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I U C L I D

Data Set

Existing Chemical : ID: 117-08-8
CAS No. : 117-08-8
EINECS Name : Tetrachlorophthalic Anhydride
TSCA Name : 1,3-Isobenzofurandione, 4,5,6,7-tetrachloro-

Producer Related Part
Company : Solutia Inc.
Creation date : 06.06.0002

Substance Related Part
Company : Solutia Inc.
Creation date : 06.06.0002

Memo :

Printing date : 02.11.2002
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Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 OECD AND COMPANY INFORMATION

06.06.2002

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

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1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1. General Information

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1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

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1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

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1.14.3 AIR POLLUTION

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1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2. Physico-Chemical Data

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2.1 MELTING POINT

Value : = 254.5 °C
Sublimation :
Method : other
Year : 1979
GLP : no
Test substance : no data
Reliability : (2) valid with restrictions
Acceptable reference text.
Flag : Critical study for SIDS endpoint
24.10.2002 (13)

2.2 BOILING POINT

Value : = 371 °C at
Decomposition :
Method : other
Year : 1977
GLP : no
Test substance : no data
Reliability : (2) valid with restrictions
Acceptable reference text. Consistant with EPIWIN calculated value of 346 degrees C.
Flag : Critical study for SIDS endpoint
24.10.2002 (3)

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : .21 hPa at 145° C
Decomposition :
Method : other (measured)
Year :
GLP : no
Test substance : no data
Conclusion : EPIWIN calculated value of 5.16E -007 mm/Hg using modified Grain method; model is accepted tool for this purpose.
Reliability : (2) valid with restrictions
Acceptable reference text.
Flag : Critical study for SIDS endpoint
24.10.2002 (3)

2.5 PARTITION COEFFICIENT

Log pow : = 3.57 at °C
Method : other (calculated)
Year : 1978

2. Physico-Chemical Data

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GLP : no
Test substance : no data
Method : Log P value
Conclusion : Consistent with Log KOW value of 4.65. using KOWWIN in EPIWIN, an accepted estimation model
Reliability : (2) valid with restrictions
Reliable reference value from Leo, AJ. 1978. Report on the Calculation of octanol/water Log P values for structures in EPA files.
Flag : Critical study for SIDS endpoint
24.10.2002

2.6.1 WATER SOLUBILITY

Value : < 1 mg/l at 21 °C
Qualitative :
Pka : at 25 °C
PH : at and °C
Method : other
Year :
GLP : no
Test substance : no data
Reliability : (2) valid with restrictions
Reference value consistent with WSKOW calculated value of 1.59 mg/L. using EPIWIN, an accepted derivation model.
Flag : Critical study for SIDS endpoint
24.10.2002 (4)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 117-08-8
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3.1.1 PHOTODEGRADATION

Indirect photolysis

Sensitizer :
Conc. of sens. :
Rate constant : = .0000000000000316 cm³/(molecule*sec)
Degradation : = 50 % after 338.4 day
Deg. Product :
Method : other (calculated)
Year : 2002
GLP : no
Test substance :
Method : Used AOP Computer program, ver 1.90, Syracuse Research Corp. The AOP program estimates the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic chemical.

Reliability : (2) valid with restrictions
Estimation based on an EPA-accepted estimation model.

Flag : Critical study for SIDS endpoint
24.10.2002 (1)

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media : other
Air (level I) : 1.25
Water (level I) : 13.4
Soil (level I) : 83.9
Biota (level II / III) :
Soil (level II / III) : 1.42
Method : other
Year : 2002
Method : Estimation using measured data where available and EPIWIN -derived inputs where otherwise needed; based on Meylan et al 1993 methodology as adopted from Mackay et al 1996. Derived assuming emissions equivalent to 1000 kg/hr each for air, water and soil. Input data used: Henry's LC=1.91e-006 atm-m³/mole (Henrywin program), Vapor Press=5.16e-007 mm Hg (Mpbpwin program), Liquid VP=9.6e-005 mm Hg (super-cooled), Melting Pt=255 deg C (user entry), Log Kow=3.57 (user entry), Soil Koc=1.52e+003 (calc. by model).

Result : The second Soil data point refers to Sediment concentration estimations.
Reliability : (2) valid with restrictions
Used accepted estimation model recommended by US EPA.

Flag : Critical study for SIDS endpoint
24.10.2002 (1)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	
Concentration	:	100mg/l related to Test substance related to
Contact time	:	4 month
Degradation Result	:	= .2 % after 24 hour(s) under test conditions no biodegradation observed
Deg. Product	:	
Method	:	other
Year	:	1973
GLP	:	no
Test substance Method	:	other TS A Semi-Continuous Activated Sludge (SCAS) biodegradation test procedure was employed, patterned after the standard method as found in JAOCS 42:986 (1965) and JAOCS 46:432 (1969). Due to the low solubility of Tetrathal in water, sodium tetrachlorophthalate was used in this test. The agent was added at a rate of 100 mg per 24 hr cycle. Direct UV spectroscopic analysis was used to determine loss from the aqueous phase after sludge filtration at predetermined points of analysis between day 16 and 122.
Result	:	Mean disappearance rate between study days 16 and 122 was 0.2+/-2.0. Sodium Tetrachlorophthalate appeared to be essentially inert with respect to any toxic effects on the bacterial sludge. No inhibition of the sludge growth rate was noted during the course of the testing.
Test substance	:	Sodium tetrachlorophthalate was used since the anhydride form was considered too insoluble to use in this assay.
Reliability	:	(2) valid with restrictions The methods used in this test have subsequently been standardized and codified in national and international test guidelines, hence supporting its use. While conducted prior to GLP codification, the results of this study have been well documented.
Flag	:	Critical study for SIDS endpoint
02.11.2002		

