritation of the test substance. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

Remarks:

1D

Reliable without restrictions; study was terminated due to skin irritation.

**References**

Shaw, D.C. 1981. E1069.02: A 13 Week Percutaneous Toxicity Study in the Rabbit, ECM BTS 306. Unpublished report no. 2805-110/367, for The Procter and Gamble Limited, Longbenton, Newcastle-Upon-Tyne, England, from Hazleton Laboratories Europe, Ltd., Harrogate, North Yorkshire, England.

**Other**

Last changed/Initials:

September 21, 2001

Order number for sorting:

302

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: PA-17 (CAS RN 68511-40-0; 1-Propanamine, 3-(tridecyloxy)-, branched)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Plate incorporation method described by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res.* **31**:347-364; and updated by Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res.* **113**:173-215.

Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Yes  
Year: 1994  
Species/Strain: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538.  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats  
Concentrations tested: 0.33, 1.0, 3.3, 10, 33 and 100 µg per plate.  
Statistical methods: Not stated  
Remarks: A dose-range finding study indicated that a maximum of 100 µg per plate be used for the mutagenicity assay, the maximum dose tested was 5000 µg per plate and results indicated no precipitate but toxicity was observed. The test substance was diluted in 100% ethanol, which was also used as the vehicle control. 2-Aminoanthracene (1.0 µg/plate) was the positive control for all tester strains with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (1.0 µg/plate, TA98 and TA 1538); sodium azide (1.0 µg/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The positive control, vehicle control and all test substance doses were plated in triplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After vortexing, the mixture was overlaid onto the surface of 25 ml of minimal bottom agar. After

solidification, the plates were inverted and incubated for 48-72 hours at  $37\pm 2^{\circ}\text{C}$ .

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without activation.
Cytotoxic concentration:	$\geq 100 \mu\text{g}$ per plate with S-9 activation $\geq 33 \mu\text{g}$ per plate without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	1B
Remarks:	Reliable without restrictions; comparable to guideline study.

## References

San, R. H. C. and M. L. Klug. 1994. *Salmonella* Plate Incorporation Mutagenicity Assay (Ames Test). Report No. G94AV84.501. Microbiological Associates, Inc., USA.

## Other available reports

### Other

Last changed:	July 15, 2002
Order number for sorting:	140
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Farmin DM 40 (CAS RN 112-75-4  
1-Tetradecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res.* **31**:347-364; and Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res.* **113**:173-215.  
Type: Reverse mutation assay (pour-plate assay)  
System of testing: Bacterial  
GLP: Yes  
Year: 1995-1996  
Species/Strain: *Salmonella typhimurium* strains TA98, and TA100.  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system.  
Concentrations tested: 0.5, 1.6, 5.0, 15.8 and 50 µg per plate.  
Statistical methods: Not stated  
Remarks: Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and Benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in this bacterial system.
Cytotoxic concentration:	50 µg per plate
Genotoxic effects:	Negative with and without activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2D
Remarks:	Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated.

## References

May, K. 1996. Farmin DM40: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

## Other

Last changed:	July 11, 2002
Order number for sorting:	257
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Hexadecylamine (CAS RN 143-27-1)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Not stated  
Year: 1983  
Species/Strain: *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535  
Metabolic activation: With and without S-9 activation; S-9 mix obtained by 9000 x g liver of Aroclor 1254-induced male Sprague Dawley rats and Syrian hamsters  
Concentrations tested: 0.3, 1.0, 3.0, 10.0, 33.0, 66.0 and 100.00 µg/plate  
Statistical methods: Not stated  
Remarks: A preincubation modification of the *Salmonella* test was used; the test substance was incubated with the tester strain, in either a 10% S-9 plus cofactor mix or buffer, for 20 minutes at 37°C prior to the addition of soft agar and plating on minimal agar plates for detection of induced mutation. The test substance was tested, in triplicate, at seven doses, along with positive and solvent (water) controls in the absence of exogenous metabolic activation, in the presence of rat liver S-9, and in the presence of hamster liver S-9. For those tests that yielded an equivocal response, the entire test was repeated with 30% S-9 at least one week after the initial test. A positive response was defined as a reproducible, dose-related increase in histidine-independent (revertant) colonies. An equivocal response was either a non-dose-related increase or a response that was not reproducible

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without metabolic activation.  
Cytotoxic concentration: Not stated  
Genotoxic effects: Negative with and without activation  
Statistical results: Not stated  
Remarks:

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1D

Remarks:

Reliable without restriction; older study, prior to  
guideline development.

**References**

Akzo Chemie America. 1984. Letter from Akzo  
Chemie America to US EPA regarding Oleylamine  
test results with attachment. EPA Doc.  
No. 40-8484007, Microfiche No. OTS0526846.

**Other**

Last changed:

July 18, 2002

Order number for sorting:

73a

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Hexadecylamine (CAS RN 143-27-1)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Not stated  
Year: 1988  
Species/Strain: *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535  
Metabolic activation: With and without metabolic activation; Aroclor-induced liver homogenate from rats and hamsters  
Concentrations tested: 0.3 to 100µg per plate  
Statistical methods: Not stated  
Remarks: Preincubation test

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system.  
Cytotoxic concentration: Not stated  
Genotoxic effects: Negative with and without activation  
Statistical results: Not stated  
Remarks:

### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 2D  
Remarks: Reliable with restrictions; data from summary document; acceptable because data consistent with other data in subcategory.

## References

Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K. Mortelmans. 1988. *Salmonella* Mutagenicity Tests: IV. Results from the Testing of 300 Chemicals. Supplement 12. Environ. Mol. Mutagen. 11:1-158. As cited in German Chemical Society. 1994. Primary Fatty Amines. GDCh-Advisory Committee on Existing Chemicals of Environmental Relevance (BUA). BUA Report 177; December. S. Hirzel, Wissenschaftliche Verlagsgesellschaft Stuttga.

## Other available reports

### Other

Last changed:

June 5, 2002

Order number for sorting:

73b

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Farmin DM 60 (CAS RN 112-69-6  
1-Hexadecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res.* **31**:347-364; and Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res.* **113**:173-215.  
Type: Reverse mutation assay (pour-plate assay)  
System of testing: Bacterial  
GLP: No  
Year: 1995-1996  
Species/Strain: *Salmonella typhimurium* strains TA98, and TA100.  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system.  
Concentrations tested: 0.5, 1.6, 5.0, 15.8 and 50 µg per plate.  
Statistical methods: Not stated  
Remarks: Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and Benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in this bacterial system.
Cytotoxic concentration:	50 µg per plate
Genotoxic effects:	Negative with and without activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2D
Remarks:	Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated.

## References

May, K. 1996. Farmin DM60: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

## Other

Last changed:	July 11, 2002
Order number for sorting:	4e
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: 1-Octadecyl amine (CAS RN 124-30-1)  
Purity: 90%  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Not stated  
Year: 1988  
Species/Strain: *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535  
Metabolic activation: With and without metabolic activation; Aroclor-induced liver homogenate from rats and hamsters both at 10% and 30%.  
Concentrations tested: 0, 100, 333, 1000, 3333 and 6666 µg per plate  
Statistical methods: Not stated  
Remarks: Preincubation test. Each test was run in triplicate. The vehicle used was water, which was also used as the negative control. The following positive control groups were included with activation: sodium azide (TA100 and TA1535), 9-aminoacridine (TA97) and 4-nitro-o-phenolenediamine. 2-aminoanthracene was used as the positive control for all strains without activation. The criteria used for positive results was a dose-related increase in the number of revertant colonies.

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system.  
Cytotoxic concentration: Not stated  
Genotoxic effects: Negative with and without activation  
Statistical results: Not stated  
Remarks: In the test using 10% rat S-9, precipitate was observed at the 333 µg/plate dosage level. In the test using 10% hamster S-9, precipitate was observed at the 1000 µg/plate dosage level. This would implicate that only 100 and 333 µg/plate concentrations could be evaluated for these tests. For all other tests no presence of precipitate was reported; therefore, overall validity of the results for the remaining tests is not affected. All positive controls exhibited sufficient mutant colonies.

**Conclusions**

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch): 2A  
Remarks: Reliable with restrictions; acceptable, well-  
documented publication/study report which meets  
basic scientific principles.

**References**

Zeiger, E., B. Anderson, S. Haworth, T. Lawlor and K.  
Mortelmans. 1988. *Salmonella* Mutagenicity Tests:  
IV. Results from the Testing of 300 Chemicals.  
Supplement 12. Environ. Mol. Mutagen. 11:1-158.

**Other available reports**

**Other**

Last changed: June 5, 2002  
Order number for sorting: 40d  
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: 1-Octadecyl amine (CAS RN 124-30-1)  
Purity: ca. 100%  
Remarks:

### Method

Method/guideline followed: Method described by Green, M.H.L. and W.J. Muriel: Mutagen testing using  $\text{trp}^+$  reversion in *Escherichia coli*, Mutation Res. 38 (1976) 3-32.

Type: Ames test  
System of testing: Bacterial  
GLP: Yes  
Year: 1988  
Species/Strain: *Salmonella typhimurium*/strains TA 100, TA 1535, TA 1537, TA 1538, TA 98  
*Escherichia coli*/ strain WP2uvrA

Metabolic activation: With and without metabolic activation; S-9 mix prepared from liver homogenate of Aroclor 1254-induced male Sprague Dawley rats

Concentrations tested: Experiment 1: 0, 4, 20, 100, 500, 2500, 10000  $\mu\text{g}/\text{plate}$   
Experiment 2: 0, 4, 20, 100, 500, 2500 and 5000  $\mu\text{g}/\text{plate}$

Statistical methods: Not stated

Remarks: Toxicity tests were performed prior to the mutagenicity test. Liver homogenate fraction and S-9 mix were prepared at the laboratory. On the day of the experiment the test substance was dissolved in ethanol at appropriate concentrations. Two independent experiments were performed. Positive and negative controls were run with each experiment. The positive controls without metabolic activation were: Sodium azide (TA100, TA1535), 9-aminoacridine (TA 1537), 2-nitrofluorene (TA98, TA1538) and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). The positive controls with metabolic activation were: benzo[a]pyrene and 2-aminoanthracene (all strains). The negative control was exposed to the solvent, ethanol. After mixing the agar, nutrient broth culture of the bacterial tester strain, test compound solution, S-9 mix (for tests with activation) or buffer (for tests without activation), the liquid was poured into a petri dish with minimal agar and incubated for 48 to 72 hours at 37°C in the dark.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in these bacterial systems.
Cytotoxic concentration:	100 µg/plate
Genotoxic effects:	Negative with and without activation
Statistical results:	Not stated
Remarks:	Visible precipitation of the test compound on the plates was observed at 500 µg/plate and higher. Therefore, only the 4, 20 and 100 µg/plate concentrations were considered valid for interpretation.

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	1D
Remarks:	Reliable without restrictions; only two dose levels were used to evaluate mutagenicity since cytotoxicity was observed at 100 µg/plate. Guideline studies need at least five concentrations evaluated. However, the highest nontoxic concentrations were negative thus providing a negative assay.

## References

Müller, W. 1988. Genamin 18 R 100 D, Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames test) and *Escherichia coli*. Report No. 88.0407. 01, Hoechst AG, ATA, TH-TVS.

## Other available reports

### Other

Last changed:	August 12, 2002
Order number for sorting:	40c
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Octadecylamine (CAS RN 124-30-1)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Not stated  
Year: 1983  
Species/Strain: *Salmonella typhimurium* strains TA 97, TA 98, TA 100 and TA 1535  
Metabolic activation: With and without S-9 activation; S-9 mix obtained by 9000 x g liver of Aroclor 1254-induced male Sprague Dawley rats and Syrian hamsters  
Concentrations tested: 100, 333, 1000, 3333 and 6666 µg/ plate  
Statistical methods: Not stated  
Remarks: A preincubation modification of the *Salmonella* test was used; the test substance was incubated with the tester strain, in either a 10% S-9 plus cofactor mix or buffer, for 20 minutes at 37°C prior to the addition of soft agar and plating on minimal agar plates for detection of induced mutation. The test substance was tested, in triplicate, at five doses, along with positive and solvent (water) controls in the absence of exogenous metabolic activation, in the presence of rat liver S-9, and in the presence of hamster liver S-9. For those tests that yielded an equivocal response the entire test was repeated with 30% S-9 at least one week after the initial test. A positive response was defined as a reproducible, dose-related increase in histidine-independent (revertant) colonies. An equivocal response was either a non-dose-related increase or a response that was not reproducible.

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system with and without metabolic activation.  
Cytotoxic concentration: Not stated  
Genotoxic effects: Negative with and without activation  
Statistical results: Not stated  
Remarks:

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1D

Remarks:

Reliable without restriction; older study, prior to  
guideline development.

**References**

Akzo Chemie America. 1984. Letter from Akzo  
Chemie America to US EPA Regarding Oleylamine  
Test Results with Attachment. EPA Doc.  
No. 40-8484007, Microfiche No. OTS0526846.

**Other**

Last changed:

July 18, 2002

Order number for sorting:

73

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: ODA-FG-11-27-87 (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Yes  
Year: 1985  
Species/Strain: *Salmonella typhimurium* strains TA 1535, TA 1537,  
TA 1538, TA 98 and TA 100  
Metabolic activation: With and without S-9 activation; S-9 mix obtained  
from the liver of Aroclor 1254-induced rats  
Concentrations tested: 100, 50, 25, 10 and 2 µg per plate with activation;  
15, 10, 5, 1 and 0.2 µg per plate without activation  
Statistical methods: None performed  
Remarks: Test substance was diluted in acetone, which was also  
used as the negative control. All positive controls,  
solvent controls and test substance doses were plated  
in triplicate. The S-9 homogenate and mix was  
prepared at the testing facility. The S-9 mix was  
prepared immediately before use. The initial toxicity  
assay indicated the following concentrations be used  
for the mutagenicity testing: 200, 100, 50, 10 and 2 µg  
per plate with activation, and 20, 10, 5, 1 and 0.2 µg  
per plate without activation. The results of this assay  
were more toxic than predicted so another assay was  
run with the following concentrations: 100, 50, 25, 10  
and 2 µg per plate with activation, and 15, 10, 5, 1 and  
0.2 µg per plate without activation.

### Results

Result: The test substance did not induce reverse mutations in  
the tested strains of *Salmonella typhimurium* in the  
presence or absence of S-9 activation.  
Cytotoxic concentration: 100 µg/plate with activation, 15 µg/plate without  
activation  
Genotoxic effects: Negative; with and without activation  
Statistical results: None  
Remarks:

### Conclusions

Remarks:

The results indicated that under the conditions of this study the test article did not cause a positive response on any of the tester strains with or without metabolic activation by Aroclor-induced rat liver microsomes.

(Author of report)

The endpoint has been adequately characterized.

(American Chemistry Council, Fatty Nitrogen

Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Haworth, S. R. 1985. *Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test.). Report No. T2693.501.

Microbiological Associates, Inc., Bethesda, MD, USA.

Submitted to EPA by Chem. Manuf. Assoc. as EPA

Doc. No. 40-8584197.

### Other

Last changed:

July 17, 2002

Order number for sorting:

19

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: (Z)-9-Octadecenylamine (CAS RN 112-90-3)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Based on published methodologies: Machanoff, R. *et al.*, 1981, Quantitative analysis of cytotoxicity and mutagenicity of benza(a)pyrene in mammalian cells (CHO/HGPRT), *Chem. Biol. Interactions* 34:1-10 and O'Neill, J. P. *et al.*, 1977, A quantitative assay of mutation induction at the hypoxanthineguanine phosphoribosyl transferase locus in Chinese hamster ovary cells (CHO/HGPRT system): Development and definition of the system, *Mutat. Res.* 45:91-101.

Type: Mammalian cell forward mutation assay (HGPRT gene mutation)

System of testing: Nonbacterial

GLP: Not stated

Year: 1984-1985

Species/Strain: Chinese hamster ovary cells

Metabolic activation: With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced male Fischer 344 rats

Concentrations tested: First assay:  
0.1, 0.5, 1.0, 1.5 and 2.0 nl/ml (absence of S-9)  
5.0, 6.0, 7.0, 8.0 and 9.0 nl/ml (presence of S-9)  
Second assay (two independent parallel experiments were performed):  
1.0, 1.5, 2.0, 2.25 and 2.5 nl/ml (absence of S-9)  
7.0, 8.0, 9.0, 9.5 and 10.0 nl/ml (presence of S-9)

Statistical methods: Not stated

Remarks: Two preliminary toxicity tests were performed to determine dose levels in the gene mutation assay. The high dose level in the gene mutation assay was selected to produce a cell survival rate of 10 to 30% of control values, when possible. The lowest dose level was to be non-toxic.  
Exponentially growing CHO-K<sub>1</sub>-BH<sub>4</sub> cells were plated in F12FBS5 at a density of 5 x 10<sup>5</sup> cells/25 cm<sup>2</sup> flask and were incubated at 37 ± 1°C in a humidified atmosphere of 5% CO<sub>2</sub> in air for 18-24 hours. Duplicate cultures per treatment condition were used for the mutation assay. The solvent for the test substance was DMSO. Cells were exposed to the concentrations listed above for five hours at 37 ± 1°C.

The pH of the media was monitored, and no adjustment was required. After the treatment period, all media were aspirated, the cells washed with HBSS and cultured in F12FBS5 for an additional 18-24 hours at  $37 \pm 1^\circ\text{C}$ . At this time the cells were subcultured to assess cytotoxicity and to initiate the phenotypic expression period. EMS was used as the positive control in the assay conducted in the absence of S-9 at a concentration of  $0.2 \mu\text{l/ml}$ . BaP was used as the positive control in the assay conducted in the presence of S-9 at a concentration of  $4.0 \mu\text{g/ml}$ . The solvent vehicle for the test substance (DMSO) was used as the solvent control at the same concentration as that found in the test substance-treated groups. Growth medium was used in the untreated (negative) control. The assay was considered positive in the event a dose-dependent increase in mutation frequency was observed with one or more of the four concentrations tested inducing a mutation frequency that is at least twice that of the solvent control. The assay was considered suspect if there was no dose response but one or more doses induced a mutation frequency that was at least twice that of the solvent control. The assay was considered negative if none of the doses tested induced a mutation frequency that was at least twice that of the solvent control.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in this mammalian cell gene mutation assay.
Cytotoxic concentration:	2.5 nl/ml in the absence of metabolic activation 10.0 nl/ml in the presence of metabolic activation
Genotoxic effects:	Negative with and without metabolic activation
Statistical results:	Described below
Remarks:	In the absence of S-9, relative to the solvent control, survival (relative cloning efficiency) was 102, 101, 74, 67 and 62% at 0.1, 0.5, 1.0, 1.5 and 2.0 nl/ml, respectively, for the first assay; was 98, 101 and 65% at 1.0, 1.5 and 2.0 nl/ml, respectively, in the first parallel experiment of the second assay; and was 107, 126 and 58% at 1.0, 1.5 and 2.0 nl/ml, respectively, in the second parallel experiment of the second assay. The higher dose levels, 2.25 and 2.5 nl/ml in the absence of S-9, were too toxic to clone. In the initial assay, the highest dose tested (2 nl/ml without S-9 and 9 nl/ml with S-9) induced more than a two-fold

increase in the number of mutants. In the repeat assay with two independent parallel experiments, the test substance did not induce significant mutation frequencies compared to the solvent or the untreated controls, even at concurrent toxicity lower than the first assay. A high mutant frequency at a single dose that was observed in the first assay, was not reproduced in either the second or third experiment; therefore, the high mutant frequency at this single point was considered an anomaly.

### **Conclusions**

Remarks:

The test substance should be considered negative in the CHO/HGPRT mutation assay in the presence and absence of S-9 (Author of report).  
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

### **References**

Yang, L. L. 1985. CHO/HGPRT Mutation Assay in the Presence and Absence of Exogenous Metabolic Activation. Study No. T2693.332001. Microbiological Associates Inc., Bethesda, MD, USA.

### **Other**

Last changed:

July 17, 2002

Order number for sorting:

20

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Oleylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Based on procedure described by Clive, D and J. F. S. Spector, 1975, Laboratory procedure for assessing specific locus mutations at the TK locus in cultured L5178Y TK+/- mouse lymphoma cells, *Mutat. Res.* 31:17-29.

Type: Mammalian cell forward mutation assay  
System of testing: Nonbacterial  
GLP: Yes  
Year: 1989  
Species/Strain: L5178Y TK+/- mouse lymphoma cells  
Metabolic activation: With and without S-9 activation; S-9 mix obtained from the liver of Aroclor-induced rats

Concentrations tested: 1<sup>st</sup> Initial assay:  
0.13 to 0.32 nl/ml (absence of S-9)  
1.3 to 10.0 nl/ml (presence of S-9)

2<sup>nd</sup> Initial assay:  
0.13 to 1.8 nl/ml (absence of S-9)  
1.3 to 13.0 nl/ml (presence of S-9)

Confirmatory assay:  
0.2 to 1.0 nl/ml (absence of S-9)  
1.5 to 11.0 nl/ml (presence of S-9)

Statistical methods: Not stated  
Remarks: Single cultures per dose were used for the initial assays. For the initial assays the test substance was diluted and serial eighth log dilutions were carried out, which produced 16 dose levels for both activated and non activated portions of the assays. In the confirmatory assay, using duplicate cultures at each dose, the test substance was diluted and serially diluted, producing eight doses each for the activated and non-activated portions of the assay. Two controls received the solvent, acetone, only and the positive controls were treated with EMS (non-activated) and 7,12-DMBA (activated). The following criteria were used when evaluating the results: 1) a result was positive if there was a positive dose response and one or more of the three highest doses in the 10% or

greater total growth range exhibited a mutant frequency that was two-fold greater than the background level, the first and confirmatory assays must both demonstrate a positive response to call the test substance a positive mutagen; 2) a result was equivocal if there was no dose response but any one or more of the three highest doses with 10% or greater total growth exhibited a two-fold increase in mutant frequency over background, or if there was a dose response but no culture exhibited a two-fold increase in mutant frequency over background, if an assay produces a positive response and the confirmatory assay produced an equivocal or negative response, then the results for the test substance were classified as equivocal; and 3) a result was negative if there was no dose response in cultures with 10% or greater total growth and none of these test cultures exhibited a two-fold or greater increase in mutant frequency over background, both assays must demonstrate a negative response for the test substance to be considered negative.

## Results

Result: The test substance showed no evidence of mutagenic activity when tested in this mammalian cell gene mutation assay.