(11)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : other
Species :
Exposure period :
Unit : mg/l
Analytical monitoring :
LC50 : c = 7.086
Method : other
Year : 2002
GLP : no
Test substance :
Method : Predictive value obtained from ECOSAR for a 96-hr fish EC50 of a Neutral Organic, based on following properties specific to TCPA and inserted into the program (mol. wt.= 285.9, log Kow = 3.57, water solubility =0.98 mg/L).
Result : Predicted value is above the level of water solubility (<0.98 mg/L) for TCPA.
Reliability : (2) valid with restrictions
Value was derived from use of ECOSAR a program within EPIWIN, a predictive program recommended by EPA.
Flag : Critical study for SIDS endpoint
02.11.2002

(1)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : static
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
Analytical monitoring : no
NOEC : = 180
EC50 : > 1000
Method : other
Year : 1984
GLP : yes
Test substance : other TS
Method : Study design followed recommendations from the US EPA Committee on Methods for Toxicity Testing with Aquatic Organisms, 1975. Groups of 10 first instar D. magna were exposed to one of 5 test concentrations ranging in logarithmic series from 100 to 1000 mg/l (i.e. 100, 180, 320, 560 and 1000 mg/l). Each group was placed in a 250 ml glass beaker filled with 200 ml well water, held at 20 degrees C. with 16 hrs artificial light per day @ 50-70 footcandles. Test article was suspended in 1 ml acetone and added to the respective beaker. A solvent control and untreated control group were also run. All test concentrations were evaluated in duplicate. Daphnia were observed every 24 hrs for morbidity and mortality. Water quality indices (temp., pH, dissolved oxygen) were measured prior to study start and at the end of the study. Water hardness was between 225-275 ppm. LC50 values (24 and 48 hr) were calculated using the method of Stephen, Busch, Smith, Burke and Anderson, USEPA Duluth Labs computer model, 1978.
Result : White precipitate was observed at the top of all beakers containing test article. Insufficient deaths occurred at either 24 or 48 hrs to calculate an LC50. Thus, the LC50 is considered to be > 1000 mg/L at each time point. Water quality indices were diss. oxygen - 6.1-8.1 mg/L, temp. of 20 degrees C., and pH of 8.1-8.5; all were judged within acceptable limits. However, it is recognized that even the low dose used in this study exceeded the limit (<1 mg/l) of solubility of TCPA.

Test substance	: exceeded the limit (<1 mg/l) of solubility of TCPA.	
Reliability	: Purity of 99%	
	: (2) valid with restrictions	EC50 value is excessive as this study was conducted at test levels above solubility; however, it can be stated that no toxic effects were observed at the limits of solubility in an otherwise well conducted study. ECOSAR predicted a 48-hr Daphnid LC50 (using EPIWIN, 2002) value for a Neutral Organic of 8.463 mg/L which is above the limit of solubility of TCPA [parameters entered were log Kow of 3.57, mol wt. of 285.9, and water solubility of 0.98 mg/L].
Flag	: Critical study for SIDS endpoint	
02.11.2002		(6)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	: Selenastrum sp. (Algae)	
Endpoint	: other	
Exposure period	:	
Unit	: mg/l	
Analytical monitoring	:	
EC50	: c = 5.791	
Method	: other	
Year	: 2002	
GLP	: no	
Test substance	:	
Method	: Predictive value obtained from ECOSAR for a 96-hr green algae EC50 of a Neutral Organic, based on following properties specific to TCPA and inserted into the program (mol. wt.= 285.9, log Kow = 3.57, water solubility =0.98 mg/L).	
Result	: Predicted value is above the level of water solubility (<0.98 mg/L) for TCPA.	
Reliability	: (2) valid with restrictions	
	: Value was derived from use of ECOSAR a program within EPIWIN, a predictive program recommended by EPA.	
Flag	: Critical study for SIDS endpoint	
02.11.2002		(1)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4. Ecotoxicity

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4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

Type	: LD0
Species	: rat
Strain	: Sprague-Dawley
Sex	: male/female
Number of animals	: 12
Vehicle	: other
Value	: > 15800 mg/kg bw
Method	: other
Year	: 1965
GLP	: no
Test substance	: other TS
Method	: Administered as a 33% corn oil suspension via single dose gavage to groups of fasted rats at dosages of 500 (1 F), 1000 (1 M), 1580 (1F), 2510 (1M), 3980 (1F), 5010 (1M, 1F), 10000 (1M:1F) and 15800 (2M:1F) to define a Minimum Lethal Dose. Animals were observed for clinical signs daily and weighed on day 0 and day 5.
Result	: No deaths occurred; some weakness and severe diarrhea were observed.
Test substance	: 99% purity
Conclusion	: Acceptable study to define the low acute oral toxicity since dosage levels far exceeded current Limit Test standard used today. When test groups are combined, a total of 6M and 5F rats were dosed at test levels equal to or greater than the internationally accepted Limit Test value of 1,000 mg/kg; no deaths were recorded at any of these test levels such that it can be concluded that the LD50 (also the Minimum Lethal Dose or LD0) exceeds 1000 mg/kg.
Reliability	: (2) valid with restrictions Conducted prior to GLP requirements, but adequately documented; also used limited no. animals per treatment group.
Flag	: Critical study for SIDS endpoint
25.09.2002	

(12)

5.1.2 ACUTE INHALATION TOXICITY

Type	: LC0
Species	: rat
Strain	: Sprague-Dawley
Sex	: male/female
Number of animals	: 20
Vehicle	: no data
Exposure time	: 4 hour(s)
Value	: > 3.6 mg/l
Method	: other
Year	: 1975
GLP	: no
Test substance	: other TS
Method	: Groups of 5 male and 5 female rats were exposed to atmospheres containing either 3.16 or 3.60 mg/l. test material for 4 hrs. Air concentrations were generated using a ferris wheel generator to create a dust and passing clean air through the generator at 30 L/min. to an 80 L. glass and steel chamber containing the animals. Particle size means were calculated. Rats were held for 14 days for observation, then sacrificed and necropsied. Physical signs were recorded.
Result	: No deaths occurred at either test level. 3.6 mg/L was determined to be the maximum attainable concentration using this equipment. No untoward reactions were observed during the exposure or observation periods nor were there any alterations attributable to test material seen at necropsy.

were there any alterations attributable to test material seen at necropsy.
Greater than 43 % of the dust particles were < 5 microns in diameter, and > 65% were less than 10 microns.

Test condition : Test material purity of 99%

Reliability : (2) valid with restrictions
Study was conducted prior to GLPs and test guidelines; had limited documentation, but is useful in arriving at lower limit of inhalation toxicity potential in that the maximum achievable atmospheric concentration did not produce lethality after acute exposure.

25.09.2002 (10)

5.1.3 ACUTE DERMAL TOXICITY

Type : LD0

Species : rabbit

Strain : New Zealand white

Sex : male/female

Number of animals : 6

Vehicle : other

Value : > 5010 mg/kg bw

Method : other

Year : 1965

GLP : no

Test substance : other TS

Method : Groups of single rabbits were treated dermally with either 501 (1F), 794 (1M), 1260 (1F), 2000 (1M), 3160 (1F) or 5010 (1M) mg/kg test article (ground powder in a 10% corn oil suspension) to define a Minimum Lethal Dose. All animals had their dorsal region closely shaved and test material applied to intact skin under an occlusive patch and held in place for 24 hours. Thereafter, the test article was wiped off. All animals were observed daily for signs of toxicity and weighed prior to and at study term (5 days).

Result : No deaths occurred in the study at any dose level; The only manifestation of toxicity was generalized reduced activity.

Test substance : Purity of 99%

Conclusion : Data is sufficient to establish low acute toxicity by dermal route as most of the dose levels exceeded the Limit Test dosage.

Reliability : (2) valid with restrictions
Conducted before GLP requirements but is adequately documented.
Limited no. of animals and shorter duration for observation used.

27.08.2002 (12)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Species : rat

5. Toxicity

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Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	gavage
Exposure period	:	Five days per week for 13 weeks
Frequency of treatment	:	Once daily
Post obs. period	:	none
Doses	:	0, 94, 187, 375, 750 or 1500 m/kg/d
Control group	:	yes, concurrent vehicle
NOAEL	:	< 94 mg/kg bw
LOAEL	:	= 94 mg/kg bw
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
Year	:	1987
GLP	:	yes
Test substance	:	other TS
Method	:	This study was conducted under the auspices of the US National Toxicology Program (NTP). Ten (10) male and 10 female F344 rats of approx 6 weeks of age were administered TCPA in corn oil by gavage at doses of 0, 94, 187, 375, 750 or 1500 mg/kg/d for 5 days/week, for 13 consecutive weeks. Animals were housed, 5/cage, in stainless steel mesh cages with water and diet available ad libitum. Animal rooms were maintained at 67-77 degrees F and between 30-70% rel. humid, and had at least 10 room air changes/hr and a 12 hr light:dark cycle. All animals were observed twice daily for morbidity and mortality and detailed clinical signs were recorded on a weekly basis. Food consumption was recorded weekly by cage and individual body weights were recorded at study initiation and then weekly thereafter until study term. All rats underwent a hematology evaluation (RBC, HCT, HGB, MCH, MCHC, MCV, WBC, differential/morphological leukocyte exams, reticulocyte analysis and platelet counts) at the end of the study. Clinical chemistries (ALT, ALB, CRET, GGT, GLU, BUN) were analyzed on study days 6, 20, and at study term for all rats on test. Absolute and relative weights were recorded for the following organs of all rats at study term: brain, heart, kidney, liver, lung, spleen, testis (males only), and thymus. Complete necropsies were performed on all animals. Over 40 organs and tissues were examined for gross lesions and fixed in 10% neutral buffered formalin. Complete histopathologic examinations were performed on all control animals, on all animals in the highest dose group with at least 60% survivors, and on all animals, including those that died or were killed moribund before the end of the study, in the higher dose groups. The kidneys were identified as a target organ, hence kidneys were evaluated for all males and females at all dose levels, along with any gross lesions observed in-life. Organ and body weight data, which are approximately normally distributed, were analyzed statistically using parametric multiple comparison procedures outlined by Williams (1971/1972 Biometrics 27: 103 & 519) or Dunnett (1955. J. Am. Stat. Assoc. 50:1096). Hematology and clinical chemistry data, which typically have skewed distributions, were analyzed using the nonparametric multiple comparisons methods of Shirley (1977. Biometrics 33:386.) or Dunn (1964. Technometrics 6:241). Jonckheere's test (1954. Biometrika 41:133) was used to assess the significance of dose-response trends and to determine whether a trend-sensitive test was more appropriate for pairwise comparisons than a test capable of detecting departures from monotonic dose response. P-values were set at < 0.01. No ophthalmoscopic exam, consistent with Guideline 408, was conducted.
Remark	:	No effects on organ weight or morphology was observed for any of the gonads (male and female) in this study.
Result	:	Treatment-related deaths occurred at 1500 mg/kg (5/10 males; 1/10 females) and 750 mg/kg (1/10 females). Mean final body weights and weight gains were statistically significantly reduced in groups of male rats given 375, 750 and 1500 mg/kg TCPA and in all female TCPA-treated groups. All groups (males and females) at all treatment levels exhibited decreased feed consumption compared to controls. No compound-specific clinical signs of toxicity were observed at any test level. Absolute and

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clinical signs of toxicity were observed at any test level. Absolute and relative kidney weights were increased in a dose-dependent manner to female rats while males were significantly increased (relative wt) at 187 mg/kg and higher. Other changes (spleen, thymus and liver) were either small, inconsistent or attributed to the marked decrease in body weights exhibited, and thus were not considered treatment-related. Changes in several hematology and clinical chemistry parameters were judged as minor and sporadic and were not considered clinically significant. No gross lesions attributable to treatment were observed at necropsy. Treatment-related microscopic lesions were identified in the kidney of male and female rats from all test groups, and consisted of renal tubular degenerative changes. These changes involved epithelial necrosis at higher dose levels and tubular dilation at lower dose levels. No other microscopic findings attributable to treatment were found. Thus, a NOEL was not established in this study.