Cytotoxic concentration: Concentrations too toxic to clone:  
1<sup>st</sup> Initial assay:  
0.42 nl/ml (without S-9)  
13.0 nl/ml (with S-9)  
2<sup>nd</sup> Initial assay:  
2.4 nl/ml (without S-9)  
18.0 nl/ml (with S-9)  
Confirmatory assay:  
1.2 nl/ml (without S-9)  
11.0 nl/ml (with S-9)

Genotoxic effects: Negative with and without metabolic activation  
Statistical results: Described below  
Remarks: 1<sup>st</sup> Initial assay: total growth from 75 to 99% and 6 to 106% were observed in non-activated and activated cultures, respectively.  
2<sup>nd</sup> Initial assay: total growth from 3 to 110% and 13 to 107% were observed in non-activated and activated cultures, respectively.  
Confirmatory assay: total growth from 6 to 109% and 2 to 115% were observed in non activated and activated cultures, respectively.

### Conclusions

Remarks:

Under the conditions of this test, Oleylamine was negative in both the presence and absence of exogenous metabolic activation (Author of report). The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

### References

Harbell, J. W. 1989. L5178Y TK +/- Mouse Lymphoma Mutagenesis Assay with Confirmation. Study No. T8461.701020. Microbiological Associates Inc., Bethesda, MD, USA.

### Other

Last changed:

July 17, 2002

Order number for sorting:

24

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: ODA-FG-11-27-84 (CAS RN 112-90-3;  
Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Cytogenetic assay (chromosomal aberration)  
System of testing: Nonbacterial  
GLP: Yes  
Year: 1985  
Species/Strain: Chinese hamster ovary cells (CHO)  
Metabolic activation: With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced male Sprague-Dawley rats  
Concentrations tested: 0.05, 0.15, 0.5, 1.5 and 5.0 nl/ml (absence of S-9)  
0.2, 0.6, 2.0, 6.0 and 20.0 nl/ml (presence of S-9)  
Statistical methods: Chi-square analysis using a 2 x 2 contingency table  
Remarks: CHO cells were seeded in duplicate for each treatment condition at  $6.0 \times 10^5$  cells/25 cm<sup>2</sup> flask and were incubated at  $37 \pm 1^\circ\text{C}$  in a humidified atmosphere of  $5 \pm 0.5\%$  CO<sub>2</sub> in air for 18-24 hours. TEM was used as the positive control in the non-activation study at a concentration of 1 µg/ml. CP was used as the positive control in the S-9 activated study at a concentration of 50 µg/ml. The solvent vehicle, acetone, was used as the solvent control at the same concentration as that found in the test substance-treated groups. Growth medium was used in the untreated control. In the study without S-9 activation, duplicate cultures per treatment condition were exposed for 16 hours at  $37 \pm 1^\circ\text{C}$  in a humidified atmosphere of  $5 \pm 0.5\%$  CO<sub>2</sub> in air. At the end of the 16-hour period, flasks were harvested and cytotoxicity was estimated. Also at this time, medium was removed from a second set of duplicate flasks for each treatment condition, and the cells were washed and refed with complete medium containing 0.1 µg/ml of colcemid. In the study with S-9 activation, duplicate cultures per treatment condition were exposed for two hours at  $37 \pm 1^\circ\text{C}$  in a humidified atmosphere of  $5 \pm 0.5\%$  CO<sub>2</sub> in air. After the exposure period, the treatment medium was removed, the cells were washed with PBS, refed with complete medium

and returned to the incubator for an additional 14 hours. At the end of the 14-hour period, flasks were harvested and cytotoxicity was estimated. Also at this time, colcemid was added to a second set of duplicate flasks for each treatment condition at a final concentration of 0.1 µg/ml. Two and ½ hours after the addition of colcemid, metaphase cells were harvested for both studies by mitotic shake-off. Slides were prepared from fixed cells and scored. One hundred cells were scored for each dose level. The following aberrations were scored: chromatid gaps and breaks, chromosome gaps and breaks, chromatid fragments, acentric fragments, dicentrics, rings, triradials, quadriradials, complex rearrangements, pulverized chromosomes and cells, endoreduplication, and severely damage cells (> 10 aberrations). The criteria for determination of a valid test included: 1) the number of cells with chromosome aberrations in the negative control must be in accordance with the historical data and 2) the number of cells with chromosome aberration in the positive control must be at least 25% of the cells scored. The four highest doses with scoreable metaphases were selected for evaluation of chromosome aberrations.

## Results

Result:	The test substance showed no evidence of mutagenic activity in the presence and absence of an S-9 metabolic activation system.
Cytotoxic concentration:	5.0 nl/ml without S-9 (24% cell survival) 20 nl/ml with S-9 (24% cell survival)
Genotoxic effects:	Negative with and without metabolic activation
Statistical results:	Described below
Remarks:	In the absence of S-9 activation, relative to the solvent control, survival ranged from 24 to 111% and 24 to 133% in the presence of S-9 activation. At the time of harvest, the flasks receiving 5.0 nl/ml in the absence of S-9 appeared very toxic with few cells in metaphase. When slides were made of the mitotic shakeoff, few scoreable metaphases were observed in that treatment group; therefore this group was not evaluated for chromosome aberrations. In the absence of S-9, the frequency of cells with structural aberrations was not significantly increased above that of the solvent control (0.05) in all dose levels scored. The number of structural aberrations per cell in the treated groups ranged from 0 to 0.02, with a frequency of cells with

structural aberrations from 0 to 1%. TEM induced 0.49 aberrations per cell and a frequency of cells with structural aberrations of 25%. In the presence of S-9, the frequency of cells with structural aberrations in the test substance-treated groups was not statistically increased above that of the solvent control and ranged from 0.01 to 0.03 with a frequency of cells with structural aberrations from 1 to 3%. CP induced 0.81 aberrations per cell and a frequency of cells with structural aberrations of 39%. The modal chromosome numbers of the negative and solvent controls as well as all test substance-treated groups was 19.

### Conclusions

Remarks:

Under the conditions of the assay described in this report, the test substance did not produce chromosome aberrations in CHO cells when tested in the presence and absence of an S-9 metabolic activation system (Author of report).  
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1B  
Reliable without restriction; comparable to guideline study.

### References

Putman, D. L. 1985. Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells. Study No. T2693.337010. Microbiological Associates Inc., Bethesda, MD, USA.

### Other

Last changed:  
Order number for sorting:  
Remarks:

July 17, 2002  
25

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Genamin SH 301 (CAS RN 4088-22-6;  
1-Octadecanamine, N-methyl-N-octadecyl)  
Purity: ca. 100%  
Remarks:

### Method

Method/guideline followed: Procedures developed by: Ames, B. N., W. W. Durston, E. Yamasaki and F. D. Lee. 1973. Carcinogens are mutagens. A simple test system combining liver homogenate for activation and bacteria for detection. *Proc. Nat. Acad. Sci. USA* **70**:2281-2285;  
Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with *Salmonella*/mammalian-microsome mutagenicity test. *Mutation Res.* **31**:347-364; and  
Green, M.H.L and W.J. Muriel. 1976. Mutagen testing using trp+ reversion in *Escherichia coli*. *Mutation Res.* **38**:3-32.

Type: Mutagenicity assay (Ames Test)  
System of testing: Bacterial  
GLP: Yes  
Year: 1988  
Species/Strain: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* WP2uvrA

Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male Sprague-Dawley rats was used as the metabolic activation system.

Concentrations tested: 5000, 2500, 500, 100, 20, and 4 µg per plate  
Statistical methods: Not stated  
Remarks: Test substance was diluted in DMSO, which was also used as the vehicle control. The following substances were used as positive controls in tests without activation: sodium azide (TA 100, TA 1535); 9-aminoacridine (TA 1537); 2-nitrofluorene (TA 98, TA 1538); and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). Benzo[a]pyrene and 2-aminoanthracene were used as the positive controls in tests with activation for all *Salmonella* and *Escherichia coli* tester strains. The positive controls, vehicle control and all test substance doses were plated in triplicate. The S-9 homogenate and mix were prepared at the testing facility. The S-9 mix was prepared

immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. The top agar was prepared with histidine-biotin solution for the *Salmonella* strains and with tryptophan for *E. coli*. After solidification, the plates were incubated for 48-72 hours at 37°C in the dark.

## Results

Result:	The test substance showed no evidence of toxicity or mutagenic activity when tested in this bacterial system.
Cytotoxic concentration:	No cytotoxicity was observed at concentrations up to and including 5000 µg per plate
Genotoxic effects:	Negative with and without activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	1B
Remarks:	Reliable without restrictions; comparable to guideline study.

## References

Müller, W. 1988. Genamin SH 301 – Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escheria coli*. Report No. 88.0293. Pharma Research Toxicology and Pathology, Frankfurt, Germany

## Other

Last changed:	July 12, 2002
Order number for sorting:	77b
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Farmin DM 80 (CAS RN 124-28-7  
1-Octadecanamine, N,N-dimethyl)  
Purity: 100%  
Remarks:

### Method

Method/guideline followed: Procedures developed by: Ames, B. N., J. McCann and E. Yamasaki. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Res.* **31**:347-364; and Maron, D. M. and Ames, B. N. 1983. Revised methods for the *Salmonella* mutagenicity test. *Mutation Res.* **113**:173-215.

Type: Reverse mutation assay (pour-plate assay)  
System of testing: Bacterial  
GLP: No  
Year: 1995-1996  
Species/Strain: *Salmonella typhimurium* strains TA98, and TA100.  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from male CD rats was used as the metabolic activation system.

Concentrations tested: 0.5, 1.6, 5.0, 15.8 and 50 µg per plate.  
Statistical methods: Not stated  
Remarks: Test substance was diluted in ethanol. The following positive control substances were included: sodium azide (2 µg/plate, TA 100, without S-9), 2-nitrofluorene (1 µg/plate, TA 98, without S-9) and benzo[a]pyrene (5 µg/plate, TA 98 and TA 100, with S-9). The positive controls, solvent control and all test substance doses were plated in duplicate. The S-9 homogenate and mix was prepared at the testing facility. The S-9 mix was prepared immediately before use. The S-9 mix, tester strain and vehicle, test article, or positive control were added to molten selective top agar. After solidification, the plates were incubated for two days at 37°C.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in this bacterial system.
Cytotoxic concentration:	50 µg per plate
Genotoxic effects:	Negative with and without activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has not been adequately characterized because only two tester strains were evaluated. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2D
Remarks:	Reliable with restrictions; well documented study report that meets basic scientific principles however, only two tester strains were evaluated.

## References

May, K. 1996. Farmin DM80: Preliminary Toxicity Screen: Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium* (the Ames test). Report No. 96/KAS182/0143. Huntingdon Life Sciences Ltd., Eye, Suffolk England.

## Other

Last changed:	July 11, 2002
Order number for sorting:	38h
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Genamin C 100 D (CAS RN 61788-46-3; Coco alkyl amine)  
Purity: ca. 100% dist.  
Remarks:

### Method

Method/guideline followed: Ames et al. 1973. Proc. Nat. Acad. Sci. USA 70. 2281-2285. and Ames et al. 1975. Mutation Res. 21. 347-364.  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Yes  
Year: 1988  
Species/Strain: *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and *Escherichia coli* strain WP2uvrA  
Metabolic activation: With and without metabolic activation  
Concentrations tested: 0.16, 0.8, 4, 20, 100, 500, 2500 and 10000µg per plate  
Statistical methods: Not stated  
Remarks: Three replicates were run at each dose level. The compound was dissolved in 100 µl acetone. Positive and negative controls were run with each experiment. The positive controls without metabolic activation were: Sodium azide (TA100, TA1535), 9-aminoacridine (TA 1537), 2-nitrofluorene (TA98, TA1538) and N-methyl-N-nitro-N-nitrosoguanidine (WP2uvrA). The positive controls with metabolic activation were: benzo[a]pyrene and 2-aminoanthracene. The negative controls were exposed to the vehicle, acetone. The direct plate assay procedure was employed. Independent repeat assays were run.

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system. Precipitation was observed at 500 µg/plate and above.  
Cytotoxic concentration: Cytotoxic effects were observed at concentrations above 20 µg per plate with *Salmonella typhimurium* and at concentrations above 100 µg per plate with *Escherichia coli*  
Genotoxic effects: Negative with and without metabolic activation  
Statistical results: Not stated

Remarks: With cytotoxicity observed at 20 µg/plate and above, only three dose levels were left to evaluate mutagenicity.

### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1D  
Remarks: Reliable without restriction; comparable to guideline study. According to the guideline (OECD 471, 1997) at least 5 concentrations should be evaluated; however, the three highest non-toxic concentrations were negative thus providing for a negative assay.

### References

Müller, W. 1988. Genamin CC 100 D. Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Report No. 88.0193. Hoechst AG, Pharma Research Toxicology and Pathology, Frankfurt/Main, 30 S.

### Other available reports

#### Other

Last changed: June 5, 2002  
Order number for sorting: 79b  
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine)  
Purity: 97.0%  
Remarks:

### Method

Method/guideline followed: *Salmonella*/Mammalian Microsome Mutagenesis Assay (Ames Test), 9/1/1981; modified from Ames, B.N. et al. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Research* 31:347-364.

Type: Microsome mutagenicity assay (Ames test)  
System of testing: Bacterial  
GLP: Yes  
Year: 1982  
Species/Strain: *Salmonella typhimurium*, strain TA100 (range-finding toxicity); and strains TA98, TA100, TA1535, TA1537, TA1538

Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats

Concentrations tested: 0.33, 1.0, 3.3, 10, 33 and 100 µg per plate.  
Statistical methods: Not stated  
Remarks: A dose-range finding study indicated that a maximum of 10 µL of the test substance per plate be used for the mutagenicity assay, the maximum dose tested was 20 µL per plate. Results indicated slight precipitate at 0.3 and 1.0 µL per plate, moderate precipitate at 3.1 µL per plate and heavy precipitate at 10 and 20 µL per plate. Bacterial background lawn appeared normal at concentrations below 10 µL per plate and slightly reduced at 10 and 20 µL per plate.

The test substance was diluted in tetrahydrofuran, which was also used as the vehicle control (25 µL per plate). 2-Aminoanthracene (1.0 or 4.0 µg/plate, depending on tester strain) was the positive control for all tester strains with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (10.0 µg/plate, TA98 and TA 1538); 1,2-propane sultone (0.4 µL/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The negative and solvent controls and all

test substance doses were plated in triplicate, while positive controls were tested with no replication. The S-9 homogenate and mix was prepared at the testing facility. The test substance or positive control, tester strain and S-9 mix, when applicable, were added to molten selective top agar in said order.

The criteria for a valid test were: 1) A sterility check on the S-9 mix must yield less than two viable cells per plate; 2) A sterility check on all levels of test substances at conclusion must yield less than two viable colonies per plate; 3) the positive controls must produce at least a 3-fold increase in the number of revertant colonies; and 4) the average number of revertant colonies in the negative controls must fall within the historical limit for each strain.

## Results

Result:	The test substance showed no evidence of mutagenic activity when tested in these tester strains with and without activation.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2C
Remarks:	Reliable with restrictions; comparable to guideline study; no confirmatory assay.

## References

Haworth, S.R. 1982. *Salmonella*/Mammalian-Microsome Mutagenesis Assay (Ames Test). Report No. T1727.501; for The Procter & Gamble Company, Cincinnati, OH, USA; from Microbiological Associates, Bethesda, MD, USA.

## Other available reports

### Other

Last changed/Initials:	September 23, 2003
Order number for sorting:	293
Remarks:	

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine)  
Purity: 97.0%  
Remarks:

### Method

Method/guideline followed: Test for Chemical Induction of Mutation in Mammalian Cells in Culture, the L5178Y/TK<sup>+/-</sup> Mouse Lymphoma Assay, 9/15/1980; based on Clive, D. and Spector, J.F.S. 1975. Laboratory procedure for assessing specific locus mutations at the TK locus in cultured L517BY Mouse Lymphoma cells. *Mutation Research* 31:17-29.

Type: Mouse lymphoma assay  
System of testing: TK<sup>+/-</sup> L5178Y cells  
GLP: Yes  
Year: 1982  
Species/Strain:  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats  
Concentrations tested: 0.33, 1.0, 3.3, 10, 33 and 100 µg per plate.  
Statistical methods: Not stated  
Remarks: A preliminary toxicity test with and without S-9 activation indicated that threshold levels of complete toxicity at 1.0 µL/mL of the test substance for non-activated cultures, and at about 10 µL/mL for the S-9 activated cultures. Based on these data, the test substance concentrations used in the mutagenesis assay ranged from 0.013 to 1.0 µL/mL and from 0.27 to 20 µL/mL for the non-activated and S-9 activated groups, respectively. The test substance, solubilized in tetrahydrofuran (0.005 mL/mL), diluted to the prescribed test concentrations and added to tubes with and without the S-9 activation mix to yield a final cell suspension of 0.6x10<sup>6</sup> cells/mL. Two additional tubes received solvent only and the positive controls were treated with EMS (1.0 and 0.5 µL/mL) and 7,12-DMBA (7.5 and 5.0 µg/mL). After the initial 4-hour exposure to the test substance, the cells were washed, resuspended and incubated for two days with a cell population adjustment at 24 and 48 hours, yielding 0.3x10<sup>6</sup> cells/mL. After the 2-day expression period, ten cultures without activation and seven cultures with activation were selected for cloning based on the

degree of toxicity. The cultures were transferred to cloning medium for duplicate cloning, one with 3 µg trifluorothymidine (TFT)/mL as a restrictive agent and one for viable counts (V.C.). Cells from each culture were then plated in triplicate for both TFT and V.C. and were incubated at 37°C in a humidified 5% CO<sub>2</sub> atmosphere for 10-12 days. Following incubation, both the TFT and V.C. plates were scored for the total number of colonies per plate. Mutation frequency was calculated using the medians of triplicate machine counts. The following criteria were used as a guideline in judging response: increases in mutant frequencies that occur only at highly toxic concentrations may be due to epigenetic events; a Positive response is considered if there is a positive dose response and one or more of the three highest doses exhibits a mutant frequency which is 2-fold above background; the response is Negative if there is no dose response and no test cultures have a 2-fold or greater increase in mutant frequency above background.

## Results

Result:	None of the cloned cultures, treated in either the presence or absence of induced rat liver S-9, exhibited mutant frequencies which were significantly different from average mutant frequency for the corresponding solvent control cultures. The percent total growth for ranged from 11 to 86% and 8 to 101% for the non-activated and S-9 activated cultures, respectively.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks: This test substance was tested in the L5178Y TK<sup>+/-</sup> Mouse Lymphoma Mutagenesis Assay with and without exogenous metabolic activation by Aroclor induced rat liver S-9. Under these test conditions, this test substance is considered negative in this mutagenicity assay.

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restrictions; comparable to guideline study.

**References**

Kirby, P.E. 1982. Evaluation of Test Article B0390-01 (MA#T1727) for Mutagenic Potential Employing the L5178Y TK<sup>+/−</sup> Mutagenesis Assay. Report No. T1727.701; for The Procter & Gamble Company, Cincinnati, OH, USA; from Microbiological Associates, Bethesda, MD, USA.

**Other available reports**

**Other**

Last changed/Initials:

September 23, 2003

Order number for sorting:

294

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine)  
Purity: 97.0%  
Remarks:

### Method

Method/guideline followed: Test for Chemical Induction of Unscheduled DNA Synthesis in Primary Cultures of Rat Hepatocytes (by Autoradiography), 5/1/1981; based on Williams, G.M. 1977. Detection of chemical carcinogens by unscheduled DNA synthesis in rat liver primary cell cultures. *Cancer Research* 37:1845-1851; Williams, G.M. 1978.

Type: Unscheduled DNA synthesis  
System of testing: Hepatocyte primary cell culture  
GLP: Yes  
Year: 1982  
Species/Strain: Sprague-Dawley rat  
Metabolic activation: Not applicable  
Concentrations tested: 340, 261.5, 201.2, 154.8, 119.0, 91.6, 70.4, 54.2, 41.7 and 32.1 µg/mL

Statistical methods: Not stated  
Remarks: A dose-range finding study indicated that a maximum of 340 µg/mL be used for the unscheduled DNA synthesis (UDS) assay. Little or no cytotoxicity was observed at any but the highest dose tested, 340 µg/mL. Based on these data, the test substance concentrations used in the UDS assay were 340, 261.5, 201.2, 154.8, 119.0, 91.6, 70.4, 54.2, 41.7 and 32.1 µg/mL. The test substance was dissolved in absolute ethanol. The positive control, 7,12-dimethylbenzanthracene (DMBA) was dissolved in dimethyl sulfoxide (DMSO). Only the ethanol was included as a solvent control in the UDS assay, as DMSO was known to not induce UDS at the levels used in this study. Primary cultures for the UDS assay were prepared from  $5.6 \times 10^8$  cells from a male Sprague-Dawley rat, which were estimated to be 88% viable by exclusion of tryptophan blue. Following a 1.5-2 hour period allowing for culture attachment to each coverslip, cultures were exposed to both test substance and 10 µCi/mL  $^3\text{H}$ -thymidine for 18-20 hours at 37°C under an atmosphere of 5% CO<sub>2</sub> in air. Cultures were then scored for toxicity or processed for

autoradiography, viability was estimated again by exclusion of tryptophan blue and <sup>3</sup>H-thymidine incorporation was quantified in 25 randomly selected but normal appearing cells from at least two coverslips per dose group (total of 50 cells/group).

## Results

Result: Percent survival relative to untreated control was varied among treatment concentrations, ranging from 87.3 to 99.3%, with a 71.1% relative survival in the positive control. The mean net number of grains per nucleus ranged from -2.65 to 0.91 for the 10 treatment concentrations. Grains per nucleus for the positive control (DMBA) were 105 ± 13. Solvent and untreated controls all had mean net nucleus grain counts in an acceptable range. No indication of induction of UDS by the test substance was observed.

Cytotoxic concentration: > 340 µg/mL  
Genotoxic effects: None observed  
Statistical results: Not stated  
Remarks: None

## Conclusions

Remarks: This test substance did not induce unscheduled DNA synthesis in freshly prepared primary cultures of rat hepatocytes under the conditions employed in this assay.

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 1B  
Remarks: Reliable without restrictions; comparable to guideline study.

## References

Coppinger, W.J. 1982. Unscheduled DNA Synthesis Assay in Primary Cultures of Rat Hepatocytes. Report No. YE-532, The Procter & Gamble Company, BTF – Miami Valley Laboratories, Cincinnati, OH, USA.