Test substance	:	Test substance was 99% pure.
Reliability	:	(2) valid with restrictions Used a reduced no. of clinical chemistry parameters and no in-life ophthalmoscopic exam.
Flag 02.11.2002	:	Critical study for SIDS endpoint
Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	gavage
Exposure period	:	5 Days/week for 13 weeks
Frequency of treatment	:	Once per day
Post obs. period	:	none
Doses	:	0, 94, 187, 375, 750, or 1500 mg/kg/d
Control group	:	yes, concurrent vehicle
NOEL	:	>= 187 mg/kg bw
LOAEL	:	= 375 mg/kg bw
Method	:	other
Year	:	1992
GLP	:	yes
Test substance	:	other TS
Method	:	This study was conducted under the auspices of the US National Toxicology Program (NTP). Ten (10) male and 10 female B6C3F1 mice of approx 5 weeks of age were administered TCPA in corn oil by gavage at doses of 0, 94, 187, 375, 750 or 1500 mg/kg/d for 5 days/week, for 13 consecutive weeks. Animals were individually housed in stainless steel mesh cages with water and diet available ad libitum. Animal rooms were maintained at 67-77 degrees F and between 30-70% rel. humid, and had at least 10 room air changes/hr and a 12 hr light:dark cycle. All animals were observed twice daily for morbidity and mortality and detailed clinical signs were recorded on a weekly basis. Food consumption was recorded weekly for each animal and individual body weights were recorded at study initiation and then weekly thereafter until study term. All mice underwent a hematology evaluation (RBC, HCT, HGB, MCH, MCHC, MCV, WBC, differential/morphological leukocyte exams, reticulocyte analysis and platelet counts) at the end of the study. No clinical chemistries or ophthalmoscopic exams were performed. Absolute and relative weights were recorded for the following organs of all mice at study term: brain, heart, kidney, liver, lung, spleen, testis (males only), and thymus. Complete necropsies were performed on all animals. Over 40 organs and tissues were examined for gross lesions and fixed in 10% neutral buffered formalin. Complete histopathologic examinations were performed on all control animals, on all animals in the highest dose group with at least 60% survivors, and on all animals, including those that died or were killed moribund before the end of the study, in the higher dose groups. Organ and body weight data, which are approximately normally distributed, were

(5)

	and body weight data, which are approximately normally distributed, were analyzed statistically using parametric multiple comparison procedures outlined by Williams (1971/1972 Biometrics 27: 103 & 519) or Dunnett (1955. J. Am. Stat. Assoc. 50:1096). Hematology data, which typically has a skewed distribution, were analyzed using the nonparametric multiple comparisons methods of Shirley (1977. Biometrics 33:386.) or Dunn (1964. Technometrics 6:241). Jonckheere's test (1954. Biometrika 41:133) was used to assess the significance of dose-response trends and to determine whether a trend-sensitive test was more appropriate for pairwise comparisons than a test capable of detecting departures from monotonic dose response. P-values were set at < 0.01.	
Result	: One female mouse died at 750 mg/kg; all other animals survived the test period, and thus this death was not attributed to treatment. No differences were observed in feed consumption or final body weights that were attributed to TCPA. No clinical signs of toxicity were observed. No clearly discernable effect of treatment could be made on organ weight changes. A dose-related decrease in HGB concentration was observed in male mice given 375 mg/kg and higher TCPA and in females given 750 mg/kg or above. Decreases in HCT and RBC also were observed in male mice given 1500 mg/kg. No treatment-related gross lesions were seen at necropsy nor where any treatment-related microscopic lesions identified after microscopic examination of tissues. No effects on the testes were observed.	
Test substance	: Reported as 99% pure	
Reliability	: (2) valid with restrictions	
02.11.2002	No clinical chemistry or in-life ophthalmoscopic exams were conducted.	(5)
Species	: rat	
Sex	: male/female	
Strain	: Sprague-Dawley	
Route of admin.	: inhalation	
Exposure period	: 6 hr/d, 5d/week for 13 weeks	
Frequency of treatment	: daily, 5d/week	
Post obs. period	: none	
Doses	: 0, 0.5, 5 and 50 mg/m ³ (nominal) and 0, 0.73, 4.15 and 36.3 mg/m ³ (analytical), respectively	
Control group	: yes, concurrent vehicle	
NOAEL	: < .73 mg/m ³	
Method	: other	
Year	: 1982	
GLP	: no	
Test substance	: other TS	
Method	: Groups of 15 male and 15 female rats exposed to atmospheric dust levels targeted at 0, 0.5, 5 and 50 mg/m ³ for 6 hr/d, 5d/week for 13 weeks. Animals exposed in stainless steel and glass cages; whole body exposures. Air flow rate of approximately 280 L/min, during which test agent was added using a Wright dust feed device. Chamber concentrations were analyzed using a GCA Respirable dust monitor for the first 5 weeks and then spectrophotometrically during the remainder of the study. Analytical exposure levels for the first 5 weeks were calculated by extrapolation based on regression analysis of daily nominal concentrations. Daily analytical concentrations were used for the last 8 weeks of the study. Correlation coefficients for regression analysis of analytical and nominal concentrations was 0.97 for the low, mid and high doses combined, and was 0.90 for the high and mid dose, but only 0.50 for the low dose; hence the low dose level may not be accurately described. Particle size distribution was determined using a Batelle cascade impactor. Animals were observed twice daily for morbidity and mortality and weekly for detailed physical examinations and body weight. At 7 and 13 week intervals, the following clinical parameters were measured for all surviving control and high dose animals: hematology (HGB, HCT, RBC, Clotting	

control and high dose animals: hematology (HGB, HCT, RBC, Clotting time, total and differential leukocytes), blood chemistries (ALP, BUN, SGPT, GLU), and urinalysis (gross appearance, spec. grav. pH, PRO, GLU, ketones, Bilirubin, occult blood and microscopic elements). Complete necropsies were conducted on all surviving animals after 13 weeks and organ weights and weight ratios (body and brain) were recorded for: brain, ovaries, testes, kidneys, heart, liver, lungs, pituitary and spleen.

Microscopic examination of the following tissues were performed for all control and high dose rats: adrenals, bone marrow, brain, eyes, heart, colon, duodenum, ileum, kidneys, liver, lungs, lymph nodes, mammary gland, ovaries, pancreas, pituitary, prostate, salivary gland, skeletal muscle, skin, spinal cord, spleen, stomach, testes with epididymus, thyroid, parathyroid, urinary bladder and uterus. Lungs were also evaluated for all surviving animals in the mid and low dose groups. Mean group values for body weights, organ weights and weight ratios were evaluated statistically using Dunnett's test (J AM Stat Assn. 1955. vol 50:1 096 and Biometrics 20:482, 1964). The F-test and Students' T test were used to compare group means for hematology and clinical chemistry parameters. When variances were observed in the F-test, a Student's t test, as modified using Cochran's approximation test was employed (Snedecor, GS. Statistical Methods. 1967. Iowa State University Press.) All comparisons were made at both the 5% and 10% level of significance.

- Result** : Cumulative mean analytical concentrations were 0.73, 4.15, and 36.3 mg/m³ respectively based on spectrophotometric analysis of chamber samples. Although the mean analytical chamber concentrations for the low and mid level appear close to target levels, extreme variations in chamber concentrations were observed from day to day and also during any given day. At the high dose level, similar daily excursions occurred. In general, during weeks 2 through 5, animals appeared to have been exposed to concentrations well below the target levels; the mean nominal concentration for the low, mid and high-dose level were 9, 17.7 and 198 mg/m³. The mean aerodynamic mass median diameter for the low, mid and high levels were 2.69, 3.34 and 3.45 micrometers, respectively. All animals survived the study duration. Physical observations were limited to the high dose group, and consisted of increased nasal discharge, ano-genital staining and excessive lacrimation. Body weight gains for all levels for both sexes were considered comparable to controls. Clinical blood parameters were considered unaffected by treatment. High dose males exhibited slight proteinuria at 7 weeks and 13 weeks. Microscopic examination of the urine revealed a slight increase in the amount of amorphous matter in the urine after 13 weeks. An increase in absolute and relative lung weights in the mid-dose males and high dose males and females were considered treatment-related. The several other small changes in organ weights or ratios were considered unrelated to treatment since there was no dose-response evident. The only gross pathological observation attributable to treatment was the appearance of petechial hemorrhages in the lungs of several treated rats. Histopathological changes in the lungs were also noted in all dose groups. Irregular thickening of the alveolar septa, scattered pigmented macrophages and multinucleate giant cells, multifocal accumulation of alveolar macrophages and multifocal alveolar hemorrhages were noted. High dose animals also exhibited mild centrilobular hepatocellular hypertrophy. No effects, either in organ weight or pathology (gross and histo-) were noted for either the ovaries or testes/epididymides of rats treated at any dose level.
- Test substance** : Dust of product-specific Fines; test material was 99% pure.
- Reliability** : (2) valid with restrictions
In view of the excursions in exposure concentrations and the problems of extrapolation of analytical concentrations at the low dose level, the accuracy of this dose level is questionable.

27.08.2002

(7)