## Other

Last changed/Initials: September 23, 2003  
Order number for sorting: 296  
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Tallow alkyl amine (CAS RN 61790-33-8)  
Purity: >99%  
Remarks:

### Method

Method/guideline followed: Not stated  
Type: Reverse mutation assay  
System of testing: Bacterial  
GLP: Yes  
Year: 1988  
Species/Strain: *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and *Escherichia coli* strain WP2uvrA  
Metabolic activation: With and without metabolic activation  
Concentrations tested: 0.16 to 10000 µg per plate  
Statistical methods: Not stated  
Remarks: The S9 mix was prepared from Aroclor 1254 induced rats. Compound was dissolved in 100 µl ethanol. Dosing was performed as follows: 0, 0.16 µg/plate (exp. 2 –S9), 0.8 µg/plate (exp. 2) 4, 20, 100, 500 and 2500 µg/plate (exp. 1, exp. 2 +S9) and 10000 µg/plate (exp. 1). Three replicates were run per concentration. The following positive controls were used without metabolic activation: Sodium azide (TA100, TA1535), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98, TA1538), N-methyl-N-nitro-N-nitrosoguanidine (WU2uvrA). The following positive controls were used without metabolic activation: benzo[a]pyrene and 2-aminoanthracene. A vehicle (ethanol) negative control was also included. The direct plate assay was employed for this test.

### Results

Result: The test substance showed no evidence of mutagenic activity when tested in this bacterial system. Cytotoxicity and precipitation were observed at 20 µg/plate, meaning that only 2 or 3 concentrations of the test substance were left to evaluate the mutagenicity.  
Cytotoxic concentration: 20 µg/plate with and without activation  
Genotoxic effects: Negative with and without activation  
Statistical results: Not stated  
Remarks: None

### Conclusions

Remarks: The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1D  
Remarks: Reliable without restriction; comparable to guideline  
study. According to guideline OECD 471, at least 5  
concentrations should have been evaluated; however,  
the three highest non-toxic concentrations were  
negative thus providing for a negative assay.

### References

Hoechst AG. 1988. Genamin TA 100 D, Study of the  
Mutagenic Potential in Strains of *Salmonella*  
*typhimurium* (Ames Test) and *Escherichia coli*.  
(Unveröffentlichte Untersuchung, Bericht Nr.  
88.0411). Hoechst AG, Pharma Research Toxicology  
and Pathology, Frankfurt/Main, 30 S.

### Other available reports

### Other

Last changed: August 9, 2002  
Order number for sorting: 1 and 223  
Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: Genamin S080 (20% in water + H<sub>3</sub>PO<sub>4</sub>);  
Alkylamineethoxylate (CAS RN 61791-44-4; Ethanol,  
2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: 99.5%  
Remarks:

### Method

Method/guideline followed: *Salmonella*/Mammalian Microsome Mutagenesis Assay (Ames Test), 9/15/1980; modified from Ames, B.N. et al. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Research* 31:347-364.

Type: Microsome mutagenicity assay (Ames test)  
System of testing: Bacterial  
GLP: Yes  
Year: 1981  
Species/Strain: *Salmonella typhimurium*, strain TA100 (range-finding toxicity); and strains TA98, TA100, TA1535, TA1537, TA1538

Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats

Concentrations tested: 0.0008, 0.02, 0.04 and 0.08 µL per plate.

Statistical methods: Not stated

Remarks: A dose-range finding study indicated that a maximum of <0.1 µL of the test substance per plate be used for the mutagenicity assay. The maximum dose tested was 40 µL/plate. Results indicated that the background bacterial lawn was normal to moderately reduced at 0.003 to 0.1 µL/plate, with complete disappearance of bacterial lawn above 1.0 µL/plate. No precipitation was reported.

For the *Salmonella* mutagenesis assay, the test substance was diluted in water, which was also used as the vehicle control (50 µL per plate). 2-Aminoanthracene (1.0 µg/plate) was the positive control for strains TA98 and TA100 with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (10.0 µg/plate, TA98 and TA 1538); 1,2-propane sultone (0.4 µL/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The solvent controls and all test substance doses were plated in

triplicate, while positive controls were tested with no replication. The S-9 homogenate and mix was prepared at the testing facility. The test substance or positive control, tester strain and S-9 mix, when applicable, were added to molten selective top agar in said order. The criteria for a valid test were: 1) A sterility check on the S-9 mix must yield less than two viable cells per plate; 2) A sterility check on all levels of test substances at conclusion must yield less than two viable colonies per plate; 3) the positive controls must produce at least a 3-fold increase in the number of revertant colonies; and 4) the average number of revertant colonies in the negative controls must fall within the historical limit for each strain.

## Results

Result:	There was no increase in the number of revertant colonies in any tester strain at any dose.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks: The results of this Salmonella/mammalian-microsome mutagenicity assay indicate that this test substance did not cause a significant increase in the number of revertants per plate of any of the tester strains with or without metabolic activation.

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):	2C
Remarks:	Reliable with restrictions; comparable to guideline study; no confirmatory assay.

## References

Haworth, S.R. 1981. *Salmonella*/Mammalian-Microsome Mutagenesis Assay (Ames Test). Report No. 003-407-637-1; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA.

## Other available reports

**Other**

Last changed/Initials: September 23, 2003

Order number for sorting: 305

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: “TAMET” Benzoate (20% in water)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: Not stated

Remarks:

### Method

Method/guideline followed: *Salmonella*/Mammalian Microsome Mutagenesis Assay (Ames Test), 9/15/1980; modified from Ames, B.N. et al. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Research* 31:347-364.

Type: Microsome mutagenicity assay (Ames test)

System of testing: Bacterial

GLP: Yes

Year: 1981

Species/Strain: *Salmonella typhimurium*, strain TA100 (range-finding toxicity); and strains TA98, TA100, TA1535, TA1537, TA1538

Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats

Concentrations tested: 2.0, 10, 50, 100 and 200 µg/plate

Statistical methods: Not stated

Remarks: A dose-range finding study indicated that a maximum of 200 µg of the test substance per plate be used for the mutagenicity assay. Results indicated that the background bacterial lawn was reduced at concentrations 305 µg/plate, with complete disappearance of bacterial lawn above 977 µg/plate. Moderate precipitation was reported only at the maximum dose tested (20,000 µg/plate).

For the *Salmonella* mutagenesis assay, the test substance was diluted in ethanol, which was also used as the vehicle control (50 µL per plate). 2-Aminoanthracene (1.0 or 4.0 µg/plate, depending on tester strain) was the positive control for all tester strains with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (10.0 µg/plate, TA98 and TA 1538); 1,2-propane sultone (0.4 µL/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The negative and solvent controls and all test substance

doses were plated in triplicate, while positive controls were tested with no replication. In order to clarify erratic plate counts observed in tester strain TA1537 with the test substance without activation, this strain was retested. Additionally, tester strain TA100 was retested over an extended dose range (including 300 and 400 µg/plate) in order to clarify the corresponding initial plate counts. The S-9 homogenate and mix was prepared at the testing facility. The test substance or positive control, tester strain and S-9 mix, when applicable, were added to molten selective top agar in said order. The criteria for a valid test were: 1) A sterility check on the S-9 mix must yield less than two viable cells per plate; 2) A sterility check on all levels of test substances at conclusion must yield less than two viable colonies per plate; 3) the positive controls must produce at least a 3-fold increase in the number of revertant colonies; and 4) the average number of revertant colonies in the negative controls must fall within the historical limit for each strain.

## Results

Result:	There was no increase in the number of revertant colonies in any tester strain at any dose.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The results of this Salmonella/mammalian-microsome mutagenicity assay indicate that this test substance did not cause a significant increase in the number of revertants per plate of any of the tester strains with or without metabolic activation by Aroclor induced rat liver microsomes.
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The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):	2C
Remarks:	Reliable with restrictions; comparable to guideline study; no confirmatory assay.

**References**

Haworth, S.R. 1981. *Salmonella*/Mammalian-Microsome Mutagenesis Assay (Ames Test). Report No. 003-468-677-1; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA.

**Other available reports**

**Other**

Last changed/Initials:

September 23, 2003

Order number for sorting:

306

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,  
N-tallow alkyl derivs. )  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: *Salmonella*/Mammalian Microsome Mutagenesis Assay (Ames Test), 11/1/1979; modified from Ames, B.N. et al. 1975. Methods for detecting carcinogens and mutagens with the *Salmonella*/mammalian microsome mutagenicity test. *Mutation Research* 31:347-364.

Type: Microsome mutagenicity assay (Ames test)  
System of testing: Bacterial  
GLP: Yes  
Year: 1980  
Species/Strain: *Salmonella typhimurium*, strain TA100 (range-finding toxicity); and strains TA98, TA100, TA1535, TA1537, TA1538

Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats

Concentrations tested: 0.0008, 0.004, 0.02, 0.04 and 0.08 µL/plate

Statistical methods: Not stated

Remarks: A dose-range finding study indicated that a maximum of 0.08 µL of the test substance per plate be used for the mutagenicity assay. Results indicated that the background bacterial lawn was normal to slightly reduced at 0.003 to 0.1 µL/plate, and extremely reduced from 0.3 to 10 µL/plate. No precipitation was reported.

For the *Salmonella* mutagenesis assay, the test substance was diluted in water, which was also used as the vehicle control (50 µL per plate).

2-Aminoanthracene (1.0 µg/plate) was the positive control for strains TA98 and TA100 with S-9 activation. The positive controls utilized without S-9 activation were as follows: 2-nitrofluorene (10.0 µg/plate, TA98 and TA 1538); 1,2-propane sultone (0.4 µL/plate, TA 100 and TA 1535); and 9-aminoacridine (75 µg/plate, TA 1537). The solvent controls and all test substance doses were plated in triplicate, while positive controls were tested with no

replication. In order to clarify the reduced (81%) plasmid content in cells from the TA100 culture, indicated by a “halo” surrounding the Ampicillin disc, this strain was simply retested. The S-9 homogenate and mix was prepared at the testing facility. The test substance or positive control, tester strain and S-9 mix, when applicable, were added to molten selective top agar in said order. The criteria for a valid test were: 1) a sterility check on the S-9 mix must yield less than two viable cells per plate; 2) a sterility check on all levels of test substances at conclusion must yield less than two viable colonies per plate; 3) the positive controls must produce at least a 3-fold increase in the number of revertant colonies; and 4) the average number of revertant colonies in the negative controls must fall within the historical limit for each strain.

## Results

Result:	There was no increase in the number of revertant colonies in any tester strain at any dose.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks:	The results of this Salmonella/mammalian-microsome mutagenicity assay indicate that this test substance did not cause a significant increase in the number of revertants per plate of any of the tester strains with or without metabolic activation by Aroclor induced rat liver microsomes. The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability (Klimisch):	2C
Remarks:	Reliable with restrictions; comparable to guideline study; no confirmatory assay.

## References

Haworth, S.R. 1980. *Salmonella/Mammalian-Microsome Mutagenesis Assay (Ames Test)*. Report No. 003-692-420-1; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA.

## Other available reports

**Other**

Last changed/Initials:	September 23, 2003
Order number for sorting:	307

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,  
N-tallow alkyl derivs.)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Test for Chemical Induction of Mutation in Mammalian Cells in Culture, the L5178Y/TK<sup>+/-</sup> Mouse Lymphoma Assay, 9/15/1980; based on Clive, D. and Spector, J.F.S. 1975. Laboratory procedure for assessing specific locus mutations at the TK locus in cultured L517BY Mouse Lymphoma cells. *Mutation Research* 31:17-29.

Type: Mouse lymphoma mutagenesis assay  
System of testing: TK<sup>+/-</sup> L5178Y cells  
GLP: Yes  
Year: 1980  
Species/Strain:  
Metabolic activation: With and without metabolic activation; Aroclor 1254-induced rat liver S-9 from Sprague-Dawley rats  
Concentrations tested: 0.33, 1.0, 3.3, 10, 33 and 100 µg per plate.  
Statistical methods: Not stated  
Remarks: A preliminary toxicity test with and without S-9 activation indicated that threshold levels of complete toxicity at 0.1 µL/mL of the test substance for non-activated cultures, and at about 10 µL/mL for the S-9 activated cultures. Based on these data, the test substance concentrations used in the mutagenesis assay ranged from 0.0013 to 0.1 µL/mL. The test substance, solubilized in ethanol, diluted to the prescribed test concentrations and added to tubes with and without the S-9 activation mix to yield a final cell suspension of 3x10<sup>5</sup> cells/mL. Two additional tubes were prepared as solvent controls. Positive controls were treated with EMS (1.0 and 0.5 µL/mL) and 7,12-DMBA (7.5 and 5.0 µg/mL), each with and without duplicate solvent controls. After the initial 4-hour exposure to the test substance, the cells were washed, resuspended and incubated for two days with a cell population adjustments to maintain the 3x10<sup>5</sup>-cells/mL concentration for a continuous active growth state. After the 2-day expression period, cultures with and without activation (10 each) exhibiting 10 to 90%

relative growth inhibition during the expression period were selected for cloning. The cultures were transferred to cloning medium for duplicate cloning, one with trifluorothymidine (TFT)/mL as a selective agent and one for viable counts (V.C.). Cells from each culture were then plated in triplicate for both TFT and V.C. and were incubated at 37°C in a humidified 5% CO<sub>2</sub> atmosphere for 10-12 days. Following incubation, both the TFT and V.C. plates were scored for the total number of colonies per plate and mutation frequency was calculated.

## Results

Result:	None of the cloned cultures, treated in either the presence or absence of induced rat liver S-9, exhibited mutant frequencies which were significantly different from average mutant frequency for the corresponding solvent control cultures. The percent total growth ranged from 25 to 116% and 36 to 113% for the non-activated and S-9 activated cultures, respectively.
Cytotoxic concentration:	Negative with and without S-9 activation
Genotoxic effects:	Negative with and without S-9 activation
Statistical results:	Not stated
Remarks:	None

## Conclusions

Remarks: This test substance was tested in the presence and absence of Aroclor induce rat liver S-9 in the L5178Y TK<sup>+/−</sup> Mutagenesis Assay, did not significantly increase the mutation frequency of treated cultures over that of the solvent control cultures. Under these test conditions, this test substance is considered negative in this mutagenicity assay.

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):	1B
Remarks:	Reliable without restrictions; comparable to guideline study.

## References

Kirby, P.E. 1980. Test for Chemical Induction of Mutation in Mammalian Cells in Culture – the L5178Y TK<sup>+/-</sup> Mouse Lymphoma Assay. Report No. 003-692-420-7; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G Mason Research Institute, Rockville, MD, USA.

## Other available reports

### Other

Last changed/Initials:

September 23, 2003

Order number for sorting:

304

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: 100%

Remarks:

### Method

Method/guideline followed: .

Type: Cytogenicity Study – Chinese Hamster Ovary (CHO) Cells *in vitro*

System of testing: Nonbacterial

GLP: Yes

Year: 1982

Species/Strain: Chinese hamster ovary (CHO) cells

Metabolic activation: With and without S-9 activation; S-9 mix obtained from the liver of Aroclor 1254-induced male Sprague-Dawley rats

Concentrations tested: 0.005, 0.007, 0.01, 0.013, 0.017, 0.023, 0.03 µL/mL (absence of S-9)  
0.05, 0.07, 0.1, 0.13, 0.17, 0.23, 0.3 µL/mL (presence of S-9)

Statistical methods: Chi-square analysis using a 2 x 2 contingency table

Remarks: Approximately  $7.4 \times 10^6$  CHO cells/ flask were seeded for the assay and were incubated in a humidified atmosphere of  $5 \pm 0.5\%$  CO<sub>2</sub> in air for approximately 24 hours. The cells were harvested and resuspended to a final cell density of  $5 \times 10^6$  cells/mL. Based upon results of the initial cytotoxicity test, cultures in the chromosome aberrations assay were dosed with one of seven decreasing dose levels from 0.03 µL/mL in the non-activated system and from 0.3 µL/mL in the S-9 activated systems, respectively. TEM was used as the positive control in the non-activation study at a concentration of 0.5 µg/mL. CP was used as the positive control in the S-9 activated study at a concentration of 35 µg/mL. The solvent vehicle, ethanol, was used as the solvent control at the same concentration as that found in the test substance-treated groups. Cultures were exposed to treatment for 4 hours in a 37°C waterbath, were washed and resuspended, incubated again for 16 hours at  $37 \pm 1^\circ\text{C}$  in a humidified atmosphere of  $5 \pm 0.5\%$  CO<sub>2</sub> in air, treated with colcemid (1 µg/mL), and incubated for an

additional 2 hours. The metaphase cultures were then harvested and cytotoxicity was estimated. Slides were prepared from fixed cells and scored. Fifty metaphase spreads were scored for each dose level. The cells that appeared intact with chromosomes spread symmetrically were used to obtain the final count. The following aberrations were scored at three dose levels with and without activation: number of metaphase chromosomes, gaps, chromatid breaks and fragments, chromosome breaks, exchange figures, dicentrica, rings, polyploids, pulverization and severely damaged cells (>10 aberrations).

**Results**

Cytotoxic concentration: > 0.01 µL/mL without S-9 activation  
 > 0.03 µL/mL with S-9 activation

Genotoxic effects: Negative without metabolic activation; Positive with metabolic activation

Statistical results: Described below

Remarks: The following data for chromosome aberrations were collected:

Without Metabolic Activation (50 cells/analysis)

Treatment	# of Aberrations/Cell	# Cells with Aberrations	% of Cells with >1 Aberration
TA (0.01)*	0.26	18	4
TA (0.007)	0.22	14	6
TA (0.005)	0.30	24	6
Neg. Control	0.16	10	6
Pos. Control	1.94	68	48
Solvent Control	0.16	12	2

\* Test Article (µL/mL)

With Metabolic Activation (50 cells/analysis)

Treatment	# of Aberrations/Cell	# Cells with Aberrations	% of Cells with >1 Aberration
TA (0.17)*	1.98	58	36
TA (0.13)	0.92	36	22
TA (0.10)	0.64	28	18
Neg. Control	0.1	12	6
Pos. Control	3.5	80	68
Solvent Control	0.14	12	2

\* Test Article (µL/mL)

The original author stated the following: The cytotoxicity test conducted with the chromosome aberration assay did not yield the expected 50-90% toxicity at any of the dose levels without activation due to the narrow toxic range of this test substance. The cells treated with the test substance showed a significant increase in the frequency of chromosome aberrations with and without activation, relative to the negative control, although a definite dose response was only observed in the activated system.

## Conclusions

Remarks:

The original author concluded the following: “Under the conditions of the test, the test cultures which were treated with and without induced rat liver S-9 exhibited chromosome aberrations which were significantly higher than the frequency of aberrations in the negative control.”

The Sponsor of the Study concluded: “I do not agree with the conclusions drawn by the Study Director. [The test substance] clearly is positive in the presence of metabolic activation. The three doses scored show a distinct dose-related increase in the number of chromosome aberrations. In the absence of metabolic activation, an elevation in chromosome aberration occurs relative to the negative control, but there is no dose-response. Therefore, the results should be considered negative in the absence of metabolic activity.”

The test substance was positive with metabolic activation only. The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

## References

Thiagar, A. 1982. Cytogenicity Study – Chinese Hamster Ovary (CHO) Cells In Vitro. Study No. T1807.338; for The Procter & Gamble Company, Cincinnati, OH, USA; from Microbiological Associates Inc., Bethesda, MD, USA.

**Other**

Last changed/Initials: September 23, 2003

Order number for sorting: 308

Remarks:

## 5.5 GENETIC TOXICITY *IN VITRO*

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
( CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: Not stated

Remarks:

### Method

Method/guideline followed: Test for Chemical Induction of Unscheduled DNA Synthesis in Primary Cultures of Rat Hepatocytes (by Autoradiography), 5/1/1981; based on Williams, G.M. 1977. Detection of chemical carcinogens by unscheduled DNA synthesis in rat liver primary cell cultures. *Cancer Research* 37:1845-1851; Williams, G.M. 1978.

Type: Unscheduled DNA synthesis

System of testing: Hepatocyte primary cell culture

GLP: Yes

Year: 1982

Species/Strain: Sprague-Dawley rat

Metabolic activation: Not applicable

Concentrations tested:  $0.008 \times 10^{-4}$  to  $0.23 \times 10^{-4}$   $\mu\text{L/mL}$  (10 concentrations)

Statistical methods: Not stated

Remarks: Complete cytotoxicity (0% relative viability) in a preliminary toxicity and dose-range finding assay was observed at all but the lowest dose tested,  $1.0 \times 10^{-4}$   $\mu\text{L/mL}$ . Ten test substance concentrations ranging from  $0.035 \times 10^{-4}$  to  $1.0 \times 10^{-4}$   $\mu\text{L/mL}$  were chosen for use in the first UDS assay. Due to excessive toxicity (only the two lowest concentrations,  $0.035 \times 10^{-4}$   $\mu\text{L/mL}$  and  $0.051 \times 10^{-4}$   $\mu\text{L/mL}$  did not exceed acceptable toxicity) and higher than normal grain counts in the controls, this test was considered invalid. A second study with doses ranging from  $0.008 \times 10^{-4}$  to  $0.23 \times 10^{-4}$   $\mu\text{L/mL}$  was therefore conducted and was considered valid. The test substance was dissolved in absolute ethanol. The positive control, 7,12-dimethylbenzanthracene (DMBA) was dissolved in dimethyl sulfoxide (DMSO). Only the ethanol was included as a solvent control in the UDS assay, as DMSO was known to not induce UDS at the levels used in this study. Primary cultures for the second of two UDS assays were prepared from  $3.7 \times 10^8$  cells from a male Sprague-Dawley rat, which were estimated to be 92% viable by exclusion of tryptophan

blue. Following a 1.5-2 hour period allowing for culture attachment to each coverslip, cultures were exposed to both test substance, or control, and 10  $\mu\text{Ci/mL}$   $^3\text{H}$ -thymidine for 18-20 hours at 37°C under an atmosphere of 5%  $\text{CO}_2$  in air. Cultures were then scored for toxicity or processed for autoradiography, viability was estimated again by exclusion of tryptophan blue and  $^3\text{H}$ -thymidine incorporation was quantified in 25 randomly selected but normal appearing cells from at least two coverslips per dose group (total of 50 cells/group).

## Results

### Result:

This test substance was tested twice for the induction of unscheduled DNA synthesis (UDS) in primary cultures of rat hepatocytes, as results of the first UDS assay were deemed equivocal. In the first UDS assay, the mean net nuclear grain counts of treated samples were elevated with respect to the negative control. However, the standard deviations of the means were very large. Moreover, there were morphological signs of cytotoxicity throughout the dose range and the net nuclear grain count of the solvent control was above the normal cutoff point for an acceptable assay.

The second UDS assay was considered to be a valid test, as the standard deviations of mean net nuclear grain counts were reduced, significant cytotoxicity was observed in the five highest dose levels in the wider dose range employed, and the net nuclear grain counts of the solvent and positive controls were in the acceptable range. The DMBA positive control did induce a response which indicates that the cells were capable of DNA repair.

Cytotoxic concentration:

$0.052 \times 10^{-4} \mu\text{L/mL}$

Genotoxic effects:

None observed

Statistical results:

Not stated

Remarks:

None

## Conclusions

### Remarks:

Based on the results of the second assay, this test substance did not induce unscheduled DNA synthesis in freshly prepared primary cultures of rat hepatocytes under the conditions employed in this assay.