Species : rat

5. Toxicity

Id 117-08-8

Date 02.11.2002

Sex	: male/female
Strain	: Sprague-Dawley
Route of admin.	: inhalation
Exposure period	: 6 hours/day, 5 days/week for 13 weeks
Frequency of treatment	: 5 days/week for 13 weeks
Post obs. period	: none
Doses	: 0, 0.5, 5 and 50 mg/m ³ (nominal targets)
Control group	: yes, concurrent no treatment
NOAEL	: < .5 mg/m ³
Method	: other
Year	: 1982
GLP	: no
Test substance	: other TS
Method	: Groups of 15 male and 15 female rats were exposed to atmospheric fume levels targeted at 0, 0.5, 5 and 50 mg/m ³ for 6 hr/d, 5d/week for 13 weeks. Fumes were created by passing a stream of air through a flask containing the test material and heated to 200 degrees C. Animals were exposed via whole body in 1 M ³ stainless steel and glass chambers. Air flow rates were approximately 280 L/min. Chamber concentrations were analyzed using a GCA Respirable dust monitor for the first 5 weeks and then spectrophotometrically during the remainder of the study. Analytical exposure levels for the first 5 weeks were calculated by extrapolation based on regression analysis of daily nominal concentrations. Daily analytical concentrations were used for the last 8 weeks of the study. Correlation coefficients for regression analysis of analytical and nominal concentrations were 0.87 for the low, mid and high doses combined, 0.69 for the high and mid dose, but only 0.12 for the low dose; hence the low dose level may not be accurately described. Particle size distribution was determined using a Batelle cascade impactor. Animals were observed twice daily for morbidity and mortality and weekly for detailed physical examinations and body weight. At 7 and 13 week intervals, the following clinical parameters were measured for all surviving control and high dose animals: hematology (HGB, HCT, RBC, Clotting time, total and differential leukocytes), blood chemistries (ALP, BUN, SGPT, GLU), and urinalysis (gross appearance, spec. grav. pH, PRO, GLU, ketones, Bilirubin, occult blood and microscopic elements). Complete necropsies were conducted on all surviving animals after 13 weeks and organ weights and weight ratios (body and brain) were recorded/calculated for: brain, ovaries, testes, kidneys, heart, liver, lungs, pituitary and spleen. Microscopic examination of the following tissues were performed for all control and high dose rats: adrenals, bone marrow, brain, eyes, heart, colon, duodenum, ileum, kidneys, liver, lungs, lymph nodes, mammary gland, ovaries, pancreas, pituitary, prostate, salivary gland, skeletal muscle, skin, spinal cord, spleen, stomach, testes with epididymus, thyroid, parathyroid, urinary bladder and uterus. Lungs were also evaluated for all surviving animals in the mid and low dose groups. Mean group values for body weights, organ weights and weight ratios were evaluated statistically using Dunnett's test (J AM Stat Assn. 1955. vol 50:1096 and Biometrics 20:482, 1964). The F-test and Students' T test were used to compare group means for hematology and clinical chemistry parameters. When variances were observed in the F-test, a Student's t test, as modified using Cochran's approximation test was employed (Snedecor, GS. Statistical Methods. 1967. Iowa State University Press.) All comparisons were made at both the 5% and 10% level of significance.
Result	: Cumulative mean analytical exposure concentrations were 0.5, 5.6 and 26.6 mg/m ³ respectively, for the low, mid and high dose levels, based on spectrophotometric analysis and regression analysis. Although the mean analytical chamber concentrations for the low and mid-dose level appear to be close to target levels, extreme variations in chamber concentrations were observed from day to day and also during any given day at all dose levels. The respective mean nominal concentrations for the low, mid and high dose levels were 1.6, 13 and 57 mg/m ³ , respectively. The mean

high dose levels were 1.6, 13 and 57 mg/m³, respectively. The mean aerodynamic mass median diameter for these levels were: 2.6, 2.5 and 1.7 micrometers. All animals survived the study duration. Physical observations were limited to the high dose group, and consisted of increased red nasal discharge and dry rales. Body weight gains for all treated levels for both sexes were considered comparable to controls. Clinical blood parameters were considered unaffected by treatment at both time points, with the exception of a increase in blood glucose levels seen in both males and females (statistically significantly increased) after 13 weeks of testing. No treatment-related effects were observed after urinalysis at either study interval. Lung weights in high dose males and females were significantly increased over control group levels and appeared dose-related. The several other small changes in organ weights or ratios were considered unrelated to treatment since there was no dose-response evident. The only gross pathological observation attributable to treatment was the appearance of petechial hemorrhages in the lungs of several treated rats. Histopathological changes in the lungs were also noted in all dose groups. Irregular thickening of the alveolar septa, scattered pigmented macrophages and multinucleate giant cells, multifocal accumulation of alveolar macrophages and multifocal alveolar hemorrhages were noted. High dose animals also exhibited mild centrilobular hepatocellular hypertrophy. No effects, either in organ weight or pathology (gross and histo-) were noted for either the ovaries or testes/epididymides of high dose-treated rats.

Test substance : Dust of product-specific Fines fumes; test material was 99% pure.
Reliability : (2) valid with restrictions
 In view of the excursions in exposure concentration and the problems of extrapolation of analytical concentrations at the low dose level, the accuracy of this dose level is questionable.

05.09.2002

(8)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : S. typhimurium TA-1535, TA-1537, TA98 and TA100
Concentration : Test # 1-0, 33.3, 100, 333.3, 1000, 3333.3 and 6666.7 ug/plate; Test # 2-0, 1, 3.3, 10, 33, 100, 333, 1000 ug/plate
Cycotoxic conc. : Test # 1 - 3333.3 ug/plate; Test # 2 - > 1000 ug/plate
Metabolic activation : with and without
Result : negative
Method : OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year : 1985
GLP : yes
Test substance : other TS
Method : Two independently conducted studies were performed, each conducted at a separate contract facility for the US NTP. Test design met OECD Guideline 471. TCPA was incubated with S. typhimurium tester strains either in buffer or S9 mix (from Arochlor 1254-treated male SD rats or Syrian hamsters) for 20 min. at 37 degrees C. Top agar supplemented with l-histidine and d-biotin was added and the contents of the tubes were mixed and poured onto the surfaces of minimal glucose agar plates. Histidine-independent mutant colonies arising on these plates were counted following incubation for 2 days at 37 degrees C. Each trial consisted of triplicate plates of concurrent positive and negative controls and of at least 5 doses of TCPA. All assays were repeated in duplicate.
Result : TCPA was negative in four tester strains, in both trials, at both laboratories, with and without metabolic activation using hamster and rat S9 mix.
Test substance : Test substance reportedly 99% pure.
Reliability : (1) valid without restriction

Flag 25.09.2002	: Critical study for SIDS endpoint	(14)
Type	: Cytogenetic assay	
System of testing	: Chinese Hamster Ovary Cell in vitro Assay (SCEs and Chrom. Abbs).	
Concentration	: 0, 25, 75, 125, 250, 500 and 750 ug/mL.	
Cycotoxic conc.	: > 750 ug/mL.	
Metabolic activation	: with and without	
Result	: negative	
Method	: other	
Year	: 1987	
GLP	: yes	
Test substance	: other TS	
Method	: Studies conducted according to NTP study design such that both SCEs and Chrom. Abb. were identified both in the presence and absence of SD male rat Arochlor 1254-induced liver S9 fractions. Cell cultures were handled to prevent photolysis of Brdu-substituted DNA. Each test consisted of concurrent solvent and positive controls and at least 3 doses of TCPA. A single flask per dose was used and trials yielding equivocal or positive results were repeated. In the SCE test, cells were incubated for 26 hrs with TCPA in McCoy's 5A medium supplemented with fetal bovine serum, l-glutamine and antibiotics. BrdU was added 2 hrs after culture initiation; 26 hrs later the medium containing TCPA was removed and replaced with fresh medium plus BrdU and colcemid and incubated another 2 hrs. Cells were harvested by mitotic shake-off, fixed and stained with Hoechst 33258 and Giemsa. In the SCE test with S9, cells were incubated with test material, serum-free medium and S9 for 2 hrs. All slides were scored blind, with 50 second-division metaphase cells scored for frequency of SCEs/cell from each dose level. In the Chrom Abs test, cells were incubated in McCoy's 5A medium with test agent for 12 hrs (cells were treated with TCPA and S9 for 2 hrs), colcemid added and incubated for an additional 2 hrs and harvested in a fashion similar to the SCE study portion. 100 first-division metaphase cells were scored blind from prepared slides for each dose level. Classes of aberrations were recorded and included simple, complex and other abnormalities. Statistical analyses (Armitage trend test) were conducted on the slopes of the dose-response curves, with a SCE frequency 20% above the concurrent solvent control value chosen as a conservative positive response; $p < 0.01$. For evaluation of chromosomal aberrations, statistical analyses (Armitage trend test; Margolin multiple comparison) were conducted on both the dose-response curve and individual dose points, significance was determined as $p < 0.05$ for single data points and $p < 0.015$ for trend.	
Result	: TCPA did not induce SCEs or chromosomal aberrations in Chinese hamster ovary cells with or without metabolic activation. In the SCE study, a positive response was seen with S9, but was not confirmed in a subsequent trial and thus was judged as unrelated to TCPA treatment.	
Test substance	: Test substance was 99% pure.	
Reliability	: (2) valid with restrictions Combined Chromosomal Aberration and SCE study following NTP study design. Was well documented and useful for regulatory purposes.	
Flag 25.09.2002	: Critical study for SIDS endpoint	(2)

5.6 GENETIC TOXICITY 'IN VITRO'

5.7 CARCINOGENITY

5. Toxicity

Id 117-08-8
Date 02.11.2002

5.8 TOXICITY TO REPRODUCTION

Type : other
Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 5 days per week for 13 weeks
Frequency of treatment : once per day
Premating exposure period
Male :
Female :
Duration of test : 13 weeks
Doses : 0, 94, 357, 750 and 1500 mg/kg
Control group : yes, concurrent vehicle
NOAEL Parental : >= 1500 mg/kg bw
Method : other
Year : 1987
GLP : yes
Test substance : other TS
Method : Evaluations performed in conjunction with a 13 week NTP study referenced in Repeated Dose Robust Summary section. Sperm morphology was performed on male rats exposed to 0, 94, 375 and 750 mg/kg TCPA at the conclusion of the 13 week study. At necropsy, the right epididymis was isolated and weighed. The tail of the epididymis was then removed from the epididymal body and weighed. Test yolk or Tyrode's buffer was applied to slides and a small incision was made at the distal border of the epididymal tail. The sperm effluxing from the incision were dispersed in the buffer on the slides and the numbers of motile and nonmotile spermatozoa were counted for 5 fields per slide. Sperm density was then determined microscopically with the aid of a hemacytometer after the caudal tissue was incubated in saline and then heat fixed. Statistical treatment was performed using either Dunn's test or Shirley's test or Dunnett's test, as described in the Repeat Dose section of this dossier. Vaginal cytology evaluations were performed on female rats from the 0, 94, 375 and 1500 mg/kg dose groups. Seven days prior to sacrifice, the vaginal vaults of the females of each species and dose group were lavaged and the aspirated fluid and cells stained with Toluidine Blue. Relative numbers of leukocytes, nucleated epithelial cells, and large squamous epithelial cells were determined and were used to ascertain estrous cycle stage. An arcsine transformation was used to bring the proportion data into closer conformance with normality assumptions before additional statistical treatment was performed. Effects of treatment were investigated by applying a multivariate analysis (MANOVA) of variance to the transformed data to test for the simultaneous equality of measurement across dose levels.

Remark : Sperm Morphology and Vaginal Cytology Evaluation
Result : No changes between exposed animals and controls in sperm morphology and vaginal cytology were considered of biological significance for any of the parameters evaluated.

Test substance : Test material reported as 99% pure
Reliability : (4) not assignable
Study design does not meet that needed to fulfill this Endpoint; results appear reliable but not conducted according to a standardized protocol.

27.08.2002

(5)

Type : other
Species : mouse
Sex : male/female
Strain : B6C3F1

5. Toxicity

Id 117-08-8

Date 02.11.2002

Route of admin. : gavage
Exposure period : 5 days per week for 13 weeks
Frequency of treatment : once per day
Premating exposure period
Male :
Female :
Duration of test : 13 weeks
Doses : 0, 94, 375 and 1500 mg/kg
Control group : yes, concurrent vehicle
NOAEL Parental : ≥ 1500 mg/kg bw
Method : other
Year : 1987
GLP : yes
Test substance : other TS
Method : Evaluations performed in conjunction with a 13 week NTP study referenced in Repeated Dose Robust Summary section. Sperm morphology was performed on male mice exposed to 0, 94, 375 and 1500 mg/kg TCPA at the conclusion of the 13 week study. At necropsy, the right epididymis was isolated and weighed. The tail of the epididymis was then removed from the epididymal body and weighed. Tyrode's buffer was applied to slides and a small incision was made at the distal border of the epididymal tail. The sperm effluxing from the incision were dispersed in the buffer on the slides and the numbers of motile and nonmotile spermatozoa were counted for 5 fields per slide. Sperm density was then determined microscopically with the aid of a hemacytometer after the caudal tissue was incubated in saline and then heat fixed. Statistical treatment was performed using either Dunn's test or Shirley's test or Dunnett's test, as described in the Repeat Dose section of this dossier. Vaginal cytology evaluations were performed on female mice from the 0, 94, 375 and 1500 mg/kg dose groups. Seven days prior to sacrifice, the vaginal vaults of the females of each dose group were lavaged and the aspirated fluid and cells stained with Toluidine Blue. Relative numbers of leukocytes, nucleated epithelial cells, and large squamous epithelial cells were determined and were used to ascertain estrous cycle stage. An arcsine transformation was used to bring the proportion data into closer conformance with normality assumptions before additional statistical treatment was performed. Effects of treatment were investigated by applying a multivariate analysis (MANOVA) of variance to the transformed data to test for the simultaneous equality of measurement across dose levels.