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen

Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1B

Remarks:

Reliable without restrictions; comparable to guideline study.

**References**

Coppinger, W.J. 1983. Unscheduled DNA Synthesis Assay in Primary Cultures of Rat Hepatocytes. Report No. M0021, The Procter & Gamble Company, BTF – Miami Valley Laboratories, Cincinnati, OH, USA.

**Other**

Last changed/Initials:

September 24, 2003

Order number for sorting:

310

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: Genamin LA 302 D (CAS RN 112-18-5;  
N,N-Dimethyl-1-dodecanamine)  
Purity: 100%  
Remarks:

### Method

Method/Guideline followed: Mammalian Erythrocyte Micronucleus Test (OECD guideline 474), US EPA OPPTS 870.5395 and EEC Directive 92/69, L383 A, Annex B.

Type: Mouse micronucleus assay  
GLP: Yes  
Year: 1999  
Species: Mouse  
Strain: HsdWin:NMRI  
Sex: Male and female  
Route of administration: Oral gavage  
Doses/concentration levels: 0, 120, 400 and 1200 mg/kg bodyweight  
Exposure period: Doses given twice at an interval of 24 hours  
Statistical methods: One sided Wilcoxon Test  
Remarks: Groups of mice (five males and five females) were given two doses of the test substance in sesame oil by oral gavage at concentrations of 120, 400 and 1200 mg/kg at 24 hour intervals. Two additional groups of mice (five males and five females) were used as the vehicle control and positive control. The positive control, Endoxan<sup>®</sup> (cyclophosphamide dissolved in distilled water), was administered as a single oral dose at 50 mg/kg. All doses were administered at a constant volume of 10 ml/kg. Body weights were taken at the start of the study. Clinical observations were made following dosing. Bone marrow cells collected 24 hours after dose administration were examined microscopically for structural chromosome aberrations. Prior to study initiation, a dose range-finding toxicity study was conducted at dose levels of 1000, 1200, 1500 and 2000 mg/kg with three mice per sex per group.

**Results**

Dose group	PCE/NCE ratio		Mutagenic Index
	Male	Female	Sexes Combined
Vehicle control	0.53	0.46	1.0
120 mg/kg	0.51	0.52	1.5
400 mg/kg	0.48	0.50	1.3
1200 mg/kg	0.38	0.37	1.8
Positive control	0.34	0.42	35.6

Genotoxic effects:  
 NOAEL (NOEL):  
 Statistical results:  
 Remarks:

Negative  
 Not determined  
 Described below  
 Six out of ten mice in the 1200 mg/kg dose group died prematurely. The animals were replaced and the new animals survived after treatment. Clinical signs of toxicity observed in test substance-treated mice included diarrhea, decreased motor activity, palpebral fissure narrow, uncoordinated movements, stupor, tonic convulsions, and prone position. All animals were free of clinical signs of toxicity 24 hours after treatment. No statistically significant increases in percentage of micronucleated polychromatic erythrocytes were observed in the test substance-treated groups. The results of this assay indicate that under the conditions of this study, the test substance did not induce a substantial increase of micronucleated polychromatic erythrocytes in bone marrow cells of male and female mice and is not mutagenic in the micronucleus test.  
 The results of the dose range-finding study: At 2000 and 1500 mg/kg doses, 3/3 males and 3/3 females died. At 1000 mg/kg dose, no animals died and at 1200 mg/kg dose, 1/3 males and 0/3 females died.

**Conclusions**

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):  
 Remarks:

1A  
 Reliable without restriction; guideline study.

**References**

Stammberger, I. 1999. Genamin LA 302 D. Mammalian Erythrocyte Micronucleus Test in Male and Female NMRI Mice. Report No. 99.0074. Hoechst Marion Roussel Deutschland GmbH, Drug Innovation & Approval, Department of Toxicology/Pathology, Frankfurt, Germany.

**Other**

Last changed:

June 19, 2002

Order number for sorting:

124i

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: Oleylamine (CAS RN 112-90-3;  
Cis-9-Octadecenylamine,)  
Purity: 90%  
Remarks:

### Method

Method/Guideline followed: TSCA test guidelines for cytogenetic tests (40 CFR 798.5385) and the final test rule (40 CFR 799.3157)  
Type: Cytogenetics assay  
GLP: Yes  
Year: 1989  
Species: Mouse  
Strain: ICR  
Sex: Male and female  
Route of administration: Oral gavage  
Doses/concentration levels: 500, 2500 and 5000 mg/kg  
Exposure period: Single administration  
Statistical methods: Fisher's exact test and Cochran-Armitage trend test for dose response.  
Remarks: Groups of mice (five males and five females) were administered a single dose of the test substance in corn oil by oral gavage at concentrations of 500, 2500 or 5000 mg/kg at a constant volume of 10 ml/kg. Two additional groups of mice (five males and five females) were used as the vehicle control and positive control. The vehicle control group received corn oil by gavage at 10 mg/kg. The positive control, triethylenemelamine (TEM), was injected IP at a dose level of 0.5 mg/kg. Body weights were taken immediately prior to dosing and at sacrifice. Clinical observations were made prior to sacrifice. Colchicine, used to arrest dividing cells at metaphase, was administered IP at 1 mg/kg to all mice two to four hours prior to scheduled sacrifice. Bone marrow cells, arrested in metaphase and collected 6, 12 and 24 hours after treatment, were examined microscopically for structural chromosome aberrations. The following criteria were used when evaluating the results: 1) the test substance was considered to induce a positive response when the number of aberrant cells was significantly increased in a dose-responsive manner relative to the vehicle control; 2) a significant increase at the high dose only with no dose-response was considered suspect; and 3) a significant increase at one

dose other than the high dose with no dose-response was considered equivocal.

A range-finding study was conducted with five treatment levels, 763, 1221, 1953, 3125, and 5000 mg/kg. Each group consisted of five male and five female mice.

## Results

<b>Male mice</b>	<b>Mean Aberrations/Cell</b>		
<b>Dose group</b>	<b>6 hours</b>	<b>12 hours</b>	<b>24 hours</b>
Vehicle control	0	0	0.004
500 mg/kg	0	0	0
2500 mg/kg	0	0	0
5000 mg/kg	0.004	0.008	0
TEM	--	0.436	--

<b>Female mice</b>	<b>Mean Aberrations/Cell</b>		
<b>Dose group</b>	<b>6 hours</b>	<b>12 hours</b>	<b>24 hours</b>
Vehicle control	0.004	0.004	0
500 mg/kg	0	0	0
2500 mg/kg	0.004	0	0
5000 mg/kg	0.004	0	0.004
TEM	--	0.34	--

Genotoxic effects:  
 NOAEL (NOEL):  
 Statistical results:  
 Remarks:

Negative  
 Not determined  
 Described below  
 One female in the 2500 mg/kg dose group died prematurely. No significant reduction in the rate of body weight gain was observed. Clinical signs observed in test substance-treated mice included diarrhea, piloerection, lethargy, crusty eyes and irregular breathing. No statistically significant increases in percentage of aberrant cells were observed in the test substance-treated groups, regardless of dose or bone marrow harvest time. The results of this assay indicate that under the conditions of this study, the test substance did not induce chromosomal aberrations in bone marrow cells of male and female mice.  
 The results of the dose range-finding study: One female in each of the following groups died prematurely: 5000, 3125 and 1221 mg/kg

**Conclusions**

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

**Data Quality**

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

**References**

Microbiological Associates, Inc. 1989. Oleylamine:  
Acute *in vivo* Cytogenetics Assay in Mice (Final  
Report) with cover letter dated 112789. EPA Doc. No.  
40-8984323, Microfiche No. OTS0525407.

**Other**

Last changed:

July 17, 2002

Order number for sorting:

26

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: Adogen 343 (CAS RN 61788-63-4; Dihydrogenated tallow methylamine)  
Purity: 97.0%  
Remarks: None

### Method

Method/Guideline followed: Not stated  
Type: Cytogenicity Study – Rat Bone Marrow in vivo  
GLP: Yes  
Year: 1982  
Species: Rat  
Strain: Sprague-Dawley  
Sex: Male and female  
Route of administration: Oral gavage  
Doses/concentration levels: 1.5, 5 and 15 g/kg/day  
Exposure period: Daily for 5 consecutive days  
Statistical methods: Not stated  
Remarks: Groups of rats (five of each sex) were administered the test substance in corn oil by oral gavage at one of three dose levels, 1.5, 5 or 15 g/kg body weight. Three additional groups of rats (five of each sex) were used as the negative control, vehicle control and positive control. The negative and vehicle control groups received distilled water or sesame oil, respectively, by gavage. The positive control, methylmethane sulfonate (MMS), was administered by gavage at a concentration of 80 mg/kg/day. Animals were examined twice daily during the 5-day treatment period for mortality, moribund or signs of adverse reaction to treatment.

An intraperitoneal injection of colchicine (1mg/kg) was given to inhibit mitosis in each animal approximately 20 hours after the last treatment and animals were sacrifice 2-4 hours later. Following sacrifice, the bone marrow of both femurs of each animal was prepared for chromosomal analysis. Fifty metaphase spreads were analyzed per animal. Cytogenetic abnormalities such as deletions, exchanges, rings, gaps and breaks were scored and the mitotic index on each animal was determined.

### Results

Genotoxic effects: Negative

NOAEL (NOEL):

Not determined

Statistical results:

Described below

Remarks:

Two deaths were observed in the high dose group (15 g/kg/day). No mortality was observed in the remaining groups. Signs of toxicity varied from inactivity to bloated abdomen and diarrhea, depending on the dose level administered. Positive control animals displayed signs of inactivity.

The following Total Aberrations (including gaps) were recorded:

Group	Treatment	Males	Females
Control	Water	10.4	6.8
Vehicle	Sesame oil	2.8	7.6
+ Control	MMS	10.0	18.8
TS	15 g/kg	5.2	14.0
TS	5 g/kg	6.4	6.4
TS	1.5 g/kg	8.8	4.8

TS = Test Substance

It was concluded that a significant number of chromosomal aberrations were not induced by this test substance.

## Conclusions

Remarks:

Based on the results of this cytogenicity study, this test substance has no mutagenic potential despite some non-dose related variations in the total number of aberrations reported. The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch):

1B

Remarks:

Reliable without restriction; comparable to guideline study.

## References

Esher, H.J. 1982. In vivo Cytogenetics Study in Rats. Unpublished Report No. MRI-I65-PG-82-34; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G/Mason Research Institute, Worcester, MA, USA.

## Other

Last changed/Initials:

September 23, 2003

Order number for sorting:

295

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: Tallow alkyl amine (CAS RN 61790-33-8)  
Purity: 98.7%  
Remarks:

### Method

Method/Guideline followed: OECD Guideline 474, Genetic Toxicology:  
Micronucleus Test.  
Type: Micronucleus assay  
GLP: Yes  
Year: 1981  
Species: Rat  
Strain: Sprague-Dawley  
Sex: Male and female  
Route of administration: Oral gavage  
Doses/concentration levels: Single dose/2000 mg/kg  
Exposure period: Single administration  
Statistical methods: Mann-Whitney  
Remarks: Groups of rats (five males and five females) were administered a single dose of the test substance in sesame oil by oral gavage. Two additional groups of rats (five males and five females/group) were used as the vehicle control and positive control. The vehicle control group received sesame oil by gavage. The positive control, cyclophosphamide, was injected IP. The following criteria were examined: 1) mortality and/or clinical signs; 2) number of micronucleated cells/2000 erythrocytes; and 3) ratio of polychromatic to normochromatic erythrocytes (PCE/NCE) by counting a total of 1000 PCE.

### Results

Genotoxic effects: Negative  
NOAEL (NOEL): Not determined  
Statistical results: Described below  
Remarks: One male died at 48-hours. Clinical signs observed in test substance-treated rats included piloerection, shallow breathing, hunched posture and hypoactivity.. The results of this assay indicate that under the conditions of this study, the test substance did not induce chromosomal aberrations in bone marrow cells of male and female rats. The positive control elicited the expected response.

At 24-hours: 1.1 (1.2 controls)  
At 48-hours: 1.2 (1.2 controls)  
Genotoxic effects at 2000 mg/kg:  
Mean number of micronucleated cells/2000 cells  
At 24-hours: 1.3  
At 48-hours: 1.6

### Conclusions

Remarks:

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen  
Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Fassio, F. 2000. Micronucleus Test in Rat Bone  
Marrow Cells Treated by Oral Route. APAG, Istituto  
di Ricerche Biomediche, "Antoine Marxer" RBM  
S.p.A.

### Other

Last changed:

June 26, 2002

Order number for sorting:

225a

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: TallowAmine; Ethoxylate (15% TAMET solution with 5% H<sub>3</sub>PO<sub>4</sub> in water) (CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)  
Purity: 15%  
Remarks:

### Method

Method/Guideline followed: OECD Guideline 474; EEC Directive 79/831 (Annex V, Part B)  
Type: Micronucleus assay  
GLP: Yes  
Year: 1981  
Species: Mouse  
Strain: CD-1  
Sex: Male and female  
Route of administration: Oral gavage  
Doses/concentration levels: Single dose/10860 mg/kg (concentration=543 mg/mL)  
Exposure period: Single administration  
Statistical methods: Mann-Whitney  
Remarks: Groups of 30 mice (15 of each sex) were administered a single dose of the test substance by oral gavage. Based upon results of a preliminary toxicity study, a dosage of 10860 mg/kg body weight was chosen for this micronucleus test. Two additional groups of mice (15 of each sex/group) were used as the negative control and positive control. The negative control group received sterile distilled water by gavage. The positive control, mitomycin C, was injected IP as a 0.2 mg/mL solution in 0.9% saline. The animals were examined regularly for mortality or clinical signs of reaction to the test substance following dosing. Five males and five females from each group were sacrificed 24, 48 and 72 hours after dosing. One bone marrow smear was prepared per animal from the tissue cleared from each femur. Stained smears were examined by light microscopy for incidence of micronucleated cells per 1000 polychromatic erythrocytes per animal and the ratio of polychromatic to normochromatic erythrocytes was assessed by the examination of at least 1000 erythrocytes.

## Results

Genotoxic effects:	Negative
NOAEL (NOEL):	Not determined
Statistical results:	Described below
Remarks:	One male animal died approximately 30 hours after treatment. Clinical signs reported during the 72 observation period included slight pallor to the extremities and diarrhea, slight to moderate pilo-erection, lethargy, decreased respiratory rate and ptosis, walking on toes, and greasy fur. Animals showed no reaction to the vehicle control and positive, mitomycin C, control treatments.

Increases in the number of micronucleated polychromatic erythrocytes at the 48- or 72-hour kills were significant; however, a statistically significant increase in the incidence of micronucleated polychromatic erythrocytes was obtained at the 24-hour kill. These increases were concluded to be unrelated to treatment, as both the individual and group results fell well within the historical negative control range. Significant decreases were observed in the ratio of polychromatic to normochromatic erythrocytes at all three kill times, suggesting treatment-related bone marrow cell toxicity.

The positive control compound, mitomycin C, produced significantly increased frequencies of micronucleated polychromatic and normochromatic erythrocytes, and decreased ratios of polychromatic to normochromatic erythrocytes.

*Mean number of micronucleated polychromatic cells/1000 cells (vehicle control, mitomycin C control)*

At 24 hours: 1.6 (0.6; 69.2)

At 48 hours: 1.7 (0.9; 62.8)

At 72 hours: 0.2 (0.9; to few erythrocytes to count)

*Mean number of micronucleated polychromatic cells/1000 cells (vehicle control, mitomycin C control)*

At 24 hours: 1.0 (0.9; 2.1)

At 48 hours: 1.6 (1.0; 4.2)

At 72 hours: 0.9 (0.8; 4.5)

### Conclusions

Remarks:

The <1% mortality and increased incidence of micronucleated polychromatic erythrocytes at 24 hours were concluded to be unrelated to treatment. However, it was also concluded that this test substance resulted in bone marrow cell toxicity, as evidenced by the significantly decreased ratios of micronucleated polychromatic to normochromatic erythrocytes.

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Allen, J.A., R.J. Proudlock, K. McCaffrey. 1984. Micronucleus Test on E-2352.01 (ECM BTS 902/01) Tamet. Unpublished Report No. P+G 1114/84560; for Procter and Gamble N.V., Stroombeek-Bever, Belgium; from Huntingdon Research Centre plc, Huntingdon, England.

### Other

Last changed:

September 23, 2003

Order number for sorting:

303

Remarks:

## 5.6 GENETIC TOXICITY *IN VIVO*

### Test Substance

Identity: (POE)<sub>20</sub> Tallowamine (Varonic T-220)  
(CAS RN 61791-44-4; Ethanol, 2,2'-iminobis-,N-tallow alkyl derivs.)

Purity: Not stated

Remarks: None

### Method

Method/Guideline followed: Not stated

Type: Cytogenicity Study – Rat Bone Marrow in vivo

GLP: Yes

Year: 1982

Species: Rat

Strain: Sprague-Dawley

Sex: Male and female

Route of administration: Oral gavage

Doses/concentration levels: 39, 130 or 390g/kg/day

Exposure period: Daily for 5 consecutive days

Statistical methods: Not stated

Remarks: Groups of rats (five of each sex), weighing 150 to 200 g, were administered the test substance in water by oral gavage at one of three dose levels, 39, 130 or 390 mg/kg body weight. Two additional groups of rats (five of each sex) were treated in the negative control and positive control groups. The negative groups received distilled water by gavage. The positive control, methylmethane sulfonate (MMS), was administered by gavage at a concentration of 80 mg/kg/day. Animals were examined twice daily during the 5-day treatment period for mortality, moribund or signs of adverse reaction to treatment.

An intraperitoneal injection of colchicine (1mg/kg) was given to inhibit mitosis in each animal approximately 20 hours after the last treatment and animals were sacrifice 2-4 hours later. Following sacrifice, the bone marrow of both femurs of each animal was prepared for chromosomal analysis. Approximately 50 metaphase spreads were analyzed per animal. Cytogenetic abnormalities such as deletions, exchanges, rings, gaps and breaks were scored and the mitotic index on each animal was determined.

## Results

Genotoxic effects: Negative  
NOAEL (NOEL): Not determined  
Statistical results: Described below  
Remarks: All animals in the high dose group, 390 mg/kg/day, developed diarrhea, and only 2 females in the lower dose groups displayed similar signs. Some of the treated animals developed red-brownish exudates around the eyes and mount, but these signs were not considered treated related. Pale brown feces was observed in some of the animals in the positive control, MMS, group.

The following Total Aberrations (including gaps) were recorded:

Group	Treatment	Males	Females
Control	Water	0.4	1.6
+ Control	MMS	18.0	18.0
TS	390 g/kg	0.4	1.6
TS	130 g/kg	0	0.4
TS	39 g/kg	0	0.4

TS = Test Substance

It was concluded that a significant number of chromosomal aberrations were not induced by this test substance.

## Conclusions

Remarks: Based on the results of this cytogenicity study, this test substance has no mutagenic potential

The endpoint has been adequately characterized.  
(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

## Data Quality

Reliability (Klimisch): 1B  
Remarks: Reliable without restriction; comparable to guideline study.

## References

Esher, H.J. 1982. In vivo Cytogenetics Study in Rats. Unpublished Report No. MRI-182-PG-82-58; for The Procter and Gamble Company, Cincinnati, OH, USA; from EG&G/Mason Research Institute, Worcester, MA, USA.

**Other**

Last changed/Initials: September 24, 2003

Order number for sorting: 309

Remarks:

## 5.8 TOXICITY TO REPRODUCTION

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine,  
hydrofluoride; CAS RN 36505-83-6]

Purity: Amine fluoride 335 = 6.2%  
Amine fluoride 242 = 7.0%

Remarks: 1:1 mixture of each amine fluoride

### Method

Method/guideline followed: Segment I (Study of Fertility and General  
Reproductive Performance), Guidelines for  
Reproduction Studies for Safety Evaluation of Drugs  
for Human Use, U. S. Food and Drug Administration,  
1966.

Type: Oral

GLP: Not stated

Year: 1973

Species: Rat

Strain: Long-Evans

Route of Administration: Oral gavage

Doses/concentration levels: 0, 1.2, 6.0 and 30.0 mg/kg/day

Sex: Male and female

Control group and treatment: Yes, 0.25% methylcellulose at 10 ml/kg/day

Frequency of treatment: Once daily

Duration of test: Treatment began for males and females at least 60 and  
15 days, respectively, prior to and throughout mating  
of the F<sub>0</sub> generation, and continued for females during  
gestation and lactation for one litter.

Premating exposure period for  
males: At least 60 days prior to mating

Premating exposure period for  
females: At least 15 days prior to mating

Statistical methods: Comparisons between control and test groups were  
made where applicable by the Chi-square method or  
the t-test, including Cochran's adjustment if the  
variances were significantly different (F-test)

Remarks: Ten males and 20 females per group were exposed to  
the test substance by gavage at dose levels of 1.2, 6.0  
and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day  
in a vehicle of 0.25% methylcellulose for a prebreed  
period of 60 and 15 days, respectively. A control  
group with the same number of animals was treated  
with the vehicle only. Following the prebreed  
exposure period, one male and two females within

each dose group were caged together until a sign of mating was observed, for a maximum 23-day mating period. Exposure to the test substance or vehicle continued through mating for males and females, and continued through gestation and lactation for females. Body weights were collected weekly for males. Body weights for females were collected weekly prior to evidence of mating, daily during gestation and on days 0 through 7, 14 and 21 of lactation. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. Estrous cycle observations were performed beginning at study initiation and continuing until mating was observed or 23 days of cohabitation had been completed.

A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. The uterine contents were examined and implantation sites were counted for females that died prior to scheduled sacrifice. On gestation day 13 every other mated female in each group was sacrificed, and examined for evidence and status of embryos. An examination of the uterus, including the number and location of resorptions, embryos and implantation sites, and ovaries, including the number of corpora lutea, was conducted. Males were sacrificed after pregnancy was assured (by the presence of offspring) for at least two-thirds of the dams. The testes and epididymides were fixed in buffered neutral formalin.

The remaining females were allowed to deliver and lactate. Pups were examined for general condition and counted daily. They were checked for the presence of milk daily, until no longer discernible because of fur growth. Pups also were sexed and weighed individually on lactation days 0, 4 and 21. Pups that died prior to scheduled sacrifice were weighed, and examined externally and internally for malformations. The remaining dams and all surviving pups were sacrificed and necropsied on lactation day 21. The implantation scars of the dams were counted and the pups were weighed, examined externally and internally (for visceral gross pathology), and sexed internally.

## Results

NOAEL:	Parental NOAEL = 6.0 mg/kg/day Offspring NOAEL = 30.0 mg/kg/day
Actual dose received: F <sub>0</sub> and F <sub>1</sub> data:	1.2, 6.0 and 30.0 mg/kg/day One female in the high dose group died during the first week of premating. This death was not attributed to the administration of the test substance. There were no adverse effects that could be attributed to the test substance as evidenced in evaluations of female body weights and weight gains, adult mortality, mating performances, estrous cycles, pregnancy rates, lengths of gestation, intrauterine deaths, implantation efficiencies, numbers of implantations or litter size. A statistically significant decrease in mean body weight gain was observed in males for the high dose group when compared to the control group. No test substance-related gross pathology was observed in the males or females that were sacrificed or died spontaneously.
Offspring toxicity:	Evaluations of offspring viability, litter survival, offspring weight, sex ratio, and incidence of malformations showed no adverse effects attributable to administration of the test substance. Examination of the skeletons of pups dying prior to weaning revealed no malformations that could be attributed to administration of the test substance.
Statistical results: Remarks:	Described above

## Conclusions:

Remarks:	The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)
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## Data Quality

Reliability:	1A
Remarks:	Reliable without restriction; guideline study.

## References

Smith, J.M. 1973. A Segment I Rat Fertility Study of Amine Fluoride 335/242. Project Number 72R-817. Bio/dynamics Inc., East Millstone, NJ, USA.

**Other available reports:**

**Other**

Last changed:	November 19, 2002
Order number for sorting:	27a
Remarks:	

## 5.8 TOXICITY TO REPRODUCTION

### Test Substance

Identity: Genamin TA 100 (CAS RN 61790-33-8; Amines, tallow alkyl)  
Purity: >96%  
Remarks:

### Method

Method/guideline followed: OECD 421: Reproduction/Developmental Toxicity Screening Test  
Type: One generation  
GLP: Yes  
Year: 2000  
Species: Rat  
Strain: Sprague Dawley CrI:CD(SD)BR  
Route of administration: Oral gavage  
Doses/concentration levels: 0, 12.5, 50 and 150 mg/kg  
Vehicle: Sesame oil  
Sex: 10 male and 10 female per group  
Exposure period: Male rats from 14 days prior to mating until end of mating period for a maximum of 28 days.  
Female rats from 14 days prior to mating throughout mating, during pregnancy up until day 3 of lactation (approximately 54 days).  
Premating exposure period: 14 days for males and females  
Frequency of treatment: Once daily  
Control group and treatment: Yes; concurrent, treated with vehicle (sesame oil)  
Duration of test: 14 days prior to mating until day 3 of lactation  
Statistical methods: Chi-square test, Fisher's exact test, Trend test, Bartlett's test, ANOVA, Dunnett's test, Kruskal-Wallis test, Mann-Whitney "U" test  
Remarks: Ten male and ten female rats per group received the test substance by oral administration at dose levels of 0 (vehicle control), 12.5, 50 or 150 mg/kg/day at a constant dose volume of 10 ml/kg. At study initiation, animals were approximately 10 weeks of age, males weighed 303 to 347g and females weighed 233 to 275 g. Animals were observed daily for clinical signs, behavior and mortality. Body weights and food consumption were recorded weekly for males. Body weights and food consumption were recorded weekly during pre-mating for females and on gestation days 0, 7, 14 and 20 and during lactation on day 0 (parturition) and day 4. Females were examined three times daily for parturition. Maternal behavior was also evaluated. Histology was carried out on gross lesions, ovaries,

uteri, testes, epididymides, and accessory sex organs of the control and high dose group animals. Additional sections of testes of final sacrificed animals of the control and high dose groups were stained with PAS-hematoxylin to allow spermatogenesis to be classified into 14 stages.

Parameters assessed for F1 generation:

Number of live and stillbirths were recorded. Pups were observed daily (from birth to day 4) for survival and clinical observations and weighed on days 0 and day 4. Sex and external abnormalities were noted on day 0. A necropsy was performed on all pups that died.

Dose formulations were analyzed by HPLC/UV on the first and last week of treatment of the females.

## Results

Maternal toxicity NOAEL:	12.5 mg/kg/day
Offspring NOEL:	12.5 mg/kg/day
Actual dose received:	92 to 111% of nominal doses.
F0 Parental data:	Mortality – 1/10 females (gavage error); 1/10 females (day 13) and 1/10 males (day 24) at 50 mg/kg; and 5/10 females and 5/10 males at 150 mg/kg (days 9-25). Salivation, hunched posture, incidental soft stool and piloerection were observed in the 150 mg/kg group and salivation was observed in the 50 mg/kg group. A dose related decrease in pre-mating body weight gains was observed in all animals in the 50 and 150 mg/kg dose groups. A dose related decrease in gestational body weights was observed for females in the 12.5 (body weight gain), 50 and 150 mg/kg dose groups. Lactation body weights were also decreased in females in the 12.5 and 50 mg/kg dose groups. Food consumption was decreased in all animals at 50 and 150 mg/kg. This decrease was dose-related only in the males. Females in the 50 and 150 mg/kg dose groups had decreased food consumption from gestation days 0 to 14. Food consumption was also decreased in the females in the 12.5 and 50 mg/kg dose groups during lactation. Mating index was 100% (9/9), 90% (9/10), 100% (9/9) and 43% 3/7 in the 0, 12.5, 50 and 150 mg/kg dose groups, and the fertility index in these respective groups was 100% (9/9), 89% (8/9), 78% (7/9) and 33% (1/3). Precoital interval was 2.3, 3.9, 2.7 and 13.5 days in the 0, 12.5, 50 and 150 mg/kg dose groups, respectively. Implantation loss was increased (100% loss) at the 150 mg/kg group.

Duration of gestation was 22 days for females in all groups but the 150 mg/kg dose group. Gross necropsy observations for the animals that died included dilation and/or congestion of the gastrointestinal tract and congestion of the lungs. There were no macroscopic findings noted in the surviving animals. Statistically significant changes in the weight of the epididymides (decrease in absolute weight and increase in weight relative to body weight) and an increase in relative testes weight were noted 150 mg/kg dose group males. Tubular degeneration in the testes with decreased spermatogenesis in one male was noted in the males in the 150 mg/kg dose group. Atrophia of corpora lutea was observed in eight of ten females in the 150 mg/kg dose group.

Fetal data: There were no litters in the 150 mg/kg dose group. There were no treatment-related effects on the sex ratio, viability index, survival or visible abnormalities. Body weights of the pups were decreased at 50 mg/kg.

Statistical results: Effects reported were in almost all cases statistically significant in at least one sex.

Remarks: NOAEL for parental toxicity = 12.5 mg/kg (author)  
NOAEL for fertility = 50 mg/kg  
NOAEL for effects on offspring = 12.5 mg/kg (author)

### Conclusions

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch): 1

Remarks: Reliable without restriction

### References

Bussi, R. 2000. Genamin TA100: Reproduction/Developmental Toxicity Screening Test in Rats by Oral Route. APAG, Istituto di Ricerche Biomediche "Antoine Marxer" RBM S.p.A.

### Other available reports

### Other

Last changed: August 12, 2002

Order number for sorting: 225b

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:  
Amine fluoride 335 = 6.2%  
Amine fluoride 242 = 7.0%

Remarks: 1:1 mixture of each amine fluoride

### Method

Method/guideline followed: Segment II (Teratology Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966

GLP: No

Year: 1973

Species: Rat

Strain: Long-Evans

Route of administration: Oral gavage

Doses/concentration levels: 1.2, 6.0 and 30.0 mg/kg

Sex: Female

Exposure period: Days 6 through 15 of gestation

Frequency of treatment: Daily

Control group and treatment: Yes, 0.25% methylcellulose

Duration of test: Days 0 through 21 of gestation

Statistical methods: Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test).

Remarks: Twenty mated female rats/group were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 6 through day 15 of gestation. A control group of 20 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 6 through 15 (daily) and 21. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered early were sacrificed on the

day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 19 days old were fixed in buffered neutral formalin and those 19 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 21. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice all fetuses were identified, weighed, crown-rump distance measured and examined externally for malformations, and the external sex was determined. In approximately two-thirds of the fetuses, gross dissection and examination of viscera, and internal sex determination were conducted as well as an examination of the skeleton for anomalies and ossification variations after clearing and alizarin red staining of the fetuses. The remaining one-third of the fetuses were fixed with Bouin's and examined for neural and visceral defects after being serially sectioned by the Wilson slicing technique. Additionally, sex was determined internally.

## Results

Maternal toxicity NOEL:	30.0 mg/kg/day
Developmental toxicity NOEL:	Not determined. Study repeated.
Actual dose received:	1.2, 6.0 and 30.0 mg/kg/day
Maternal data:	There were 16, 16, 16 and 20 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. There were no adverse effects upon maternal body weight, pregnancy rate, mortality, early deliveries or abortions, implantation efficiency, or resorptions.
Fetal data:	There were no dead fetuses in any group. There were no adverse effects upon fetal size or fetal sex. There was no biologic or toxicologic significance attached to the incidence of ossification variations observed in this study. The incidence of malformed fetuses was 0, 0.6, 0.5 and 3.1% in the control, low, mid and high dose groups, respectively. The malformations observed in this study had been reported to occur spontaneously in control animals of other studies; however, because of the zero incidence of malformations in the control group of this study, it could not be concluded that there was no contributory effect of the test substance.
Statistical results:	Described above

Remarks: Because of the observation of sporadic malformations in the treatment groups and absence of these malformations in the control group of this study, which had been observed in control animals of other studies, this study was repeated using the exact methods of this study and was identified by Bio/dynamics project number 73R-880 (see following robust summary).

### Conclusions

Remarks: The study was repeated due to equivocal results. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Smith, J.M. 1973. A Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 72R-820. Bio/dynamics Inc., East Millstone, NJ, USA.

### Other available reports

#### Other

Last changed:

November 19, 2002

Order number for sorting:

178/195

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:  
Amine fluoride 335 = 6.2%  
Amine fluoride 242 = 7.0%

Remarks: 1:1 mixture of each amine fluoride

### Method

Method/guideline followed: Segment II (Teratological Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966

GLP: No

Year: 1973

Species: Rat

Strain: Long-Evans

Route of administration: Oral gavage

Doses/concentration levels: 1.2, 6.0 and 30.0 mg/kg

Sex: Female

Exposure period: Days 6 through 15 of gestation

Frequency of treatment: Daily

Control group and treatment: Yes, 0.25% methylcellulose

Duration of test: Days 0 through 21 of gestation

Statistical methods: Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test).

Remarks: To clarify the results of a previously reported study (Bio/dynamics project number 72R-820) in which sporadic malformations were observed, the test substance was administered under identical conditions. Twenty mated female rats/group were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 6 through day 15 of gestation. A control group of 20 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 6 through 15 (daily) and 21. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects,

and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered early were sacrificed on the day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 19 days old were fixed in buffered neutral formalin and those 19 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 21. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice all fetuses were identified, weighed, crown-rump distance measured and examined externally for malformations, and the external sex was determined. In approximately two-thirds of the fetuses gross dissection and examination of viscera, and internal sex determination were conducted as well as an examination of the skeleton for anomalies and ossification variations after clearing and alizarin red staining of the fetuses. The remaining one-third of the fetuses were fixed with Bouin's and examined for neural and visceral defects after being serially sectioned by the Wilson slicing technique. Additionally, sex was determined internally.

## Results

Maternal toxicity NOAEL:	6.0 mg/kg/day
Developmental toxicity NOAEL:	30.0 mg/kg/day
Actual dose received:	1.2, 6.0 and 30.0 mg/kg/day
Maternal data:	There were 19, 18, 18 and 17 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. One dam died on gestation day 10, but the death was not considered test substance-related as it was the result of a dosing accident. A statistically significant decrease in the mean weight gains of the high dose group dams was observed when compared to the control group. There were no adverse effects upon pregnancy rate, mortality, early deliveries, implantation efficiency, or resorptions.
Fetal data:	There were no dead fetuses in any group. There were no adverse effects upon fetal size or fetal sex. The incidences of delay in ossification were almost identical for control and test groups.
Statistical results:	Described above

Remarks: In the absence of any malformed fetuses in the high dose group, the test substance was considered to be nonteratogenic when administered to rats under the conditions of this study.

### **Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch): 1A  
Remarks: Reliable without restriction; guideline study.

### **References**

Smith, J.M. 1973. Segment II Rat Teratology Study of Amine Fluoride 335/242. Project Number 73R-880. Bio/dynamics Inc., East Millstone, NJ, USA.

### **Other available reports**

#### **Other**

Last changed: November 19, 2002  
Order number for sorting: 179/196  
Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:  
Amine fluoride 335 = 6.2%  
Amine fluoride 242 = 7.0%

Remarks: 1:1 mixture of each amine fluoride

### Method

Method/guideline followed: Segment II (Teratology Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966

GLP: No

Year: 1973

Species: Rabbit

Strain: New Zealand White

Route of administration: Oral gavage

Doses/concentration levels: 1.2, 6.0 and 30.0 mg/kg

Sex: Female

Exposure period: Days 7 through 19 of gestation

Frequency of treatment: Daily

Control group and treatment: Yes, 0.25% methylcellulose

Duration of test: Days 0 through 30 of gestation

Statistical methods: Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test).

Remarks: Fourteen, 19 and 18 mated female rabbits were exposed to the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day, respectively, at a dose volume of 1 ml/kg/day in a vehicle of 0.25% methylcellulose from days 7 through day 19 of gestation. A control group with 17 animals was treated with the vehicle only. Body weights were taken on gestation days 0, 7, 10, 13, 16, 19, 24 and 30. Physical observations were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Dams that aborted or delivered

early were sacrificed on the day clear signs of abortion or early delivery were observed, and the reproductive system was examined. Fetuses less than 28 days old were fixed in buffered neutral formalin and those 28 days or older were cleared and stained. All surviving dams were sacrificed at study termination on gestation day 30. An examination of the uterus, including the number and location of live and dead fetuses, early and late resorptions, and implantation sites, and ovaries, including the number of corpora lutea, was conducted. At sacrifice, fetuses were identified, weighed, crown-rump distance measured and examined externally for defects. Gross dissection and examination of viscera, and internal sex determination also were conducted on each fetus. Finally, an examination of the skeleton for anomalies and ossification variations was conducted after clearing and alizarin red staining of the fetuses.

## Results

Maternal toxicity NOEL:

Developmental toxicity NOEL:

Actual dose received:

Maternal data:

Not determined. The LOAEL = 1.2 mg/kg/day

30 mg/kg/day

1.2, 6.0 and 30.0 mg/kg/day

There were 12, 11, 13 and 13 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. A statistically significant decrease in maternal body weight gain in the low dose group was observed. In addition, increased maternal mortality in the mid and high dose groups was observed. Six females (three mid dose and three high dose) died between gestation days 12 and 24. Of those animals that died, one high dose and two mid dose does were pregnant. One high and two mid dose does had lesions compatible with those of toxemia (one mid dose death was considered related to pneumonia, the other two deaths being of an unknown origin); and one high dose doe had acute pneumonia. The post mortem condition of the other high-dose doe precluded a meaningful evaluation. The cause of death of the other mid dose doe was unknown. Effects described above were attributed to a secondary toxemia resulting from the antibacterial properties of the amine fluorides against Gram-positive bacteria followed by an overgrowth of Gram-negative bacteria. The incidences of resorptions in all treatment groups were substantially greater when comparisons were made to the control group incidence. This increase in resorptions was statistically significant in the high dose group only (25 resorbed of the total

103 fetuses). The cause of the increases in the number of resorptions could not be determined Due to the increases in mortality and secondary toxemia of the does. There were no adverse effects upon pregnancy rate, or incidences of early deliveries and abortions that could be attributed to the administration of the test substance.

Fetal data:

There were no dead fetuses in any group. Four fetuses (two low dose, one mid dose and one high dose) were observed to be malformed. This low incidence was not considered to express evidence of a teratogenic effect resulting from the administration of the test substance. There were no adverse effects upon fetal size, fetal sex or ossification variations that could be attributed to the administration of the test substance.

Statistical results:

Described above

Remarks:

### Conclusions

Remarks:

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Smith, J.M. 1973. Amine Fluoride 335/242 Segment II Rabbit Teratology Study. Project Number 72R-818. Bio/dynamics Inc., East Millstone, NJ, USA.

### Other available reports

#### Other

Last changed:

November 19, 2002

Order number for sorting:

177/194

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Amine fluorides 335/242  
[Hetaflur; CAS RN 3151-59-5; 9-octadecen-1-amine, hydrofluoride; CAS RN 36505-83-6]

Purity: Not provided in this report; however, the following information was provided in a Segment I study performed at this laboratory in the same time frame by the same author:  
Amine fluoride 335 = 6.2%  
Amine fluoride 242 = 7.0%

Remarks: 1:1 mixture of each amine fluoride

### Method

Method/guideline followed: Segment III (Perinatal and Postnatal Study), Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, U. S. Food and Drug Administration, 1966

GLP: No

Year: 1973

Species: Rat

Strain: Long-Evans

Route of administration: Oral gavage

Doses/concentration levels: 1.2, 6.0 and 30.0 mg/kg

Sex: Female

Exposure period: Day 15 of gestation through Day 21 of lactation

Frequency of treatment: Daily

Control group and treatment: Yes, 0.25% methylcellulose

Duration of test: Day 0 of gestation through Day 21 of lactation

Statistical methods: Comparisons between control and test groups were made where applicable by the Chi-square method or the t-test, including Cochran's adjustment if the variances were significantly different (F-test).

Remarks: Female rats were administered the test substance by oral gavage at dose levels of 1.2, 6.0 and 30.0 mg/kg/day at a dose volume of 10 ml/kg/day in a vehicle of 0.25% methylcellulose from day 15 of gestation through day 21 of lactation. A control group was treated with the vehicle only. The 0 (control), 1.2 and 6.0 mg/kg/day groups each contained 20 mated female rats and the 30.0 mg/kg/day group contained 22 mated female rats. Body weights were obtained during gestation on days 0 and 7, and daily from day 15 through the end of the gestation period. During lactation, body weights were obtained on days 0 through 7 (daily), 14 and 21. Physical observations

were conducted daily for signs of pharmacologic or toxicologic effects, and mortality. A gross necropsy was conducted on animals sacrificed at scheduled termination, on moribund animals, and on spontaneous deaths. Toward the end of gestation dams were provided with nesting material and examined daily for signs of parturition. The uterine contents were examined and implantation sites were counted for females that died during gestation, prior to scheduled sacrifice. Pups were examined for general condition and counted daily. They were checked for the presence of milk daily, until no longer discernible because of fur growth. Pups also were sexed and weighed individually on lactation days 0, 4 and 21. Pups that died prior to scheduled sacrifice were weighed, and examined externally. They were examined internally for sex determination and for the presence of milk in the stomach. Finally, they were preserved for studies of skeletal anomalies. If the entire litter died prior to lactation day 21, the dam was sacrificed, the mammary tissue was saved in buffered neutral formalin, and implantation scars were counted. If dams died prior to lactation day 21, the mammary tissue was saved in buffered neutral formalin, and implantation scars were counted. Surviving pups were sacrificed, and the same procedures were used for dead pups. The remaining dams and all surviving pups were sacrificed and necropsied on lactation day 21. The implantation scars of the dams were counted and the pups were individually weighed, examined externally and internally (for visceral gross pathology), and sexed internally.

## Results

Maternal toxicity NOEL:	30.0 mg/kg/day
Developmental toxicity NOEL:	30.0 mg/kg/day
Actual dose received:	1.2, 6.0 and 30.0 mg/kg/day
Maternal data:	There were 19, 19, 19 and 18 pregnant animals in the control, 1.2, 6.0 and 30.0 mg/kg dose groups, respectively. There were no adverse effects upon pregnancy rate, mortality, length of gestation, number of implantations, live-birth index, postnatal viability, offspring weights on lactation days 4 and 21, sex ratios, or soft-tissue malformations. There was a smaller maternal body weight gain during the period of lactation in the high dose group when compared to the controls, although this difference was not statistically

Fetal data: significant.  
There were no dead fetuses in any group. There were no adverse effects upon fetal size, fetal sex or ossification variations that could be attributed to the administration of the test substance. The mean offspring weights of all the test substance-treated groups were lower than the controls on lactation day 0, although this difference was not statistically significant, and were comparable thereafter.

Statistical results: Described above

Remarks: The administration of amine fluoride 335/242 was considered not to have a biologic or toxicologic effect in this study.

### **Conclusions**

Remarks: The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### **Data Quality**

Reliability (Klimisch): 1 A

Remarks: Reliable without restriction; guideline study.

### **References**

Smith, J.M. 1973. A Segment III Perinatal and Postnatal Study of Amine Fluoride 335/242 in Rats. Project Number 72R-819. Bio/dynamics Inc., East Millstone, NJ, USA.

### **Other available reports**

#### **Other**

Last changed: November 19, 2002

Order number for sorting: 176/197

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Oleylamine (9-Octadecenylamine, (Z)-; (CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: US EPA TSCA 40 CFR Part 798.4700  
GLP: Yes  
Year: 1989  
Species: Rat  
Strain: Sprague Dawley CrI:COBS<sup>®</sup>CD<sup>®</sup>BR<sup>®</sup> VAF/PLUS<sup>®</sup>  
Route of administration: Oral gavage  
Doses/concentration levels: 0, 10, 40 and 80 mg/kg  
Sex: Female  
Exposure period: Days 6 through 15 of gestation  
Frequency of treatment: Daily  
Control group and treatment: Yes, 5 ml/kg corn oil  
Duration of test: Days 0 through 15 or 0 through 20 of gestation  
Statistical methods: Two-tailed tests, one-way analysis of variance, Dunnett's Test, Chi-Square Test, Mann-Whitney U-Test, Fisher's Exact Test  
Remarks: Groups of 28 mated female rats, 14 weeks old and weighing 229 to 316 g, were administered the test substance at dose levels of 10, 40 and 80 mg/kg/day at a dose volume of 5 ml/kg. The control rats received corn oil at an equivalent volume. All rats were administered the test substance and/or vehicle for ten consecutive days, from GD 6 through GD 15. The rats were observed daily, and individual body weights and food consumption were taken on GDs 0, 6, 9, 12, 16 and 20. Evidence of mating was determined by the presence of a copulatory plug in the vagina or a sperm positive vaginal smear and was considered day 0 of gestation. Two rats in each group were sacrificed after treatment on GD 15. The gastrointestinal tract was examined for signs of irritation. Cesarean sections were performed for the remaining rats on GD 20 and included a maternal necropsy examination. Individual gravid uterine weights were recorded. The fetuses were individually weighed, sexed and examined for external abnormalities. Fetuses were subsequently processed and examined for visceral and skeletal abnormalities.

*Range-finding study:* A range-finding study was conducted prior to this study to provide information concerning the effects of Oleylamine when administered orally to pregnant rats on gestation day (GD) 6 through 15 to aid in dose level selection for the definitive developmental toxicity study. The test substance was administered at dose levels of 5, 50, 100, 150 and 250 mg/kg/day in corn oil at a dose volume of 5 ml/kg. A control group received corn oil at 5 ml/kg. Each group consisted of eight mated females. Two females from each group were sacrificed on GD 15 and examined for signs of gastrointestinal irritation. The study parameters evaluated in the range-finding study were identical to the definitive study except that at necropsy, the fetuses were examined externally and then discarded without further evaluation.

## Results

Maternal toxicity NOEL:	10 mg/kg/day
Developmental toxicity NOEL:	80 mg/kg/day
Actual dose received:	10, 40 and 80 mg/kg
Maternal and fetal data:	All rats survive to scheduled sacrifice. Clinical signs of toxicity were observed at the 40 and 80 mg/kg/day dose levels. In the 40 and 80 mg/kg/day dose groups, the most notable clinical findings included rales, salivation, soft stools, diarrhea, few feces, abnormal colored feces, fecal and/or urine stain, and unkempt appearance. Clinical signs observed only in the 80 mg/kg/day dose group included emaciation, rough coat and dark red material around the eyes, nose and/or mouth. Significant post dose observations included salivation in the 40 and 80 mg/kg/day dose groups and rales in the 80 mg/kg/day dose group. Dose-dependent body weight losses or reduced weight gain, along with a corresponding reduction in food consumption occurred during the treatment period at the 40 and 80 mg/kg/day dose levels. Gross necropsy evaluation of the gastrointestinal tracts from females sacrificed on GD 15 revealed no irritative effects. No treatment-related changes were apparent at any level tested concerning necropsy observations, cesarean section data or fetal external, visceral or skeletal examinations.
Statistical results:	Described above
Remarks:	Range-finding study results: Treatment-related deaths occurred in the 100, 150 and 250 mg/kg/day dose groups. Outward clinical signs of toxicity occurred at

dose levels of 50 mg/kg/day and higher. The findings were primarily related to changes in the amount, color and consistency of the feces. Other clinical signs included emaciation, unkempt appearance, dark red material around the eyes, nose and/or mouth and reddish colored vaginal discharge and/or urogenital staining. Post dose observations also revealed transient toxic signs including salivation, tremors, gasping, scratching at the cage floor and dragging chin on the cage floor. Body weight losses or reduced weight gain also occurred at dose levels from 50 mg/kg/day and higher throughout the treatment period. After treatment, weight gain was observed in all dose groups except the 150 mg/kg/day group. Necropsy findings of animals that did not survive to scheduled sacrifice included enlarged and/or dark red adrenals and dark red foci in the stomach mucosa. No other signs of gastrointestinal irritation were noted at the GD 15 sacrifice; however, dark red and enlarged adrenals were observed in the 100, 150 and 250 mg/kg/day groups. All of the females sacrificed on GD 20 were normal internally. The mean post-implantation loss was increased and the mean fetal weight was reduced at the 150 and 250 mg/kg/day group.

### Conclusions

Remarks:

Oral administration of 40 and 80 mg/kg/day of Oleylamine to pregnant CD<sup>®</sup> rats induced dose dependent maternal toxicity exhibited by adverse clinical signs, body weight losses and reduced food consumption. Oleylamine was neither developmentally toxic nor teratogenic at dosages up to 80 mg/kg/day. (Author of report)  
The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):  
Remarks:

1A  
Reliable without restriction; guideline study.

**References**

Mercieca, M. D. 1989. Teratology Study in Rats with Oleylamine. Study No. 3205.9. Springborn Laboratories Inc., Spencerville, OH, USA.

Mercieca, M. D. 1989. Range-Finding Teratology Study in Rats with Oleylamine. Study No. 3205.8. Springborn Laboratories Inc., Spencerville, OH, USA.

**Other**

Last changed:

July 17, 2002

Order number for sorting:

29a

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: Oleylamine (CAS RN 112-90-3; Cis-9-Octadecenylamine)  
Purity: Not stated  
Remarks:

### Method

Method/Guideline followed: U.S. EPA TSCA 40 CFR 798.4700  
GLP: Yes  
Year: 1989  
Species: Rabbits  
Strain: New Zealand White  
Route of administration: Oral gavage  
Doses/concentration levels: 0, 3, 10 and 30 mg/kg/day  
Sex: Female  
Exposure period: Days 6 through 18 of gestation  
Frequency of treatment: Daily  
Control group and treatment: Yes (concurrent, dosed with corn oil at a dose volume of 0.5 ml/kg)  
Duration of test: Days 0 through 29 of gestation  
Statistical methods: Continuous data evaluated used a one-way ANOVA. If significant, group comparisons were performed using Dunnett's test. Count data analyzed using Chi-Square test for fetal sex ratios, Mann-Whitney U-Test for resorptions, and a Fisher's Exact test for the number of fetal variations and malformations. The doe or litter were considered the experimental unit of measure.  
Remarks: The test substance, in the vehicle corn oil, was administered orally to 3 groups of artificially inseminated female rabbits (22 rabbits/group). The vehicle alone was administered orally to one group of 22 rabbits. Animals were treated at dose levels of 0, 3, 10 and 30 mg/kg/day at a dose volume of 0.5 ml/kg. Animals were administered the test substance or vehicle for 13 consecutive days, from gestation day (GD) 6 through GD 18. Dose solutions were prepared daily. Animals were observed daily, and individual body weights and food consumption were measured on GD 0, 6, 9, 12, 15, 19, 24 and 29. Two animals from each group were sacrificed after treatment on GD 18. Fecal samples were collected from these animals to determine the proportion of gram positive to gram negative organisms in the microflora. The gastrointestinal tract also was examined for signs of

irritation. Cesarean sections were performed on the surviving animals on GD 29 and included a maternal necropsy examination. Individual gravid uterine weights were recorded. The fetuses were individually weighed, sexed and examined for external abnormalities. Fetuses subsequently were processed and examined for visceral and skeletal abnormalities. *Range-finding study:* A range-finding study was conducted prior to this study to provide information concerning the effects of Oleylamine when administered orally to pregnant rabbits on gestation day (GD) 6 through 18 to aid in dose level selection for the definitive developmental toxicity study. The test substance was administered at dose levels of 5, 25, 50, 100 and 150 mg/kg/day in corn oil at a dose volume of 5 ml/kg. A control group received corn oil at 5 ml/kg. Each group consisted of seven mated female rabbits. The study parameters evaluated in the range-finding study were identical to the definitive study except that at necropsy, the fetuses were examined externally and then discarded without further evaluation.

## Results

Maternal toxicity NOEL:	3 mg/kg/day
Developmental toxicity NOEL:	30 mg/kg/day
Actual dose received:	0, 3, 10 and 30 mg/kg/day
Maternal data:	Two females died in the 30 mg/kg/day group. Clinical signs of toxicity and irritation of the lips and chin were observed in animals dosed at 10 and 30 mg/kg/day. Salient clinical signs at 10 and 30 mg/kg/day included labored breathing and rales. Animals at 30 mg/kg/day were also emaciated. Dose-dependent body weight losses or reduced weight gain, along with a corresponding reduction in food consumption occurred during the treatment period in animals dosed at 10 and 30 mg/kg/day. Gross necropsy evaluation of the gastrointestinal tracts from females sacrificed on GD 18 revealed no signs of gastrointestinal irritation. No treatment-related changes were apparent at any level tested concerning necropsy observations or cesarean section data.
Fetal data:	The mean fetal weight of the 30 mg/kg/day group was slightly lower than the control group; however not statistically significant. A similar lower mean occurred in the 3 mg/kg/day but not at 10 mg/kg/day, where the mean fetal weight was comparable to the control value. This lack of a dose response in addition

to the variability of the fetal weights suggests that the apparent lower mean in the 30 mg/kg/day group was not related to treatment. No treatment-related changes were apparent at any level tested concerning fetal morphological examinations.

Statistical results:

Mean maternal body weights were significantly reduced in the 30 mg/kg/day group on GD 19. Mean maternal body weight gains were significantly reduced in the 30 mg/kg/day group for all intervals throughout the treatment period (GD 6-19). A significant increase in weight gain was observed in this group from GD 19 to 24 indicating a recovery from the affects of the test substance. Both absolute and relative food consumption were significantly reduced in the 30 mg/kg/day group as compared to control for the entire treatment interval (GD 6-19) and the entire gestation interval (GD 0-29).

Remarks:

*Range-finding study results:* Treatment-related mortalities occurred in the 50, 100 and 150 mg/kg/day groups. Two females in the 50 mg/kg/day group died and all females in the 100 and 150 mg/kg/day group died prior to study termination. One female aborted at the 50 mg/kg/day dose level. Clinical signs of toxicity were observed at all dose levels tested and included rales, labored breathing, emaciation, changes in the amount and consistency of feces, no urine and fecal stain. In addition, irritation of the lips and chin characterized by swollen, raised white areas progressing to scab-like lesions and sloughing of the tissue, were observed in animals dosed at 25, 50, 100 and 150 mg/kg/day. Various signs were also observed following dosing including salivation, labored breathing, gasping, cyanosis, rales and decreased activity. Body weight losses occurred during the treatment period in animals dosed at 25 mg/kg/day and above. Necropsy findings for the animals that died were indicative of an irritative effect on the epithelial lining of the stomach. Pale yellow, cheesy material was found in the trachea in one animal each in the 5, 25 and 50 mg/kg/day groups during the day 18 sacrifice. The proportion of gram negative to gram positive bacteria appeared to be consistent at 24 and 48 hours in the treated groups and the control groups. The females sacrificed for cesarean section were internally normal. The mean post implantation loss was increased at the 50 mg/kg/day dose level. No other changes were observed in the cesarean section data.

One fetus in the 25 mg/kg/day group had an omphalocele. All other fetuses were normal externally.

### Conclusions

Remarks:

Oleylamine was neither developmentally toxic nor teratogenic at dose levels of 3, 10 and 30 mg/kg/day. (Author of the study report)

The endpoint has been adequately characterized. (American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

1A

Remarks:

Reliable without restriction; guideline study.

### References

Mercieca, M. D. 1989. Teratology Study in Rabbits with Oleylamine. Study No. 3205.11. Springborn Life Sciences, Inc., USA.

Mercieca, M. D. 1989. Range-Finding Teratology Study in Rabbits with Oleylamine. Study No. 3205.10. Springborn Life Sciences, Inc., USA.

### Other

Last changed:

July 17, 2002

Order number for sorting:

29c

Remarks:

## 5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl-  
(CAS RN 4088-22-6)  
Purity: Not stated  
Remarks:

### Method

Method/guideline followed: Not stated  
GLP: Yes  
Year: 1980  
Species: Rabbit  
Strain: New Zealand White  
Route of administration: Oral gavage  
Doses/concentration levels: 0, 50, 250, 1000 mg/kg/day  
(referred to as control, low, intermediate and high dose groups, respectively)  
Sex: Female  
Exposure period: Days 6 through 18 of gestation, inclusive  
Frequency of treatment: Daily  
Control group and treatment: Yes, 2 mL/kg corn oil  
Duration of test: Days 0 to 28 of gestation  
Statistical methods: Analysis of variance for body weights; T-test for weight gains; Kruskal-Wallis and Wilcoxon's tests for fetal parameters; Fisher's randomization test with a Monte Carlo simulation for all defects and implantation loss;  $p < 0.05$  was considered significant.  
Remarks: Groups of 16 mated female rats, each weighing 3.14 to 4.23 kg, were administered the test substance by gavage at dose levels of 50, 250 and 1000 mg/kg/day at a dose volume of 2 mL/kg. The control rabbits received corn oil at an equivalent volume. All rabbits were administered the test substance and/or vehicle for 15 consecutive days, from gestational day (GD) 6 through GD 18, inclusive, then maintained without treatment through GD 28. The rabbits were observed once daily after mating for signs of ill-health, toxicity or behavioral change. Individual body weights and food consumption were measured on GDs 0, 3, 6, 9, 12, 15, 18, 21, 24 and 28. Animals showing signs of abortion were killed, and animals killed or found dead were subjected to gross necropsy. The fetuses were individually weighed, sexed and examined for external abnormalities. Fetuses were subsequently processed and examined for visceral and skeletal abnormalities.

## Results

Maternal toxicity NOEL:	50 mg/kg/day
Developmental toxicity NOEL:	250 mg/kg/day
Actual dose received:	As above
Maternal and fetal data:	Incidence of mortality was 2, 1, 1 and 3 in the control, low, intermediate and high dose groups, respectively, none of which was considered to be related to administration of the test substance. One female in the high dose group (1000 mg/kg/day) was killed after aborting on Day 28, again not considered to be treatment-related. Clinical observations during gestation were minor, generally non-specific, and did not indicate a treatment-related effect.

Group mean body weight and food consumption were calculated using only data from pregnant animals surviving to GD 28. Body weight gain in the low dose group was unaffected by treatment. Control animals showed an unusual weight loss during the first half of the dosing period and body weight gain in the treated groups was consequently significantly higher, but the consistent weight gain in the treated groups suggested that there was no effect of treatment on body weight during this early period. A treatment effect on maternal body weight in the high dose group was apparent in the latter half of the dosing period. Body weight gain in the intermediate and high dose groups was significantly lower GD 12 through 18, as compared to the control group, but increased again after dosing ceased. There was no effect of treatment on food consumption.

The inconsistent pattern of minor, non-specific lesions observed in animals of all groups at necropsy gave no indication of a treatment effect.

There was no effect of treatment on pregnancy incidence, implantation or pre-implantation loss at any dose level. Post-implantation loss was high in the high dose group, but not statistically significant because control values were unusually high. Therefore, the possibility of an embryo-lethal effect cannot be disregarded.

A slight reduction in fetal weight was observed in the intermediate and high dose groups, perhaps a consequence of the retardation of maternal weight gain.

Embryonic growth retardation was not concluded to be treatment-related, particularly as there was no effect on fetal crown/rump length. Nor was there a treatment effect on fetal sex distribution.

The incidence of major and minor fetal defects and variants in the treated groups was either comparable to or lower than that of the control group.

Remarks:

### Conclusions

Remarks:

Administration of the test substance, by gavage, during the period of organogenesis at dose levels up to and including those eliciting slight maternal toxicity (250mg/kg/day) did not elicit embryoletality, direct embryonic growth retardation, or teratogenicity. A dose of 1000 mg/kg/day produced a greater maternal toxic effect, without an indication of direct embryonic growth retardation or teratogenicity. However, the possibility of embryoletality due treatment at this dose level cannot be disregarded. The highest 'no effect' level, with regard to fetal development, established in this study is 250 mg/kg/day. No maternal toxic effect was observed at the low dose level (50 mg/kg/day).

The endpoint has been adequately characterized.

(American Chemistry Council, Fatty Nitrogen Derivatives Panel, Amines Task Group)

### Data Quality

Reliability (Klimisch):

Remarks:

1B

Reliable without restriction; comparable to guideline study.

### References

Armitage, A.K. 1981. E0016: Oral Teratology Study in the New Zealand White Rabbit: ECM BTS 294. Unpublished report (No. 2630-110/334), for Procter and Gamble Ltd., Newcastle upon Tyne, England; from Hazleton Laboratories Europe Ltd., Harrogate, England.

### Other

Last changed/Initials:

Order number for sorting:

Remarks:

September 21, 2003

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## Appendix B

### Robust Summaries for SAR Model Data

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ACC FND Panel – Ether Amines Category**

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## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Propanamine, 3-(isodecyloxy)- (CAS RN 30113-45-2)

Melting Point (°C)	51
Boiling Point (°C)	278
Vapor Pressure (hPa)	0.0035
Partition Coefficient (log K <sub>w</sub> )	3.92
Water Solubility (mg/l)	165
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	64 E-12 [2.0]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 90% Soil: <1% Sediment: 10%
Acute Fish Toxicity – 96-hour LC <sub>50</sub> (mg/l)	126 – as cationic surfactant 3.50– as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	7.9 – as cationic surfactant 0.33– as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant 1.21– as aliphatic amine

NC – Not calculated by Model

### Model Input/Output

SMILES : NCCCCCCCCCCC(C)C  
 CHEM : 1-Propanamine, 3-(isodecyloxy)-  
 CAS NUM: 030113-45-2  
 MOL FOR: C13 H29 N1 O1  
 MOL WT : 215.38

----- EPI SUMMARY (v3.05) -----

#### Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

#### Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 3.92

#### Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 278.48 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 51.27 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.00348 (Modified Grain method)

#### Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 165.1  
 log Kow used: 3.92 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 2.00E-006 atm-m<sup>3</sup>/mole

Group Method: 4.99E-007 atm-m<sup>3</sup>/mole

Henry's LC [VP/WSol estimate using EPI values]: 5.973E-006 atm-m<sup>3</sup>/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.4515

Non-Linear Model : 0.0855

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.7390 (weeks-months)

Primary Survey Model : 3.5705 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.5504

Non-Linear Model : 0.5375

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 63.5274 E-12 cm<sup>3</sup>/molecule-sec

Half-Life = 0.168 Days (12-hr day; 1.5E6 OH/cm<sup>3</sup>)

Half-Life = 2.020 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 1261

Log Koc: 3.101

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.322 (BCF = 209.9)

log Kow used: 3.92 (estimated)

Volatilization from Water:

Henry LC: 4.99E-007 atm-m<sup>3</sup>/mole (estimated by Group SAR Method)

Half-Life from Model River: 1723 hours (71.81 days)

Half-Life from Model Lake : 1.892E+004 hours (788.5 days)

Removal In Wastewater Treatment:

Total removal: 26.57 percent

Total biodegradation: 0.29 percent

Total sludge adsorption: 26.25 percent

Total to Air: 0.02 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.274	4.04	1000
Water	28.7	900	1000
Soil	67.7	900	1000

Sediment 3.32 3.6e+003 0  
 Persistence Time: 652 hr

CHEM : 30113452  
 CAS Num: 30113452  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 165.1 mg/L

Avg Length Carbon Chain: 9.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Daphnid	acute	LC50	7.943
Fish	acute	LC50	125.892

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	6.150
Aliphatic Amines	: Fish	96-hr	LC50	3.503
Aliphatic Amines	: Daphnid	48-hr	LC50	0.331
Aliphatic Amines	: Green Algae	96-hr	EC50	1.213
Aliphatic Amines	: Green Algae	96-hr	ChV	0.422

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

Chem Name : 1-Propanamine, 3-(isodecyloxy)-

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Molecular Wt: 215.38  
 Henry's LC : 4.99e-007 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.00348 mm Hg (Mpbpwin program)  
 Liquid VP : 0.00633 mm Hg (super-cooled)  
 Melting Pt : 51.3 deg C (Mpbpwin program)  
 Log Kow : 3.92 (Kowwin program)  
 Soil Koc : 3.41e+003 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00242	4.04	0
Water	89.6	900	1000
Soil	0.0151	900	0
Sediment	10.4	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.71e-014	2.58	0.15	0.258	0.015
Water	6.4e-012	428	556	42.8	55.6
Soil	1.47e-016	0.0722	0	0.00722	0
Sediment	4.5e-012	12.4	1.29	1.24	0.129

Persistence Time: 620 hr  
 Reaction Time: 1.4e+003 hr  
 Advection Time: 1.11e+003 hr  
 Percent Reacted: 44.3  
 Percent Advected: 55.7

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 4.042  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.739 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Propanamine, 3-(tridecyloxy)-, branched (CAS RN 68511-40-0)

Melting Point (°C)	81
Boiling Point (°C)	322
Vapor Pressure (hPa)	0.00017
Partition Coefficient (log K <sub>w</sub> )	5.40
Water Solubility (mg/l)	5.38
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	68 E-12 [1.9]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 26% Soil: <1% Sediment: 74%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	3.24 – as cationic surfactant 0.05 – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant 0.33 – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : NCCCCCCCCCCCCC(C)C  
 CHEM : 1-Propanamine, 3-(tridecyloxy)-, branched  
 CAS NUM: 068511-40-0  
 MOL FOR: C16 H35 N1 O1  
 MOL WT : 257.46

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 5.40

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 322.28 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 80.96 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.000174 (Modified Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 5.377

log Kow used: 5.40 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 4.68E-006 atm-m3/mole

Group Method: 1.41E-006 atm-m3/mole

Henry's LC [VP/WSol estimate using EPI values]: 1.096E-005 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.4314

Non-Linear Model : 0.0489

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.6460 (weeks-months)

Primary Survey Model : 3.5098 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.5735

Non-Linear Model : 0.5557

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 67.7665 E-12 cm3/molecule-sec

Half-Life = 0.158 Days (12-hr day; 1.5E6 OH/cm3)

Half-Life = 1.894 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 7909

Log Koc: 3.898

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.456 (BCF = 286)

log Kow used: 5.40 (estimated)

Volatilization from Water:

Henry LC: 1.41E-006 atm-m3/mole (estimated by Group SAR Method)

Half-Life from Model River: 667.9 hours (27.83 days)

Half-Life from Model Lake : 7421 hours (309.2 days)

Removal In Wastewater Treatment:

Total removal: 86.88 percent

Total biodegradation: 0.74 percent

Total sludge adsorption: 86.14 percent

Total to Air: 0.01 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.175	3.79	1000
Water	14.3	900	1000

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Soil 44.6 900 1000  
 Sediment 40.9 3.6e+003 0  
 Persistence Time: 978 hr

CHEM : 68511400  
 CAS Num: 68511400  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 5.377 mg/L

Avg Length Carbon Chain: 12.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Daphnid	acute	LC50	3.236
Fish	acute	LC50	9.772 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.378
Aliphatic Amines	: Fish	96-hr	LC50	0.473 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.054
Aliphatic Amines	: Green Algae	96-hr	EC50	0.330
Aliphatic Amines	: Green Algae	96-hr	ChV	0.161

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

Chem Name : 1-Propanamine, 3-(tridecyloxy)-, branched  
 Molecular Wt: 257.46  
 Henry's LC : 1.41e-006 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.000174 mm Hg (Mpbpwin program)

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Liquid VP : 0.000622 mm Hg (super-cooled)  
 Melting Pt : 81 deg C (Mppwin program)  
 Log Kow : 5.4 (Kowwin program)  
 Soil Koc : 1.03e+005 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00163	3.79	0
Water	26	900	1000
Soil	0.00374	900	0
Sediment	74	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	2.5e-014	4.82	0.263	0.482	0.0263
Water	9.82e-012	322	419	32.2	41.9
Soil	7.42e-018	0.0464	0	0.00464	0
Sediment	6.61e-012	230	23.9	23	2.39

Persistence Time: 1.61e+003 hr  
 Reaction Time: 2.9e+003 hr  
 Advection Time: 3.64e+003 hr  
 Percent Reacted: 55.7  
 Percent Advected: 44.3

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 3.787  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.646 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched  
 (CAS RN 68479-04-9)

Melting Point (°C)	130
Boiling Point (°C)	380
Vapor Pressure (hPa)	2.2 x 10 <sup>-6</sup>
Partition Coefficient (log K <sub>w</sub> )	5.37
Water Solubility (mg/l)	2.64
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	154 E-12 [0.8]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 27% Soil: <1% Sediment: 73%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant 0.07 – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant 0.42 – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : NCCCNCCCCCCCCCCCCC(C)C  
 CHEM : 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched  
 CAS NUM: 068479-04-9  
 MOL FOR: C19 H42 N2 O1  
 MOL WT : 314.56

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:  
 Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):  
 Log Kow (KOWWIN v1.66 estimate) = 5.37

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):  
 Boiling Pt (deg C): 380.33 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 130.24 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 2.2E-006 (Modified Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 2.639  
log Kow used: 5.37 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):  
Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:  
Bond Method : 1.86E-009 atm-m3/mole  
Group Method: 1.23E-010 atm-m3/mole  
Henrys LC [VP/WSol estimate using EPI values]: 3.450E-007 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):  
Linear Model : 0.5581  
Non-Linear Model : 0.0649  
Expert Survey Biodegradation Results:  
Ultimate Survey Model: 2.5442 (weeks-months)  
Primary Survey Model : 3.4707 (days-weeks )  
Readily Biodegradable Probability (MITI Model):  
Linear Model : 0.5852  
Non-Linear Model : 0.3964

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:  
Hydroxyl Radicals Reaction:  
OVERALL OH Rate Constant = 153.5476 E-12 cm3/molecule-sec  
Half-Life = 0.070 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 0.836 Hrs  
Ozone Reaction:  
No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):  
Koc : 5.166E+004  
Log Koc: 4.713

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:  
Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):  
Log BCF = 2.439 (BCF = 274.6)  
log Kow used: 5.37 (estimated)

Volatilization from Water:  
Henry LC: 1.23E-010 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 8.442E+006 hours (3.518E+005 days)  
Half-Life from Model Lake : 9.21E+007 hours (3.837E+006 days)

Removal In Wastewater Treatment:  
Total removal: 86.41 percent  
Total biodegradation: 0.73 percent  
Total sludge adsorption: 85.67 percent  
Total to Air: 0.00 percent

Level III Fugacity Model:  
Concentration Half-Life Emissions  
(percent) (hr) (kg/hr)  
Air 0.00122 1.67 1000

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Water	11.2	900	1000
Soil	58.5	900	1000
Sediment	30.2	3.6e+003	0

Persistence Time: 1.39e+003 hr

CHEM : 68479049

CAS Num: 68479049

ChemID1:

ChemID2:

ChemID3:

WatDisp: 2.639 mg/L

Avg Length Carbon Chain: 12.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Daphnid	acute	LC50	3.236 *
Fish	acute	LC50	9.772 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.490
Aliphatic Amines	: Fish	96-hr	LC50	0.604 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.069
Aliphatic Amines	: Green Algae	96-hr	EC50	0.416
Aliphatic Amines	: Green Algae	96-hr	ChV	0.202

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

=====  
 Chem Name : 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched  
 Molecular Wt: 314.56  
 Henry's LC : 1.23e-010 atm-m3/mole (Henrywin program)  
 Vapor Press : 2.2e-006 mm Hg (Mppbwin program)

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Liquid VP : 2.42e-005 mm Hg (super-cooled)  
 Melting Pt : 130 deg C (Mpbpwin program)  
 Log Kow : 5.37 (Kowwin program)  
 Soil Koc : 9.61e+004 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	1.51e-009	1.67	0
Water	27.1	900	1000
Soil	3.37e-005	900	0
Sediment	72.9	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.78e-020	9.85e-006	2.38e-007	9.85e-007	2.38e-008
Water	7.22e-016	329	427	32.9	42.7
Soil	5.01e-024	0.000409	0	4.09e-005	0
Sediment	4.86e-016	221	23	22.1	2.3

Persistence Time: 1.58e+003 hr  
 Reaction Time: 2.86e+003 hr  
 Advection Time: 3.5e+003 hr  
 Percent Reacted: 55  
 Percent Advected: 45

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 1.672  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.544 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: Dodecylamine (CAS RN 124-22-1)

Melting Point (°C)	28.3
Boiling Point (°C)	259
Vapor Pressure (hPa)	0.0081
Partition Coefficient (log K <sub>w</sub> )	4.76
Water Solubility (mg/l)	45.1
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	46 E-12 [2.8]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: < 1% Water: 75% Soil:< 1% Sediment:25%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	9.77 – as cationic surfactant 0.87 – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	3.24 – as cationic surfactant 0.09 – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant 0.45 – as aliphatic amine

NC – Not calculated by Model

### Model Input/Output

SMILES : NCCCCCCCCCCCC  
 CHEM : 1-Dodecanamine  
 CAS NUM: 000124-22-1  
 MOL FOR: C12 H27 N1  
 MOL WT : 185.36

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:  
 Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):  
 Log Kow (KOWWIN v1.66 estimate) = 4.76

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):  
 Boiling Pt (deg C): 254.63 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 35.06 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.0156 (Modified Grain method)  
 MP (exp database): 28.3 deg C  
 BP (exp database): 259 deg C  
 VP (exp database): 8.05E-03 mm Hg at 25 deg C

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 45.13  
log Kow used: 4.76 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 1.71E-004 atm-m3/mole  
Group Method: 2.74E-004 atm-m3/mole

Henrys LC [VP/WSol estimate using EPI values]: 8.431E-005 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.9216  
Non-Linear Model : 0.9655

Expert Survey Biodegradation Results:

Ultimate Survey Model: 3.1123 (weeks )  
Primary Survey Model : 3.8927 (days )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7380  
Non-Linear Model : 0.8367

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 45.7176 E-12 cm3/molecule-sec  
Half-Life = 0.234 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 2.807 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 8125  
Log Koc: 3.910

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 1.968 (BCF = 92.89)  
log Kow used: 4.76 (estimated)

Volatilization from Water:

Henry LC: 0.000274 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 4.298 hours  
Half-Life from Model Lake : 161.1 hours (6.71 days)

Removal In Wastewater Treatment:

Total removal: 70.40 percent  
Total biodegradation: 0.59 percent  
Total sludge adsorption: 66.52 percent  
Total to Air: 3.29 percent

Level III Fugacity Model:

Concentration	Half-Life	Emissions
(percent)	(hr)	(kg/hr)

Air	1.16	5.62	1000
Water	27.5	360	1000
Soil	62.2	360	1000
Sediment	9.17	1.44e+003	0
Persistence Time: 278 hr			

CHEM : 124221  
 CAS Num: 124221  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 45.13 mg/L

Avg Length Carbon Chain: 12.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Daphnid	acute	LC50	3.236
Fish	acute	LC50	9.772

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.982
Aliphatic Amines	: Fish	96-hr	LC50	0.874
Aliphatic Amines	: Daphnid	48-hr	LC50	0.092
Aliphatic Amines	: Green Algae	96-hr	EC50	0.451
Aliphatic Amines	: Green Algae	96-hr	ChV	0.190

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none

Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

-----  
 Level III Fugacity Model (Full-Output):  
 =====

Chem Name : 1-Dodecanamine  
 Molecular Wt: 185.36  
 Henry's LC : 0.000274 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.0156 mm Hg (Mppbwin program)  
 Liquid VP : 0.0196 mm Hg (super-cooled)  
 Melting Pt : 35.1 deg C (Mppbwin program)  
 Log Kow : 4.76 (Kowwin program)  
 Soil Koc : 2.36e+004 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.709	5.62	0
Water	74.5	360	1000
Soil	0.0103	360	0
Sediment	24.8	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	2.88e-012	269	21.8	26.9	2.18
Water	1.63e-009	441	229	44.1	22.9
Soil	4.59e-015	0.061	0	0.0061	0
Sediment	4.98e-010	36.8	1.53	3.68	0.153

Persistence Time: 308 hr  
 Reaction Time: 412 hr  
 Advection Time: 1.22e+003 hr  
 Percent Reacted: 74.7  
 Percent Advected: 25.3

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 5.616  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 3.112 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Dodecanamine, N,N-dimethyl- (CAS RN 112-18-5)

Melting Point (°C)	22
Boiling Point (°C)	260
Vapor Pressure (hPa)	0.0159
Partition Coefficient (log K <sub>w</sub> )	5.44
Water Solubility (mg/l)	8.58
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	93 E-12 [1.4]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 42% Soil: <1% Sediment: 58%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	3.24 – as cationic surfactant 0.04 – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant 0.26 – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : N(CCCCCCCCCC)(C)C  
 CHEM : 1-Dodecanamine, N,N-dimethyl-  
 CAS NUM: 000112-18-5  
 MOL FOR: C14 H31 N1  
 MOL WT : 213.41

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 5.44

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 260.12 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 22.53 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.0159 (Mean VP of Antoine & Grain methods)  
 MP (exp database): 22 deg C  
 BP (exp database): 260 deg C

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 8.575  
log Kow used: 5.44 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:  
Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 8.24E-004 atm-m3/mole  
Group Method: 4.88E-003 atm-m3/mole

Henry's LC [VP/WSol estimate using EPI values]: 5.207E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.5491  
Non-Linear Model : 0.4011

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.7711 (weeks )  
Primary Survey Model : 3.5209 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.5372  
Non-Linear Model : 0.5764

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 93.2472 E-12 cm3/molecule-sec  
Half-Life = 0.115 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 1.376 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 1.308E+004  
Log Koc: 4.116

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.489 (BCF = 308.6)  
log Kow used: 5.44 (estimated)

Volatilization from Water:

Henry LC: 0.00488 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 1.666 hours  
Half-Life from Model Lake : 140.7 hours (5.861 days)

Removal In Wastewater Treatment:

Total removal:	90.25	percent
Total biodegradation:	0.61	percent
Total sludge adsorption:	79.63	percent
Total to Air:	10.01	percent

Level III Fugacity Model:

Concentration	Half-Life	Emissions
(percent)	(hr)	(kg/hr)

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Air	0.55	2.75	1000
Water	18.8	360	1000
Soil	54.7	360	1000
Sediment	25.9	1.44e+003	0

Persistence Time: 315 hr

CHEM : 112185  
 CAS Num: 112185  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 8.575 mg/L

Avg Length Carbon Chain: 12.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Daphnid	acute	LC50	3.236
Fish	acute	LC50	9.772 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.289
Aliphatic Amines	: Fish	96-hr	LC50	0.370 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.042
Aliphatic Amines	: Green Algae	96-hr	EC50	0.263
Aliphatic Amines	: Green Algae	96-hr	ChV	0.130

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

=====  
 Chem Name : 1-Dodecanamine, N,N-dimethyl-  
 Molecular Wt: 213.41

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Henry's LC : 0.00488 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.0159 mm Hg (Mpbpwin program)  
 Log Kow : 5.44 (Kowwin program)  
 Soil Koc : 1.13e+005 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.322	2.75	0
Water	41.9	360	1000
Soil	0.00332	360	0
Sediment	57.8	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.56e-012	344	13.7	34.4	1.37
Water	1.72e-008	342	178	34.2	17.8
Soil	6.61e-015	0.0271	0	0.00271	0
Sediment	5.17e-009	118	4.9	11.8	0.49

Persistence Time: 424 hr  
 Reaction Time: 528 hr  
 Advection Time: 2.16e+003 hr  
 Percent Reacted: 80.4  
 Percent Advected: 19.6

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 2.753  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 2.771 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Tetradecanamine, N,N-dimethyl- (CAS RN 112-75-4)

Melting Point (°C)	43
Boiling Point (°C)	292
Vapor Pressure (hPa)	0.0020
Partition Coefficient (log K <sub>w</sub> )	6.42
Water Solubility (mg/l)	0.88
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	96 E-12 [1.3]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 7% Soil: <1% Sediment: 93%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant 0.01– as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : N(CCCCCCCCCCCCC)(C)C  
 CHEM : 1-Tetradecanamine, N,N-dimethyl-  
 CAS NUM: 000112-75-4  
 MOL FOR: C16 H35 N1  
 MOL WT : 241.46

----- EPI SUMMARY (v3.05) -----

#### Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

#### Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 6.42

#### Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 292.24 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 43.18 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.00201 (Modified Grain method)

#### Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.8787

log Kow used: 6.42 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 1.45E-003 atm-m3/mole

Group Method: 9.74E-003 atm-m3/mole

Henry's LC [VP/WSol estimate using EPI values]: 7.268E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.5358

Non-Linear Model : 0.3102

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.7091 (weeks-months)

Primary Survey Model : 3.4804 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.5526

Non-Linear Model : 0.5883

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 96.0733 E-12 cm3/molecule-sec

Half-Life = 0.111 Days (12-hr day; 1.5E6 OH/cm3)

Half-Life = 1.336 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 4.448E+004

Log Koc: 4.648

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.746 (BCF = 556.7)

log Kow used: 6.42 (estimated)

Volatilization from Water:

Henry LC: 0.00974 atm-m3/mole (estimated by Group SAR Method)

Half-Life from Model River: 1.679 hours

Half-Life from Model Lake : 148.6 hours (6.192 days)

Removal In Wastewater Treatment:

Total removal: 93.74 percent

Total biodegradation: 0.74 percent

Total sludge adsorption: 90.41 percent

Total to Air: 2.59 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.112	2.67	1000
Water	4.85	900	1000

Soil 33.6 900 1000  
 Sediment 61.4 3.6e+003 0

Persistence Time: 1.29e+003 hr

CHEM : 112754  
 CAS Num: 112754  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.8787 mg/L

Avg Length Carbon Chain: 14.00

**ECOSAR Class: Surfactants, Cationic (C < 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Daphnid	acute	LC50	1.778 *
Fish	acute	LC50	1.778 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.046 *
Aliphatic Amines	: Fish	96-hr	LC50	0.099 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.013
Aliphatic Amines	: Green Algae	96-hr	EC50	0.112 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.069 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

Chem Name : 1-Tetradecanamine, N,N-dimethyl-  
 Molecular Wt: 241.46  
 Henry's LC : 0.00974 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.00201 mm Hg (Mppbwin program)  
 Liquid VP : 0.00304 mm Hg (super-cooled)

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Melting Pt : 43.2 deg C (Mpbwin program)  
 Log Kow : 6.42 (Kowwin program)  
 Soil Koc : 1.08e+006 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0241	2.67	0
Water	7.32	900	1000
Soil	0.000817	900	0
Sediment	92.7	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	6.23e-013	160	6.16	16	0.616
Water	1.37e-008	144	187	14.4	18.7
Soil	1.81e-015	0.0161	0	0.00161	0
Sediment	9.22e-009	456	47.3	45.6	4.73

Persistence Time: 2.55e+003 hr  
 Reaction Time: 3.36e+003 hr  
 Advection Time: 1.06e+004 hr  
 Percent Reacted: 75.9  
 Percent Advected: 24.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 2.671  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.709 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Hexadecanamine (CAS RN 143-27-1)

Melting Point (°C)	47
Boiling Point (°C)	323
Vapor Pressure (hPa)	0.00013
Partition Coefficient (log K <sub>w</sub> )	6.73
Water Solubility (mg/l)	0.48
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	51 E-12 [2.5]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 13% Soil: <1% Sediment: 87%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant 0.008 – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : NCCCCCCCCCCCCCCC  
 CHEM : 1-Hexadecanamine  
 CAS NUM: 000143-27-1  
 MOL FOR: C16 H35 N1  
 MOL WT : 241.46

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 6.73

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 316.42 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 75.64 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.000371 (Modified Grain method)  
 MP (exp database): 46.8 deg C  
 BP (exp database): 322.5 deg C  
 VP (exp database): 1.33E-04 mm Hg at 25 deg C

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.4823  
log Kow used: 6.73 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 5.31E-004 atm-m3/mole  
Group Method: 1.09E-003 atm-m3/mole  
Henrys LC [VP/WSol estimate using EPI values]: 2.444E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.8949  
Non-Linear Model : 0.9265

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.9883 (weeks )  
Primary Survey Model : 3.8117 (days )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7687  
Non-Linear Model : 0.8497

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 51.3698 E-12 cm3/molecule-sec  
Half-Life = 0.208 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 2.499 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 9.402E+004  
Log Koc: 4.973

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.981 (BCF = 956.2)  
log Kow used: 6.73 (estimated)

Volatilization from Water:

Henry LC: 0.00109 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 2.42 hours  
Half-Life from Model Lake : 156.7 hours (6.529 days)

Removal In Wastewater Treatment:

Total removal: 93.71 percent  
Total biodegradation: 0.77 percent  
Total sludge adsorption: 92.77 percent  
Total to Air: 0.17 percent

Level III Fugacity Model:

Concentration Half-Life Emissions

	(percent)	(hr)	(kg/hr)
Air	0.425	5	1000
Water	8.67	360	1000
Soil	30.8	360	1000
Sediment	60.1	1.44e+003	0
Persistence Time: 562 hr			

CHEM : 143271  
 CAS Num: 143271  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.4823 mg/L

Avg Length Carbon Chain: 16.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	acute	LC50	2.239 *
Snail	acute	LC50	0.679 *
Daphnid	acute	LC50	1.585 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.025 *
Aliphatic Amines	: Fish	96-hr	LC50	0.062 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.008
Aliphatic Amines	: Green Algae	96-hr	EC50	0.082 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.054 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

=====

Chem Name : 1-Hexadecanamine  
 Molecular Wt: 241.46  
 Henry's LC : 0.00109 atm-m<sup>3</sup>/mole (Henrywin program)  
 Vapor Press : 0.000371 mm Hg (Mppbwin program)  
 Liquid VP : 0.00118 mm Hg (super-cooled)  
 Melting Pt : 75.6 deg C (Mppbwin program)  
 Log Kow : 6.73 (Kowwin program)  
 Soil Koc : 2.2e+006 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0378	5	0
Water	12.6	360	1000
Soil	0.000802	360	0
Sediment	87.4	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	4.43e-013	60.8	4.38	6.08	0.438
Water	7.21e-010	281	146	28.1	14.6
Soil	4.41e-017	0.0179	0	0.00179	0
Sediment	2.16e-010	487	20.3	48.7	2.03

Persistence Time: 1.16e+003 hr  
 Reaction Time: 1.4e+003 hr  
 Advection Time: 6.79e+003 hr  
 Percent Reacted: 82.9  
 Percent Advected: 17.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 4.997  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 2.988 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Hexadecanamine, N,N-dimethyl- (CAS RN 112-69-6)

Melting Point (°C)	63
Boiling Point (°C)	321
Vapor Pressure (hPa)	0.00029
Partition Coefficient (log K <sub>w</sub> )	7.41
Water Solubility (mg/l)	0.089
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	99 E-12 [1.3]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 5% Soil: <1% Sediment: 95%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : N(CCCCCCCCCCCCCC)(C)C  
 CHEM : 1-Hexadecanamine, N,N-dimethyl-  
 CAS NUM: 000112-69-6  
 MOL FOR: C18 H39 N1  
 MOL WT : 269.52

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 7.41

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 320.74 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 62.77 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.000286 (Modified Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.08883

log Kow used: 7.41 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 2.56E-003 atm-m3/mole

Group Method: 1.94E-002 atm-m3/mole

Henry's LC [VP/WSol estimate using EPI values]: 1.142E-003 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.5224

Non-Linear Model : 0.2319

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.6471 (weeks-months)

Primary Survey Model : 3.4400 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.5680

Non-Linear Model : 0.6001

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 98.8994 E-12 cm3/molecule-sec

Half-Life = 0.108 Days (12-hr day; 1.5E6 OH/cm3)

Half-Life = 1.298 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 1.513E+005

Log Koc: 5.180

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.755 (BCF = 568.9)

log Kow used: 7.41 (estimated)

Volatilization from Water:

Henry LC: 0.0194 atm-m3/mole (estimated by Group SAR Method)

Half-Life from Model River: 1.725 hours

Half-Life from Model Lake : 156.5 hours (6.52 days)

Removal In Wastewater Treatment:

Total removal: 94.04 percent

Total biodegradation: 0.77 percent

Total sludge adsorption: 92.72 percent

Total to Air: 0.56 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0794	2.6	1000
Water	3.64	900	1000

Soil 27.9 900 1000  
 Sediment 68.4 3.6e+003 0

Persistence Time: 1.55e+003 hr

CHEM : 112696  
 CAS Num: 112696  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.08883 mg/L

Avg Length Carbon Chain: 0.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Daphnid	acute	LC50	117.490 *
Fish	acute	LC50	2.69e+005 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.007 *
Aliphatic Amines	: Fish	96-hr	LC50	0.026 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.004 *
Aliphatic Amines	: Green Algae	96-hr	EC50	0.046 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.036 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**Level III Fugacity Model (Full-Output):**

Chem Name : 1-Hexadecanamine, N,N-dimethyl-  
 Molecular Wt: 269.52  
 Henry's LC : 0.0194 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.000286 mm Hg (Mpbpwin program)

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Liquid VP : 0.000676 mm Hg (super-cooled)  
 Melting Pt : 62.8 deg C (Mpbpwin program)  
 Log Kow : 7.41 (Kowwin program)  
 Soil Koc : 1.05e+007 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00249	2.6	0
Water	5.05	900	1000
Soil	0.000174	900	0
Sediment	94.9	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	7.56e-014	22.3	0.835	2.23	0.0835
Water	3.37e-009	131	170	13.1	17
Soil	9.24e-017	0.0045	0	0.00045	0
Sediment	2.27e-009	613	63.7	61.3	6.37

Persistence Time: 3.35e+003 hr  
 Reaction Time: 4.38e+003 hr  
 Advection Time: 1.43e+004 hr  
 Percent Reacted: 76.6  
 Percent Advected: 23.4

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 2.597  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.647 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine (CAS RN 124-30-1)

Melting Point (°C)	52.9
Boiling Point (°C)	346.8
Vapor Pressure (hPa)	0.000087
Partition Coefficient (log K <sub>w</sub> )	7.71
Water Solubility (mg/l)	0.049
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	54 E-12 [2.4]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 10% Soil: <1% Sediment: 90%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : NCCCCCCCCCCCCCCCCC  
 CHEM : 1-Octadecanamine  
 CAS NUM: 000124-30-1  
 MOL FOR: C18 H39 N1  
 MOL WT : 269.52

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:  
 Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):  
 Log Kow (KOWWIN v1.66 estimate) = 7.71

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):  
 Boiling Pt (deg C): 341.88 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 94.34 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 8.7E-005 (Modified Grain method)  
 MP (exp database): 52.9 deg C  
 BP (exp database): 346.8 deg C

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Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.04875  
log Kow used: 7.71 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 9.36E-004 atm-m3/mole  
Group Method: 2.18E-003 atm-m3/mole

Henrys LC [VP/WSol estimate using EPI values]: 6.329E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.8815  
Non-Linear Model : 0.8943

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.9263 (weeks )  
Primary Survey Model : 3.7712 (days )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7841  
Non-Linear Model : 0.8559

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 54.1958 E-12 cm3/molecule-sec  
Half-Life = 0.197 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 2.368 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 3.198E+005  
Log Koc: 5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.337 (BCF = 217.3)  
log Kow used: 7.71 (estimated)

Volatilization from Water:

Henry LC: 0.00218 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 2.116 hours  
Half-Life from Model Lake : 160.7 hours (6.698 days)

Removal In Wastewater Treatment:

Total removal:	94.00	percent
Total biodegradation:	0.78	percent
Total sludge adsorption:	93.19	percent
Total to Air:	0.03	percent

Level III Fugacity Model:

Concentration	Half-Life	Emissions
(percent)	(hr)	(kg/hr)

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Air	0.35	4.74	1000
Water	7.43	360	1000
Soil	28.2	360	1000
Sediment	64	1.44e+003	0

Persistence Time: 614 hr

CHEM : 124301  
 CAS Num: 124301  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.04875 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	acute	LC50	2.489 *
Snail	acute	LC50	1.014 *
Daphnid	acute	LC50	2.692 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.004 *
Aliphatic Amines	: Fish	96-hr	LC50	0.016 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.003 *
Aliphatic Amines	: Green Algae	96-hr	EC50	0.034 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.029 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

=====  
 Chem Name : 1-Octadecanamine  
 Molecular Wt: 269.52

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Henry's LC : 0.00218 atm-m<sup>3</sup>/mole (Henrywin program)  
 Vapor Press : 8.7e-005 mm Hg (Mppbwin program)  
 Liquid VP : 0.000422 mm Hg (super-cooled)  
 Melting Pt : 94.3 deg C (Mppbwin program)  
 Log Kow : 7.71 (Kowwin program)  
 Soil Koc : 2.1e+007 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00426	4.74	0
Water	10.4	360	1000
Soil	0.000169	360	0
Sediment	89.6	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	5.07e-014	8.19	0.56	0.819	0.056
Water	1.58e-010	263	137	26.3	13.7
Soil	1.98e-018	0.00428	0	0.000428	0
Sediment	4.72e-011	567	23.6	56.7	2.36

Persistence Time: 1.32e+003 hr  
 Reaction Time: 1.57e+003 hr  
 Advection Time: 8.18e+003 hr  
 Percent Reacted: 83.9  
 Percent Advected: 16.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 4.738  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 2.926 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 9-Octadecen-1-amine, (Z)- (CAS RN 112-90-3)

Melting Point (°C)	93
Boiling Point (°C)	346
Vapor Pressure (hPa)	0.000037
Partition Coefficient (log K <sub>w</sub> )	7.50
Water Solubility (mg/l)	0.076
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	107 E-12 [1.2]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 11% Soil: <1% Sediment: 89%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : NCCCCCCCC=CCCCCCCC  
 CHEM : 9-Octadecen-1-amine, (Z)-  
 CAS NUM: 000112-90-3  
 MOL FOR: C18 H37 N1  
 MOL WT : 267.50

----- EPI SUMMARY (v3.05) -----

#### Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

#### Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 7.50

#### Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 345.55 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 92.87 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 3.72E-005 (Modified Grain method)

#### Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.07639

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log Kow used: 7.50 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henry's Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 8.23E-004 atm-m3/mole

Group Method: 5.73E-004 atm-m3/mole

Henry's LC [VP/WSol estimate using EPI values]: 1.714E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.8825

Non-Linear Model : 0.8969

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.9308 (weeks )

Primary Survey Model : 3.7741 (days )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7036

Non-Linear Model : 0.7384

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 107.2413 E-12 cm3/molecule-sec [Cis-isomer]

OVERALL OH Rate Constant = 114.8413 E-12 cm3/molecule-sec [Trans-isomer]

Half-Life = 1.197 Hrs (12-hr day; 1.5E6 OH/cm3) [Cis-isomer]

Half-Life = 1.118 Hrs (12-hr day; 1.5E6 OH/cm3) [Trans-isomer]

Ozone Reaction:

OVERALL Ozone Rate Constant = 13.000000 E-17 cm3/molecule-sec [Cis-]

OVERALL Ozone Rate Constant = 20.000000 E-17 cm3/molecule-sec [Trans-]

Half-Life = 2.116 Hrs (at 7E11 mol/cm3) [Cis-isomer]

Half-Life = 1.375 Hrs (at 7E11 mol/cm3) [Trans-isomer]

Reaction With Nitrate Radicals May Be Important!

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 3.198E+005

Log Koc: 5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.632 (BCF = 428.1)

log Kow used: 7.50 (estimated)

Volatilization from Water:

Henry LC: 0.000573 atm-m3/mole (estimated by Group SAR Method)

Half-Life from Model River: 3.34 hours

Half-Life from Model Lake : 173.6 hours (7.232 days)

Removal In Wastewater Treatment:

Total removal: 93.98 percent

Total biodegradation: 0.78 percent

Total sludge adsorption: 93.18 percent

Total to Air: 0.02 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0882	1.12	1000
Water	7.55	360	1000
Soil	28.4	360	1000
Sediment	63.9	1.44e+003	0

Persistence Time: 609 hr

CHEM : 112903  
 CAS Num: 112903  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.07639 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Fish	acute	LC50	2.489 *
Snail	acute	LC50	1.014 *
Daphnid	acute	LC50	2.692 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.006 *
Aliphatic Amines	: Fish	96-hr	LC50	0.022 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.003 *
Aliphatic Amines	: Green Algae	96-hr	EC50	0.042 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.033 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

=====

Chem Name : 9-Octadecen-1-amine, (Z)-  
 Molecular Wt: 267.5  
 Henry's LC : 0.000573 atm-m<sup>3</sup>/mole (Henrywin program)  
 Vapor Press : 3.72e-005 mm Hg (Mppbwin program)  
 Liquid VP : 0.000174 mm Hg (super-cooled)  
 Melting Pt : 92.9 deg C (Mppbwin program)  
 Log Kow : 7.5 (Kowwin program)  
 Soil Koc : 1.3e+007 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00134	1.12	0
Water	10.6	360	1000
Soil	0.000112	360	0
Sediment	89.4	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.59e-014	10.8	0.175	1.08	0.0175
Water	6.71e-011	266	138	26.6	13.8
Soil	5.58e-019	0.00281	0	0.000281	0
Sediment	2.01e-011	562	23.4	56.2	2.34

Persistence Time: 1.31e+003 hr  
 Reaction Time: 1.56e+003 hr  
 Advection Time: 8.09e+003 hr  
 Percent Reacted: 83.9  
 Percent Advected: 16.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 1.123  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 2.931 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine, N-methyl-N-octadecyl- (CAS RN 4088-22-6)

Melting Point (°C)	216
Boiling Point (°C)	543
Vapor Pressure (hPa)	2.0 E-11
Partition Coefficient (log K <sub>w</sub> )	16.7
Water Solubility (mg/l)	2.2 E-11
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	134 E-12 [1.0]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 5% Soil: <1% Sediment: 95%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS - as cationic surfactant NTS - as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS - as cationic surfactant NTS - as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC - as cationic surfactant NTS - as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : N(CCCCCCCCCCCCCCCCC)(CCCCCCCCCCCCCCCC)C  
 CHEM : 1-Octadecanamine, N-methyl-N-octadecyl-  
 CAS NUM: 004088-22-6  
 MOL FOR: C37 H77 N1  
 MOL WT : 536.03

----- EPI SUMMARY (v3.05) -----

#### Physical Property Inputs:

Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

#### Log Octanol-Water Partition Coef (SRC):

Log Kow (KOWWIN v1.66 estimate) = 16.74

#### Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):

Boiling Pt (deg C): 542.96 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 215.91 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 2.04E-011 (Modified Grain method)

#### Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 2.179e-011

log Kow used: 16.74 (estimated)

no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:

Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 5.58E-001 atm-m3/mole

Group Method: 1.17E+001 atm-m3/mole

Henrys LC [VP/WSol estimate using EPI values]: 6.603E-001 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.5040

Non-Linear Model : 0.0415

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.3565 (weeks-months)

Primary Survey Model : 3.3245 (days-weeks )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7140

Non-Linear Model : 0.7053

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 133.6565 E-12 cm3/molecule-sec

Half-Life = 0.080 Days (12-hr day; 1.5E6 OH/cm3)

Half-Life = 0.960 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 1E+010

Log Koc: 10.251

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 0.500 (BCF = 3.162)

log Kow used: 16.74 (estimated)

Volatilization from Water:

Henry LC: 11.7 atm-m3/mole (estimated by Group SAR Method)

Half-Life from Model River: 2.363 hours

Half-Life from Model Lake : 219.9 hours (9.163 days)

Removal In Wastewater Treatment:

Total removal: 94.04 percent

Total biodegradation: 0.78 percent

Total sludge adsorption: 93.26 percent

Total to Air: 0.00 percent

Level III Fugacity Model:

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.0509	1.92	1000
Water	3.43	900	1000

Soil 28.3 900 1000  
 Sediment 68.2 3.6e+003 0  
 Persistence Time: 1.63e+003 hr

CHEM : 4088226  
 CAS Num: 4088226  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 2.2e-011 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
Fish	acute	LC50	2.489 *
Snail	acute	LC50	1.014 *
Daphnid	acute	LC50	2.692 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	1.04e-010 *
Aliphatic Amines	: Fish	96-hr	LC50	5.44e-008 *
Aliphatic Amines	: Daphnid	48-hr	LC50	2.69e-008 *
Aliphatic Amines	: Green Algae	96-hr	EC50	8.24e-006 *
Aliphatic Amines	: Green Algae	96-hr	ChV	5.48e-005 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

=====

Chem Name : 1-Octadecanamine, N-methyl-N-octadecyl-  
 Molecular Wt: 536.03  
 Henry's LC : 11.7 atm-m<sup>3</sup>/mole (Henrywin program)  
 Vapor Press : 2.04e-011 mm Hg (Mppbwin program)  
 Liquid VP : 1.58e-009 mm Hg (super-cooled)  
 Melting Pt : 216 deg C (Mppbwin program)  
 Log Kow : 16.7 (Kowwin program)  
 Soil Koc : 2.25e+016 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	8.17e-013	1.92	0
Water	4.79	900	1000
Soil	2.86e-011	900	0
Sediment	95.2	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	2.27e-026	1.03e-008	2.85e-010	1.03e-009	2.85e-011
Water	4.98e-016	128	167	12.8	16.7
Soil	2.23e-030	7.67e-010	0	7.67e-011	0
Sediment	3.35e-016	638	66.3	63.8	6.63

Persistence Time: 3.48e+003 hr  
 Reaction Time: 4.54e+003 hr  
 Advection Time: 1.49e+004 hr  
 Percent Reacted: 76.7  
 Percent Advected: 23.3

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 1.921  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.356 (weeks-months)

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: 1-Octadecanamine, N,N-dimethyl (CAS RN 124-28-7)

Melting Point (°C)	22.9
Boiling Point (°C)	346
Vapor Pressure (hPa)	0.00017
Partition Coefficient (log K <sub>w</sub> )	8.39
Water Solubility (mg/l)	0.009
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	102 E-12 [1.3]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: < 1% Water: 5% Soil: < 1% Sediment: 95%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : N(CCCCCCCCCCCCCCCC)(C)C  
 CHEM : 1-Octadecanamine, N,N-dimethyl-  
 CAS NUM: 000124-28-7  
 MOL FOR: C20 H43 N1  
 MOL WT : 297.57

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:  
 Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):  
 Log Kow (KOWWIN v1.66 estimate) = 8.39

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):  
 Boiling Pt (deg C): 345.70 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 81.33 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 0.000167 (Modified Grain method)  
 MP (exp database): 22.89 deg C

Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.008882  
log Kow used: 8.39 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):  
Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:  
Bond Method : 4.51E-003 atm-m3/mole  
Group Method: 3.88E-002 atm-m3/mole  
Henrys LC [VP/WSol estimate using EPI values]: 7.362E-003 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):  
Linear Model : 0.5090  
Non-Linear Model : 0.1685  
Expert Survey Biodegradation Results:  
Ultimate Survey Model: 2.5851 (weeks-months)  
Primary Survey Model : 3.3995 (days-weeks )  
Readily Biodegradable Probability (MITI Model):  
Linear Model : 0.5833  
Non-Linear Model : 0.6119

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:  
Hydroxyl Radicals Reaction:  
OVERALL OH Rate Constant = 101.7254 E-12 cm3/molecule-sec  
Half-Life = 0.105 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 1.262 Hrs  
Ozone Reaction:  
No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):  
Koc : 5.147E+005  
Log Koc: 5.712

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:  
Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):  
Log BCF = 1.409 (BCF = 25.67)  
log Kow used: 8.39 (estimated)

Volatilization from Water:  
Henry LC: 0.0388 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 1.786 hours  
Half-Life from Model Lake : 164.1 hours (6.839 days)

Removal In Wastewater Treatment:  
Total removal: 94.05 percent  
Total biodegradation: 0.78 percent  
Total sludge adsorption: 93.15 percent  
Total to Air: 0.12 percent

Level III Fugacity Model:  
Concentration Half-Life Emissions  
(percent) (hr) (kg/hr)  
Air 0.0738 2.52 1000

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Water	3.5	900	1000
Soil	27.2	900	1000
Sediment	69.2	3.6e+003	0

Persistence Time: 1.59e+003 hr

-----

CHEM : 124287  
 CAS Num: 124287  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.008882 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	acute	LC50	2.489 *
Snail	acute	LC50	1.014 *
Daphnid	acute	LC50	2.692 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

-----

ECOSAR Program (v0.99f) Results:

=====

SMILES : N(CCCCCCCCCCCCCCCCC)(C)C  
 CHEM : 1-Octadecanamine, N,N-dimethyl-  
 CAS Num:  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 MOL FOR: C20 H43 N1  
 MOL WT : 297.57  
 Log Kow: 8.39 (KowWin estimate)  
 Melt Pt:  
 Wat Sol: 0.0004016 mg/L (calculated)

**ECOSAR v0.99f Class(es) Found**

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**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
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Chemical Category	Test Organism	Duration	Endpoint	Value	Notes
Neutral Organic SAR (Baseline Toxicity)	Fish	14-day	LC50	0.00109	*
Aliphatic Amines	Fish	96-hr	LC50	0.007	*
Aliphatic Amines	Daphnid	48-hr	LC50	0.00112	*
Aliphatic Amines	Green Algae	96-hr	EC50	0.019	*
Aliphatic Amines	Green Algae	96-hr	ChV	0.019	*

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

Chem Name : 1-Octadecanamine, N,N-dimethyl-  
 Molecular Wt: 297.57  
 Henry's LC : 0.0388 atm-m3/mole (Henrywin program)  
 Vapor Press : 0.000167 mm Hg (Mpbpwin program)  
 Liquid VP : 0.000602 mm Hg (super-cooled)  
 Melting Pt : 81.3 deg C (Mpbpwin program)  
 Log Kow : 8.39 (Kowwin program)  
 Soil Koc : 1.01e+008 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.000256	2.52	0
Water	4.82	900	1000
Soil	1.93e-005	900	0
Sediment	95.2	3.6e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	7.27e-015	2.44	0.0887	0.244	0.00887
Water	6.63e-010	129	167	12.9	16.7
Soil	2.01e-018	0.000517	0	5.17e-005	0
Sediment	4.46e-010	636	66	63.6	6.6

Persistence Time: 3.47e+003 hr  
 Reaction Time: 4.52e+003 hr  
 Advection Time: 1.49e+004 hr  
 Percent Reacted: 76.7  
 Percent Advected: 23.3

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 2.522  
 Water: 900  
 Soil: 900  
 Sediment: 3600  
 Biowin estimate: 2.585 (weeks-months)

Advection Times (hr):

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Air:	100
Water:	1000
Sediment:	5e+004

## SAR ROBUST SUMMARY

### Test Substance

Identity: Hydrogenated Tallow Alkyl Amines (CAS RN 61788-45-2)

Melting Point (°C)	52.9
Boiling Point (°C)	347
Vapor Pressure (hPa)	0.000087
Partition Coefficient (log K <sub>w</sub> )	7.71
Water Solubility (mg/l)	0.049
Photodegradation (cm <sup>3</sup> /molecule-sec) [t <sub>1/2</sub> (hr)]	54 E-12 [2.4]
Hydrolysis [t <sub>1/2</sub> (hr)]	NC
Level III Fugacity (All input to water)	Air: <1% Water: 10% Soil: <1% Sediment: 90%
Acute Fish Toxicity - 96-hour LC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Acute Toxicity to Aquatic Invertebrates - 48-hour EC <sub>50</sub> (mg/l)	NTS – as cationic surfactant NTS – as aliphatic amine
Toxicity to Aquatic Plants - 96-hour EC <sub>50</sub> (mg/l)	NC – as cationic surfactant NTS – as aliphatic amine

NC – Not calculated by Model

NTS – Model indicates “Not Toxic at Solubility”

### Model Input/Output

SMILES : CCCCCCCCCCCCCCCCCCN  
 CHEM : HYDROGENATED TALLOW ALKYL AMINES  
 CAS NUM: 061788-45-2  
 MOL FOR: C18 H39 N1  
 MOL WT : 269.52

----- EPI SUMMARY (v3.05) -----

Physical Property Inputs:  
 Water Solubility (mg/L): -----  
 Vapor Pressure (mm Hg) : -----  
 Henry LC (atm-m<sup>3</sup>/mole) : -----  
 Log Kow (octanol-water): -----  
 Boiling Point (deg C) : -----  
 Melting Point (deg C) : -----

Log Octanol-Water Partition Coef (SRC):  
 Log Kow (KOWWIN v1.66 estimate) = 7.71

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPWIN v1.40):  
 Boiling Pt (deg C): 341.88 (Adapted Stein & Brown method)  
 Melting Pt (deg C): 94.34 (Mean or Weighted MP)  
 VP(mm Hg,25 deg C): 8.7E-005 (Modified Grain method)  
 MP (exp database): 52.9 deg C  
 BP (exp database): 346.8 deg C

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Water Solubility Estimate from Log Kow (WSKOW v1.37):

Water Solubility at 25 deg C (mg/L): 0.04875  
log Kow used: 7.71 (estimated)  
no-melting pt equation used

ECOSAR Class Program (ECOSAR v0.99f):

Class(es) found:  
Aliphatic Amines

Henrys Law Constant (25 deg C) [HENRYWIN v3.10]:

Bond Method : 9.36E-004 atm-m3/mole  
Group Method: 2.18E-003 atm-m3/mole

Henrys LC [VP/WSol estimate using EPI values]: 6.329E-004 atm-m3/mole

Probability of Rapid Biodegradation (BIOWIN v4.00):

Linear Model : 0.8815  
Non-Linear Model : 0.8943

Expert Survey Biodegradation Results:

Ultimate Survey Model: 2.9263 (weeks )  
Primary Survey Model : 3.7712 (days )

Readily Biodegradable Probability (MITI Model):

Linear Model : 0.7841  
Non-Linear Model : 0.8559

Atmospheric Oxidation (25 deg C) [AopWin v1.90]:

Hydroxyl Radicals Reaction:

OVERALL OH Rate Constant = 54.1959 E-12 cm3/molecule-sec  
Half-Life = 0.197 Days (12-hr day; 1.5E6 OH/cm3)  
Half-Life = 2.368 Hrs

Ozone Reaction:

No Ozone Reaction Estimation

Soil Adsorption Coefficient (PCKOCWIN v1.66):

Koc : 3.198E+005  
Log Koc: 5.505

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v1.67]:

Rate constants can NOT be estimated for this structure!

BCF Estimate from Log Kow (BCFWIN v2.14):

Log BCF = 2.337 (BCF = 217.3)  
log Kow used: 7.71 (estimated)

Volatilization from Water:

Henry LC: 0.00218 atm-m3/mole (estimated by Group SAR Method)  
Half-Life from Model River: 2.116 hours  
Half-Life from Model Lake : 160.7 hours (6.698 days)

Removal In Wastewater Treatment:

Total removal:	94.00	percent
Total biodegradation:	0.78	percent
Total sludge adsorption:	93.19	percent
Total to Air:	0.03	percent

Level III Fugacity Model:

Concentration	Half-Life	Emissions
(percent)	(hr)	(kg/hr)

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Air	0.35	4.74	1000
Water	7.43	360	1000
Soil	28.2	360	1000
Sediment	64	1.44e+003	0

Persistence Time: 614 hr

CHEM : 61788452  
 CAS Num: 61788452  
 ChemID1:  
 ChemID2:  
 ChemID3:  
 WatDisp: 0.04875 mg/L

Avg Length Carbon Chain: 18.00

**ECOSAR Class: Surfactants, Cationic (C >= 16)**

Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====
Fish	acute	LC50	2.489 *
Snail	acute	LC50	1.014 *
Daphnid	acute	LC50	2.692 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

**ECOSAR v0.99f Class(es) Found**

**Aliphatic Amines**

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
=====	=====	=====	=====	=====
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	0.004 *
Aliphatic Amines	: Fish	96-hr	LC50	0.016 *
Aliphatic Amines	: Daphnid	48-hr	LC50	0.003 *
Aliphatic Amines	: Green Algae	96-hr	EC50	0.034 *
Aliphatic Amines	: Green Algae	96-hr	ChV	0.029 *

Note: \* = asterick designates: Chemical may not be soluble enough to measure this predicted effect.  
 Fish and daphnid acute toxicity log Kow cutoff: none  
 Green algal EC50 toxicity log Kow cutoff: none  
 Chronic toxicity log Kow cutoff: none  
 MW cutoff: none

Level III Fugacity Model (Full-Output):

=====  
 Chem Name : HYDROGENATED TALLOW ALKYL AMINES

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Molecular Wt: 269.52  
 Henry's LC : 0.00218 atm-m<sup>3</sup>/mole (Henrywin program)  
 Vapor Press : 8.7e-005 mm Hg (Mpbpwin program)  
 Liquid VP : 0.000422 mm Hg (super-cooled)  
 Melting Pt : 94.3 deg C (Mpbpwin program)  
 Log Kow : 7.71 (Kowwin program)  
 Soil Koc : 2.1e+007 (calc by model)

	Concentration (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.00426	4.74	0
Water	10.4	360	1000
Soil	0.000169	360	0
Sediment	89.6	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	5.07e-014	8.19	0.56	0.819	0.056
Water	1.58e-010	263	137	26.3	13.7
Soil	1.98e-018	0.00428	0	0.000428	0
Sediment	4.72e-011	567	23.6	56.7	2.36

Persistence Time: 1.32e+003 hr  
 Reaction Time: 1.57e+003 hr  
 Advection Time: 8.18e+003 hr  
 Percent Reacted: 83.9  
 Percent Advected: 16.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 4.738  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 2.926 (weeks )

Advection Times (hr):

Air: 100  
 Water: 1000  
 Sediment: 5e+004