Remark : Sperm Morphology and Vaginal Cytology Evaluation
Result : Sperm morphology evaluations revealed a statistically significant decrease to sperm motility in male mice at 1500 mg/kg; however, values were not decreased relative to historical control data. Thus, it was concluded that TCPA did not affect any of the parameters measured in this study.

Test substance : Test material reported purity of 99%.
Reliability : (4) not assignable
Study design does not meet that needed to fulfill this Endpoint; results appear reliable but not conducted according to a standardized protocol.

27.08.2002

(5)

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : female
Strain : Sprague-Dawley
Route of admin. : gavage
Exposure period : Dosing on gestation days 6 through 19

5. Toxicity

Id 117-08-8

Date 02.11.2002

Frequency of treatment	: Daily dose administered during gestation days 6-19
Duration of test	: Animals sacrificed on gestation day 20
Doses	: 0, 250, 1000 and 2000 mg/kg/d
Control group	: yes, concurrent vehicle
NOAEL Maternalt.	: = 1000 mg/kg bw
NOAEL Teratogen	: = 1000 - mg/kg bw
Method	: OECD Guide-line 414 "Teratogenicity"
Year	: 1982
GLP	: yes
Test substance	: other TS
Method	: Groups of 24 mated female rats were dosed daily by gavage (test material dissolved/suspended in corn oil) during gestation days 6 -19 at dosage levels of 0, 250, 1000 and 2000 mg/kg/d. Stability and homogeneity of the dosing solution were determined prior to initiation of the study and accuracy of dose solutions analyzed throughout the study. All rats were observed for mortality and abnormal behavior twice daily from gestation day 0 through day 20, at which time all animals were sacrificed. Detailed physical exams for signs of toxicity were recorded on study days 0, 6, 10, 15 and 20. Maternal body weights were recorded at several intervals throughout the study. At sacrifice the uterine horns were examined for implantation sites, resorptions and the number of viable or non-viable fetuses. The number of corpora lutea were also recorded. The sex and weights of all live fetuses were recorded and all fetuses were examined for external abnormalities. One-half of the fetuses per litter were examined for skeletal malformations while the other half were examined for internal anomalies. The following statistical analyses were performed: For interval data (body wts, wt changes, reproductive data) -Bartlett's test was used to determine equality of variance and ANOVA and Dunnett's test used for parametric data while the Kruskal-Wallis test and Summed Rank test (Dunn) was used for nonparametric data (Snedecor and Cochran.; Hollander and Wolfe). For Incidence data i.e. mortality rates, % and incidence of variations and malformations - comparisons were made using the Chi-square contingency table and the 2X2 Fisher Exact test using the Bonferroni inequality estimate; linear trend was evaluated using the Armitage test. Comparisons were made using the litter as the comparative entity. Both the 5% and 10% level of statistical significance were reported for each parameter.
Result	: Dosing solutions were shown to be homogeneous and stable and within 95% of the target concentrations. One female in each of the low and mid dosage groups and two females in the high dosage group died during the study, but were considered dosing error and not toxicity-related. Physical observations recorded included a lethargic appearance in several mid and high-dosage animals and pale eye color on day 20 of gestation in 4 rats in the 2000 mg/kg/d test group. Mean body weight gains in animals treated with the test article were comparable to controls. No treatment-related gross pathologic findings were seen at autopsy. Fetal body weights for male and female pups at 2000 mg/kg/d were significantly depressed when compared to controls; mid and low dose group mean pup weights were similar to controls. Pregnancy rates, mean nos. of corpora lutea, implantations, resorptions, live fetuses and fetal sex distribution were similar to control values. The incidence of external and soft tissue anomalies among treated groups was similar to controls both on a per litter and per fetus basis. The types and incidences of ossification variations were comparable between the 250 and 1000 mg/kg/d treated and control groups. At 2000 mg/kg/d, a slight increase in the incidence of asymmetric/unossified sternebra and incompletely ossified thoracic vertebral centra were observed and are considered representative of a fetotoxic effect. The incidence of skeletal malformations was comparable between the control, low and mid dosage groups. At 2000 mg/kg/d, an increase in the incidence of rib and vertebral malformations was observed. The incidence of skeletal malformations, both on a per fetus and per litter basis was comparable between the control, low and mid dosage groups. At 2000

was comparable between the control, low and mid dosage groups. At 2000 mg/kg/d, the incidence of rib and vertebral malformations was slightly higher than concurrent controls and also higher than historical controls at the testing laboratory. While not statistically elevated, due to the unusual type of malformation seen and the relative lack of maternal toxicity at this level, this was considered to represent a teratogenic response. No maternal toxicity, embryotoxicity, fetotoxicity or teratogenic effects were observed at or below 1000 mg/kg/d.

Test substance : Purity of 99%.
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
25.09.2002

(9)

5.10 OTHER RELEVANT INFORMATION

5.11 EXPERIENCE WITH HUMAN EXPOSURE

6. References

Id 117-08-8
Date 02.11.2002

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7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT