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I U C L I D

Data Set

Existing Chemical : ID: 68411-81-4
CAS No. : 68411-81-4

Producer Related Part
Company : PCA Services, Inc.
Creation date : 28.10.2001

Substance Related Part
Company : PCA Services, Inc.
Creation date : 28.10.2001

Memo :

Printing date : 21.12.2001
Revision date :
Date of last Update : 21.12.2001

Number of Pages : 37

Chapter (profile) : Chapter: 1, 2, 3, 4, 5,

1. General Information

Id 68411-81-4
Date 29.10.2001

1.0.1 OECD AND COMPANY INFORMATION

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

1.2 SYNONYMS

2-Imidazolidinon, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methyliert
28.10.2001

2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidinone, methylated
28.10.2001

4,5-Dihydroxy-1,3-bis(hydroxymethyl)-2-imidazolidone, methylee
28.10.2001

Dihydroxydimethylolethyleneurea, methylated
28.10.2001

Dimethylolglyoxalmonoureine, methylated
28.10.2001

Dimethylolglyoxalurea, methylated
28.10.2001

Imidazolidinone-2, dihydroxy-4,5-bis(hydroxymethyl)-1,3, methylee
28.10.2001

1.3 IMPURITIES

1.4 ADDITIVES

1. General Information

Id 68411-81-4
Date 29.10.2001

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

Type : industrial
Category : Textile processing industry
Reliability : (1) valid without restriction
28.10.2001

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1. General Information

Id 68411-81-4

Date 29.10.2001

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2. Physico-Chemical Data

Id 68411-81-4
Date 29.10.2001

2.1 MELTING POINT

Value	:	= -39 °C
Decomposition	:	no at °C
Sublimation	:	no
Method	:	OECD Guide-line 102 "Melting Point/Melting Range"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	At room temperature the test material was clear, colored yellow, viscous and the magnetic agitator was stirring. The test material was cooled down and at about -14 degrees C the agitator stopped stirring. The cooling was continued and at about -25 degrees C the viscosity increased. The freezing point was observed between -18.5 and -19.5 degrees C. A determination of the freezing temperature with a thermocouple showed no relevant heat effect.
Test substance	:	The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (present at about 84% concentration). The purity of test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) of formaldehyde may have been present.
Reliability 28.10.2001	:	(1) valid without restriction.

(32)

2.2 BOILING POINT

Value	:	= 118.5 °C at 980 hPa
Decomposition	:	no
Method	:	OECD Guide-line 103 "Boiling Point/Boiling Range"
Year	:	2001
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Both a thermal analysis (using a differential scanning calorimeter) and visual tests (using a capillary tester) were employed for this determination.
Test condition	:	A phase transformation, e.g., evaporation, is usually associated with a heat effect. In a preliminary study, two identical aluminum sample containers, one filled with the test material and the other empty (used as a reference), were heated in the calorimeter at a constant rate. During a preliminary experiment, the heat effect (i.e., the difference in the heat flow between the sample container and the reference container) was registered. In the main study, a small amount of the test item was filled into two small glass tubes and boiling capillaries were inserted. The samples were heated simultaneously from 25 degrees C to about 190 degrees C. The heating rate was reduced to 10 degrees Kelvin/min. The samples were observed visually through a lens. A current stream of bubbles from the capillary indicated the boiling point. The study was performed at local atmospheric pressure (980 hPa).
Result	:	The Differential Scanning Calorimeter (DSC) curve of the preliminary test (heating rate of 20 degrees Kelvin/min from 25-400 degrees C) was recorded. An endothermic heat effect was observed starting at about 70 degrees C. As the endothermic peak was not well defined, the main study

2. Physico-Chemical Data

Id 68411-81-4
Date 29.10.2001

was performed using the capillary tester. After the preliminary test, the sample had lost about 70% of its mass and the residue sample was foamed and black in color. The temperature range of the endotherm was about 70-220 degrees C.

In the main test (using the capillaries and visual examination) the primary boiling range was determined to be 118.5 +/-0.2 degrees C. The sample became darker while boiling but remained clear, indicating only minor decomposition.

Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Reliability : (1) valid without restriction .

28.10.2001

(33)

2.3 DENSITY

Value : 1.30-1.31g/ml

Method : unknown

Year :

GLP : no data

Test substance : Freerez® MTH Conc.

Reliability : (2) valid with restrictions. Manufacturer's MSDS. Method not given.

28.10.2001

(25)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

Log Pow : = -3.2 at 20° C

Method : other (calculated)

Year : 2001

GLP : yes

Test substance : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.

Remark : Neither the HPLC-method according to OECD Guideline No. 117 nor the flask-shaking method according to OECD Guideline No. 107 were applicable for the determination of the partition coefficient of Freerez® MTH Conc. Thus the log Pow-value for the test item was estimated from its solubility in n-octanol and water, respectively.

Test condition : The n-octanol solubility of the test material was determined to be < 3.25 g/l by adding 0.13-0.14 grams of test material to 40 ml n-octanol at room temperature and stirring. The result was incomplete dissolving and two phases. The water solubility of the test item was estimated to be > 5000 g/l

2. Physico-Chemical Data

Id 68411-81-4
Date 29.10.2001

in another study (see Section 2.6.1 below). The Log Pow was then calculated using the following equation:

log Pow = $\log (<3.25 \text{ g/l} / >5000 \text{ g/l}) = < -3.2$
Reliability : (1) valid without restriction.
28.10.2001 (34)

2.6.1 WATER SOLUBILITY

Value : > 5000 g/l at 20 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : OECD Guide-line 105 "Water Solubility"
Year : 2001
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Method : The water solubility of test material at room temperature was estimated by a simplified flask method.
Result : The saturated concentration was not reached, but this test indicates that the test substance is miscible in any ratio with water.
Test condition : 1 ml of water was stepwise mixed with a total amount of 5 g of Freerez® MTH Conc. This mixture was stirred at room temperature for about 24 hours. The visual observation indicated one clear, light yellow phase. The test was performed in duplicate.
Test substance : The test material (Freerez® MTH Conc.) was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.
Reliability : (1) valid without restriction
28.10.2001 (35)

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. Physico-Chemical Data

Id 68411-81-4
Date 29.10.2001

2.12 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 1854-26-8
Date 22.10.2001

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	Sun light
Light spect.	:	nm
Rel. intensity	:	based on Intensity of Sunlight
Direct photolysis		
Half-life t1/2	:	ca. 1.8 - 1.4 hour(s)
Degradation	:	% after
Quantum yield	:	
Indirect photolysis		
Sensitizer	:	OH
Conc. of sens.	:	
Rate constant	:	cm ³ /(molecule*sec)
Degradation	:	% after
Deg. Product	:	
Method	:	other (calculated)
Year	:	2001
GLP	:	not applicable
Test substance	:	other TS
Result	:	The hydroxyl rate constant was estimated to be from 73.2 - 94.5 E-12 cm ³ /molecule-sec. The first value is the rate constant calculated by EPIWIN for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), and the second value is the rate constant calculated for 2-imidazolidinone-4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Test condition	:	Photodegradation parameters were estimated using the EPIWIN/AOP Program (v1.90). This program uses an algorithm to sum up individual photodegradation rate constants for the different chemical bonds within the test substance molecule and the molecular weight. The photodegradation half-life was calculated assuming that the hydroxyl radical concentration is constant and using pseudo first order kinetics. The test substance itself could be modeled, because it does not have a precisely defined molecular structure. It is denoted to be "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-. Therefore, the following analogous substances were modeled: 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). These two analogs bound the test material, because it is partially to completely methylated in the 1,3 positions. Thus, the hydrolysis rate constant and the atmospheric half-life of the test material lies somewhere in between values for these parameters possessed by the non-methylated and bis methylated analogs. The values assigned to the test between the values calculated for the analogs.
Test substance	:	2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) and 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4).
Reliability	:	(2) valid with restrictions. Data were obtained by modeling with related chemicals

28.10.2001

3. Environmental Fate and Pathways

Id 1854-26-8

Date 22.10.2001

3.1.2 STABILITY IN WATER

Remark : Water stability for the test material cannot be calculated with EPIWIN. EPIWIN states merely that hydrolysis will occur slowly for the urea function in the molecule, but does not comment on the other functions in the molecule.

The test material is present in a proprietary mixture (Freerez® MTH Conc.) as an aqueous concentrate. Therefore it must be reasonably stable in water. There are no functional groups present in the molecule that would be expected to hydrolyze easily.

Reliability : (4) not assignable

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media : water - air
Air (level I) : 0
Water (level I) : 45.3
Soil (level I) : 54.6
Biota (level II / III) : .0755
Soil (level II / III) :
Method : other
Year : 2001
GLP : not applicable
Test substance : other TS
Remark : Mackay Level III Fugacity modeling was also conducted on the unmethylated CAS No.1854-26-8, with the following equilibrium concentrations in the environmental compartments:

Air: 0.00133%
Water: 42.8%
Soil: 57.1%
Sediment: 0.0638

Result : These values are very close to those of the dimethylated material. The Henry's Law Constants calculated by EPIWIN Henry (v3.10) for the dimethylated and non-methylated analogs of the test substance are as follows:

2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) = 1.06E-12.

2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4) = 1.09E-13.

Based on the test substance's partial to complete methylation on the 1 and

3. Environmental Fate and Pathways

Id 1854-26-8

Date 22.10.2001

- 3 positions, its Henry's Law Constant is likely to lie between the above two values.
- Test condition** : The EPIWIN Program was used to conduct MacKay Level III Fugacity modeling for the test substance. The test substance itself was not modeled, because it does not possess a precise molecular structure. The test substance is "methylated" 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- CAS No. 68411-81-4, which indicates that it is partially to completely methylated in the 1 and 3 positions. The extent of methylation is undefined for the test substance. For this reason Level III fugacity modeling was conducted for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CAS No. 3001-61-4). This material is completely methylated on both the 1 and 3 positions.
- Conclusion** : Given the values obtained by modeling both the unmethylated and completely methylated materials, one might conclude with reasonable confidence that the test substance partitions preferentially to water and soil. That conclusion is further supported by the test substances miscibility with water and its moderate volatility.
- Test substance** : The test material was an aqueous concentrate of 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CAS No. 68411-81-4), present at about 84% concentration. The purity of the test material or the presence of minor additives was not given. Trace levels (e.g., 0.18%) formaldehyde may have been present.
- Reliability** : (2) valid with restrictions. Data were obtained by modeling with a related chemical.

28.10.2001

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

- Type** : aerobic
- Inoculum** : activated sludge, industrial
- Concentration** : 400 mg/l related to DOC (Dissolved Organic Carbon)
related to
- Contact time** :
- Degradation** : = 38% after 28 day
- Result** :
- Kinetic of test substance** : 3 hour(s) = 5 %
1 day = 11 %
6 day = 31 %
13 day = 38 %
%
- Deg. Product** :
- Method** : Other: Standversuch
- Year** : 1980
- GLP** : no

3. Environmental Fate and Pathways

Id 1854-26-8

Date 22.10.2001

Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : No oxygen consumption; elimination probably not due to biodegradation.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(7)

Type : aerobic
Inoculum : activated sludge
Concentration : 50 mg/l related to Test substance
Contact time :
Degradation : > 70% after 2 month
Result : other: biodegradable
Deg. Product :
Method : other: OECD-Confirmatory-Test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), about 45 per cent solution in water.
Remark : Remark in IUCLID file states that the test report contained very few data
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(2)

Type : aerobic
Inoculum : activated sludge, non-adapted
Concentration : 10 mg/l related to DOC (Dissolved Organic Carbon)
Degradation : = 60-70% after 28 days
Result : inherently biodegradable
Kinetic : 28 day = 60-70 %
49 day = 70-80 %
Method : OECD Guide-line 301A (new version) "Ready Biodegradability: DOC Die Away Test"
Year : 1993
GLP : yes
Test substance : Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3 bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition : Medium: water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(10)

Type : aerobic
Inoculum : activated sludge, non-adapted
Concentration : 20 mg/l related to DOC (Dissolved Organic Carbon)
Degradation : Ca. 27% after 8 day
Result : inherently biodegradable
Kinetic : 5 day = 14%
8 day = 20%
58 day = 28%

3. Environmental Fate and Pathways

Id 1854-26-8

Date 22.10.2001

Method : OECD Guide-line 303A "Simulation Test- Aerobic Sewage Treatment: Coupled Unit Test"
Year : 1993
GLP : yes
Test substance : Fixapret CP conc. ((2-Imidazolidinone, 4,5-dihydroxy-1,3 bis(hydroxymethyl)- (CAS No. 1854-26-8), 26.1% solution in water). Purity 73.9%.
Test condition : Medium: water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. Reliability code was changed from 1 to 2 due to reasons stated.

(11)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Elimination :
Method : other
Year :
GLP :
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Due to the water solubility and the measured log Pow of the compound the potential for bioaccumulation is low.
Reliability : (4) not assignable. No experimental data is available. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

3.8 ADDITIONAL REMARKS

4. Ecotoxicity

Id 1854-26-8
Date 22.10.2001

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
NOEC : 1000
LC50 : ca. 2200
LC100 : 4640
Method : other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN 38 412 Teil 15
Year : 1982
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark : Symptoms: Apathy, tumbling
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(3)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type :
Species : other aquatic arthropod: Daphnia magna Straus
Exposure period : 48 hour(s)
Unit : mg/l
Analytical monitoring :
EC0 : = 500
EC50 : > 500
EC100 : > 500
Method : Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year : 1988
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active ingredient: 40%.
Remark : Same results when exposure period = 24 h.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : Scenedesmus subspicatus (Algae)
Endpoint : other: comparison of cell density at the end of test
Exposure period : 72 hour(s)
Unit : mg/l
Analytical monitoring : no
EC50 : = 36.9
EC20 : = 22.9

4. Ecotoxicity

Id 1854-26-8
Date 22.10.2001

Method : other: "Algentest in Anlehnung UBA"
Year : 1988
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.
Remark : EC90(72h)=158.7 mg/l.
Test condition : illumination: intensity =120 Mikroeinsteint/mxmxs; permanent
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

Species : Scenedesmus subspicatus (Algae)
Endpoint : other: comparison of cell density at the end of test
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
EC50 : = 28.4
EC20 : = 19.2
Method : other: "Algentest in Anlehnung UBA"
Year : 1988
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%.
Remark : EC90(96h)=68.9 mg/l.
Test condition : illumination: intensity =120 Mikroeinsteint/mxmxs; permanent
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : aquatic
Species : activated sludge, industrial
Exposure period : 30 minute(s)
Unit : mg/l
Analytical monitoring : no data
EC50 : = 280
EC20 : = 180
EC80 : = 450
Method : other: Short term respiration test
Year : 1980
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: stimulation of respiration; highest tested concentration with <20% respiration inhibition =1995 mg/l.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(5)

Type : aquatic
Species : Pseudomonas putida (Bacteria)
Exposure period : 17 hour(s)

4. Ecotoxicity

Id 1854-26-8
Date 22.10.2001

Unit : mg/l
Analytical monitoring :
EC10 : = 1260
EC50 : = 2200
EC90 : = 4490
Method : other: growth inhibition test according to Bringmann-Kuehn, DIN 38412/8 (draft)
Year : 1988
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 40%
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(6)

Type : aquatic
Species : other bacteria: activated sludge, municipal
Exposure period : 30 minute(s)
Unit : mg/l
Analytical monitoring : no
EC10 : > = 1000
EC50 : > = 1000
EC90 : > = 1000
Method : OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year : 1993
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 74%.
Remark : No toxic effects were observed for highest concentration tested (1000 mg/l substance)
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(8)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 21 day
Unit : mg/l
Analytical monitoring : no data
NOEC : >= 100
LOEC : >= 100
Method : other: EG- Richtlinie XI/681/86
Year : 1986
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Active substance: 70%.

4. Ecotoxicity

Id 1854-26-8
Date 22.10.2001

Remark : 21 day semistatic test according to EEC guideline XI/681/86, Draft 4; test substance was tested in the range 0.2 to 100 mg/l, the dilution factor was 2. As test criteria, the reproduction and mortality of the test animals are given.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(9)

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

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5. Toxicity

Id 68411-81-4
Date 29.10.2001

5.1.1 ACUTE ORAL TOXICITY

Type : LD50
Species : rat
Strain : unknown
Sex : unknown
Number of animals : unknown
Vehicle : water
Value : > 2880 mg/kg bw
Method : other: BASF test
Year : 1973
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Remark : LD50 value refers to 100% substance. No toxic symptoms.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Type : LD50
Species : rat
Strain : unknown
Sex : unknown
Number of animals : unknown
Vehicle : water
Value : > 10000 mg/kg bw
Method : other: no further details given
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.5% in water, with 0.3% formaldehyde present
Remark : Pre-test for subchronic study. LD50 value refers to 100% substance
Result : Post-mortem examination revealed no macroscopic changes
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(20)

Type : LD50
Species : mouse
Strain : unknown
Sex : unknown
Number of animals : unknown
Vehicle : water
Value : > 10000 mg/kg bw
Method : other: no further details given
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.5% in water, with 0.3% formaldehyde present
Remark : Pre-test for subchronic study. LD50 value refers to 100% substance
Result : Post-mortem examination revealed no macroscopic changes

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. (19)

5.1.2 ACUTE INHALATION TOXICITY

Type : other: IRT
Species : rat
Strain : unknown
Sex : unknown
Number of animals : unknown
Vehicle : unknown
Exposure time : 8 hour(s)
Method : other: BASF test
Year : 1973
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water (Fixapret CPN)
Result : No mortality after 8 hours of exposure to an atmosphere enriched or saturated at 20 degrees C. Mild signs of irritation of mucous membranes and dyspnea were observed.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. (4)

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type : LD50
Species : mouse
Strain :
Sex :
Number of animals :
Vehicle :
Route of admin. : i.p.
Exposure time :
Value : > 2880 mg/kg bw
Method : other: BASF test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), probably 45% solution in water (Fixapret CPN)
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. (4)

5. Toxicity

Id 68411-81-4
Date 29.10.2001

5.2.1 SKIN IRRITATION

Species : rabbit
Concentration :
Exposure :
Exposure time :
Number of animals :
PDII :
Result : not irritating
EC classification : not irritating
Method : other: BASF-Test
Year : 1974
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(4)

Species : rabbit
Concentration :
Exposure :
Exposure time :
Number of animals :
PDII :
Result :
EC classification :
Method : other: according to "Marhold"
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: "severe"
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(24)

5.2.2 EYE IRRITATION

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result : not irritating
EC classification : not irritating
Method : other: BASF-Test
Year :
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 45% solution in water

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. (4)

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result :
EC classification :
Method : other: according to "Marhold"
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Effect: "mild"
Reliability : (4) not assignable. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000. (24)

5.3 SENSITIZATION

Type : Patch-Test
Species : human
Concentration : Challenge 50%
Number of animals :
Vehicle : water
Result :
Classification :
Method : other: clinical test series
Year : 1958
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (50% in aqueous solution)
Remark : Study is also described in Section 5.11
Result : Twenty seven out of 66 responded positively to various textile finishes and additives within 48 hr. Eight out of 24 tested with test substance gave a positive response. Six out of 8 also showed a positive reaction to formaldehyde (5% in aqueous solution).
Test condition : Thirty seven substances used in textile finishes (including the test substance) were patch-tested in 66 subjects who anamnestically and/or clinically were suspected of suffering from textile finish contact eczema.
Reliability : (2) valid with restrictions. Test material was a related chemical. (23)
25.10.2001

Type : Patch-Test
Species : human
Concentration : Challenge 10 %
Vehicle : Petrolatum
Method : other: clinical test series
Year : 1980

5. Toxicity

Id 68411-81-4
Date 29.10.2001

GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (10 % in petrolatum) . The test materials contained some free formaldehyde (amount not specified).
Remark : The test material was not checked for autopolymerization or content of allergenic substances. The Calaroc resins are no longer available.
Result : Study is also described in Section 5.11
: The Calaroc PG and PK induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde.
Test condition : Four hundred twenty eight eczema patients were patch tested with textile finish resins from 1970 to 1980 (including test material). Fifteen out of the 428 had allergic textile dermatitis based on history, clinical features and patch test results. Three different resins containing test material in 10% petrolatum were patch tested [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] on ten of these subjects. Formaldehyde (2% in aqueous solution) was tested on all 15.
Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (1)(12)(17)

Type : Patch-Test
Species : human
Concentration : Challenge
Number of animals :
Vehicle : no data
Result :
Classification :
Method : other: clinical test series
Year : 1985
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark : Study is also described in Section 5.11
Result : One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde.
Reliability : (2) valid with restrictions. Test material was a related chemical. Percent test material used is unknown. Original reference (16) was not consulted.
25.10.2001 (17)(16)

Type : Patch-Test
Species : human
Concentration : Challenge
Number of animals :
Vehicle : no data
Result :
Classification :
Method : other: clinical test series
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : Study is also described in Section 5.11
Result : One out of 6 subjects reacted to the test substance; none responded to

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Test condition : formaldehyde.
: Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

25.10.2001

(31)

Type : Patch-Test
Species : human
Concentration : Challenge 4.5%
Number of animals :
Vehicle : water
Result :
Classification :
Method : other: clinical test series
Year :
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8) (4.5% in aqueous solution); Fixapret CPN

Remark : In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals.

Result : Study is also described in Section 5.11
: All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.

Test condition : Ten out of 12 subjects with known positive patch test reactions to older formaldehyde resins were patch-tested with commercial allergens, formaldehyde (1% in aqueous solution), older formaldehyde resins (including Fixapret CPN) and 6 newer, low-formaldehyde (< 200 ppm) resins (Fixapret ECO and NF (no formaldehyde), Freerez PKF, Freerez CLD, Permafresh EFR and CPD 3078-28A).

Conclusion : New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins

Reliability : (2) valid with restrictions. Test material was a related chemical.

25.10.2001

(29)

5.4 REPEATED DOSE TOXICITY

Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 90 days
Frequency of treatment : 5 days/week
Post obs. period : no

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Doses : 1000; 3000; 6000 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 1000 mg/kg/day
Method : OECD Guide-line 408 "Subchronic Oral Toxicity – Rodent: 90-day Study"
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result : 10 male and 10 female rats were treated in each group. Three males of the 6000 mg/kg/day dosage level were found dead on study day three. The males of the 6000 and 3000 mg/kg/day dosage level groups exhibited a lower mean body weight gain. The mean body weights of the males of the 1000 mg/kg/day dosage level and of the treated female rats were comparable to controls throughout the study. Pharmacotoxic signs noted for male and female animals in the 3000 and 6000 mg/kg/day dosage level groups included primarily yellow discoloration of fur - anogenital region. In addition, male animals in the 6000 mg/kg/day dosage level group exhibited yellow discoloration of fur - abdominal region and soft stool. One male animal in the 6000 mg/kg/day dosage level group was noted for hypoactivity, decreased grasping reflex, extremities hypothermic to touch, and ataxia on study day 3. Other signs noted among rats of various dosage level groups, or controls, were considered incidental and unrelated to the test article. Macroscopically, one male from the 6000 mg/kg/day dosage level group was found at the post-mortem examination to have multiple yellowish linear macroscopic lesions in the right testis. No toxicologically significant organ weight changes occurred in this study. Microscopically, treatment related mild mineralization in the heart was seen in two males of the 6000 mg/kg/day dosage level group, in one of them a moderate bilateral mineralization of testes was also seen. Mineralization in the testes and heart were considered to be test article related lesions. No other macroscopic or microscopic findings were considered to be related to the test article.
Reliability : (2) valid with restrictions. Test material was a related chemical.
28.12.01 (20)

Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 14 days (12 doses)
Frequency of treatment : daily (without weekend) with 3 consecutive administrations before the end of the study
Post obs. period : no
Doses : 256; 640; 1600; 4000; 11680 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 4000 mg/kg/day
Method : other: no further details given (pre-test for subchronic study)
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result : At 11680 mg/kg/day: There were no toxicologically significant macroscopic lesions or abnormalities with respect to organ weight. Microscopically, there were no special effects on tissues (with the exception of the nasal passages showing inflammatory reactions). Whereas 2 female control animals showed these inflammations on one side, all substance - treated

5. Toxicity

Id 68411-81-4
Date 29.10.2001

animals had bilateral inflammations of the nasal passages.

Lower doses: There were no microscopic changes of the nasal cavities or any other abnormal findings.

Reliability : (2) valid with restrictions. Test material was a related chemical. (20)
28.12.01

Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 90 days
Frequency of treatment : daily (without weekend)
Post obs. period : no
Doses : 1000; 3000; 6000 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 6000 mg/kg/day
Method : OECD Guide-line 408 "Subchronic Oral Toxicity – Rodent; 90-day Study"
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 41.4% in water, with 0.8% formaldehyde present (remainder water).
Result : Mortality: 1 male animal died during the third week of treatment in the 3000 mg/kg/day group.

Body weight gain: All dosed females showed an increased weight compared to the controls; the males of the 1000 and 6000 mg/kg/day group had the same or increased weight compared to the controls. The 6000 mg/kg/day group and controls showed no microscopically visible changes (the animals of the 1000 and 3000 mg/kg/day doses were not examined).

Chronic interstitial pneumonia in the control and animals of the 6000 mg/kg/day group was seen in correlation with the positive finding of the Sendai-virus.

Test condition : Ten/sex/dose were treated with test material (3 doses) or water (control).
Reliability : (2) valid with restrictions. Test material was a related chemical. (19)
28.12.01

Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 14 days (12 doses)
Frequency of treatment : daily (without weekend) with 4 consecutive administrations before the end of the study
Post obs. period : no
Doses : 256; 640; 1600; 4000; 11680 mg/kg/day
Control group : yes, concurrent vehicle
NOAEL : 11680 mg/kg/day
Method : other: no further details given
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). 41.4% active ingredient, with 0.8 % formaldehyde present (remainder water).
Result : No deaths or substance-induced changes (clinical picture, body and organ

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Test condition : weights, micro- or macroscopic examinations) occurred.
: 5/sex/dose group were treated with each dose of test material or water (control)
Reliability : (2) valid with restrictions. Test material was a related chemical.

(19)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : Salmonella typhimurium TA102
Concentration : 1 - 5000 micrograms/plate (Plate incorporation test and Preincubation test);
: 2 - 10000 micrograms/plate (Preincubation test)
Cytotoxic conc. :
Metabolic activation : with and without
Result : negative
Method : OECD Guide-line 471 "Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay"
Year : 1983
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
Remark : The assay was performed in three independent experiments. Experiment I was performed as plate incorporation test and experiments II and III were performed as preincubation tests.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01

(14)

Type : Ames test
System of testing : Salmonella typhimurium strains TA98, TA100, TA1535, TA1537
Concentration : 33-10000 micrograms/plate (solvent DMSO); 333- 10000 micrograms/plate (solvent H₂O)
Cytotoxic conc. : 10000 mg/plate in most strains (produced slight to complete clearing of bacterial lawn depending on strain and test).
Metabolic activation : with and without
Result : equivocal
Method : other
Year : 1987
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). The analyzed purity was 41.4%. Since the test material is commercially available in water, it is likely that the majority of the impurity is water.
Remark : Because the tests with the two solvents were performed in different laboratories, it is difficult to discern whether the variable results were due to the tests being conducted in different laboratories or the use of different solvents.

It is also not known whether the test concentrations listed were corrected for test material purity.

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Result : The test was valid, as positive controls were judged to be mutagenic. A questionable result was found in 2/4 tests (DMSO solvent) in strain TA100 incubated with S9-mix from hamster. In one test, the number of mutations at 10000 mg/plate was higher than control (182 +/- 4.6 vs. 123 +/- 3.1 in control) and in another the number of mutations at 6667 and 10000 mg/plate was higher than control (196 +/- 11.3 and 222 +/- 7.4, respectively vs. 150 +/- 10.0 in control). A questionable result also was found in 1/3 tests at 3333 and 10000 micrograms/plate (DMSO solvent) in strain TA100 incubated with S9-mix from rat (200 +/- 5.9 and 199 +/- 4.9 vs. 147 +/- 11.2 in control). A weakly positive result was found in 1/3 tests (DMSO solvent) in strain TA98 incubated with S9-mix from hamster. In this test, concentrations equal to or greater than 333 mg/plate appeared to increase the rate of mutations (ranged from 54 +/- 2.6 at 1000 mg/plate to 66 +/- 7.2 at 3333 mg/plate vs. 37 +/- 6.4 in control). All other tests with test material dissolved in DMSO solvent were negative.

A positive result was obtained with test material dissolved in water in strain TA100 incubated with S-9 from hamster or rat. The test in TA100 in the absence of S-9 had a questionable result (approximately a 30% increase in mutations at 3333 and 6667 mg/plate vs. control). In both the positive tests, dose-dependent increases in the number of mutations were observed, with an approximate 3-fold increase over control at the two highest concentrations in the presence of S-9 (6667 and 10000 mg/plate). A slight reduction of the bacterial lawn was noted at 10000 mg/plate in strain TA100. A weakly positive result was found in strain TA98 incubated with test material dissolved in water in the absence of S-9, or in the presence of hamster S-9 (approximately a 2-fold increase over control at the two highest concentrations that did not produce toxicity). The test with rat S-9 in this strain had a questionable result (a slight, dose-dependent increase).

Test condition : The test material was initially tested for toxicity to strain TA100 at the desired test concentrations. Nontoxic concentrations of test chemical (dissolved in DMSO or water), bacteria, and S-9 mix (10%) from liver of Aroclor1254-induced male rats or hamsters (or buffer) were incubated at 37 degrees C, without shaking, for 20 min. The top agar was added, and the contents of the tubes were mixed and poured onto the surface of petri dishes that contained Vogel-Bonner medium. At least 5 doses of test material were tested in triplicate. The histidine-revertant colonies were counted following 2 days of incubation. The maximum dose tested was 10 mg/plate. Concurrent solvent and positive controls (sodium azide for TA1535 and TA100, 9-aminoacridine for TA97 and TA1537, and 4-nitro-o-phenylenediamine for TA98) were run with each trial. The tests utilizing DMSO and water as the solvents were performed in different laboratories.

A chemical was judged to be mutagenic if a dose-related increase over the corresponding solvent control was seen, and was judged weakly mutagenic if a low-level dose response was seen. A trial was considered questionable if a dose-related increase was judged insufficiently high to justify a conclusion of weak mutagenicity, if only a single dose was elevated over control, or if a non dose-related increase was seen.

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Conclusion : Test material was not mutagenic in strains TA1535 or TA1537. In the presence of S-9, approximately 50% of tests in strain TA100 were questionable in one laboratory (with test material in DMSO) and all tests were positive in the other laboratory (with test material in water). Weakly positive or questionable results were found in strain TA98 in the presence or absence of S-9 in the same laboratory that found positive results in strain TA100 (material was in water). One out of five tests in the other laboratory with strain TA98 in the presence of S-9 (and test material in DMSO) showed a weak response.

Reliability : (2) valid with restrictions. The test was only performed in 4 strains.

28.12.01

(26)(36)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : Micronucleus assay
Species : mouse
Sex : male/female
Strain : NMRI
Route of admin. : gavage
Exposure period : once
Doses : 500, 1000, and 2000 (limit dose) as 75% solution in water
Result : negative
Method : OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year : 1994
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Contained 1% formaldehyde.
Test condition : Positive controls received 20 or 80 g/kg cyclophosphamide. Routine sampling of bone marrow was at 24 hrs for all doses and additionally at 48 hrs for the high dose.
Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01

(13)

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : oral feed
Exposure period : 72 hours
Doses : 60000 ppm
Result : positive
Method : other
Year : 1984
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.
Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : It is unknown if the weight of the test material was corrected for purity. The criteria for significance are unconventional. The incidence of mutations in one control brood was high (3/1969 = 0.15%).
Result : None of the treated animals died. The frequency of sex-linked recessive

5. Toxicity

Id 68411-81-4
Date 29.10.2001

mutations in broods 1, 2, and 3 from males treated with test material was 4/2175, 6/2269, and 2/2117. One brood of controls had 3 mutations in 1969 chromosomes. Chromosomes from the 2 other control broods did not have any mutations. The total frequency of mutations in the treated group was 0.18% (vs. 0.06 in control). The substance was determined to be mutagenic in this test. The p value was not stated.

Test condition : Males were fed test material in water (or water vehicle) for 3 days. The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells over 7 days. A total of at least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value of < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%, and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.

Reliability : (4) unassignable. Test conduct does not appear to be robust.
28.12.01

(15)

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : other: injection
Exposure period : 24 hours
Doses : 60000 ppm
Result : positive
Method : other
Year : 1984
GLP : no
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%. Since the test material is commercially available in water, it is presumed that the majority of the impurity is water.

Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : It is unknown if the weight of the test material was corrected for purity. The criteria for significance are unconventional. Fewer than 5000 control chromosomes were scored. One brood accounted for the majority of the mutations. Incidences in the 2 other treated broods were similar to controls. Standard deviations were not given.

Result : Test material caused 3% mortality. The frequency of sex-linked recessive mutations in broods 1, 2, and 3 from males treated with test material was 6/2160, 0/2043, and 2/1653. One brood of controls had 2 mutations in 1493 chromosomes. Chromosomes from the 2 other control broods did not have any mutations. The total frequency of mutations in the treated group was 0.14% (vs. 0.05% in control). The substance was determined to be mutagenic in this test (although p values were not given).

Test conditions : Males were injected with test material (or water vehicle). The concentration used was measured by volume and converted to ppm by weight. Treated males were mated to Basc females for a total of 3 broods of post-meiotic and meiotic male germ cells and over 7 days. A total of at least 5000 chromosomes were scored in each of the treated and control broods. Clusters were identified using the Poisson distribution and were removed before analysis. The result was considered positive if the mutant frequency exceeded 0.15% (with a p value of < 0.05) or 0.1% (with a p value of < 0.01). If the treated frequency was between 0.1 and 0.15%,

5. Toxicity

Id 68411-81-4
Date 29.10.2001

and the p value was between 0.1 and 0.01; or if the treated frequency was higher than 0.15%, and the p value was between 0.1 and 0.05, the test was considered equivocal.

Reliability : (4) unassignable. Test conduct does not appear to be robust
28.12.01 (15)

Type : other: Drosophila reciprocal translocation assay
Species : Drosophila melanogaster
Sex : male
Strain : other: Canton-S
Route of admin. : oral feed
Exposure period : 72 hours
Doses : 50000 ppm
Result : negative
Method : other: part of NTP genotoxicity program
Year : 1984
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8). Analyzed purity was 41.4%.

Method : Woodruff, R.C., Mason, J.M. et al., Environ Mutagen 6, 189-202 (1984)
Remark : The test was performed on the most sensitive brood of male germ cells identified in the injection SLRL test above. The result was considered positive if the reciprocal translocation rate was greater than a historical rage from 116,592 tests (0.0017%). At least 2 translocations out of 5000 tests were required to establish significance at the P <0.05 level.

Result : There were no reciprocal translocations in a total of 5611 chromosomes
Reliability : (2) valid with restrictions. Whether the results have been corrected for test material purity is unknown.
28.12.01 (15)

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

Type : other: examination of reproductive organs from 90-d repeated dose study
Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : gavage
Exposure period : 90 d
Frequency of treatment : 5 times/week
Duration of test : 90 days
Doses : up to 6000 mg/kg/day
Control group : yes, concurrent vehicle
Method : other: according to OECD guideline 408
Year : 1983
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water).

Remark : additional information found in Section 5.4
Result : Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males treated with up to 3000 mg/kg/day

5. Toxicity

Id 68411-81-4
Date 29.10.2001

Reliability : and females treated with up to 6000 mg/kg/day.
: (2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (20)

Type : other: examination of reproductive organs from 90-d repeated dose study
Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : gavage
Exposure period : 90 d
Frequency of treatment : 5 times/week
Duration of test : 90 days
Doses : 6000 mg/kg/day
Control group : yes, concurrent vehicle
Method : other: according to OECD guideline 408
Year : 1984
GLP : no data
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 41.4 % in water, with 0.8% formaldehyde present (remainder water)
Remark : additional information found in Section 5.4
Result : Microscopic examination of sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries, clitoral gland) gave no indication of morphological abnormalities in males and females treated with up to 6000 mg/kg/day (referring to 100% substance).
Reliability : (2) valid with restrictions. Effect on mating was not characterized. Test material was a related chemical.

28.12.01 (19)

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : female
Strain : Wistar
Route of admin. : gavage
Exposure period : Day 7-16 of pregnancy
Frequency of treatment : daily
Duration of test : 21 days
Doses : 250; 500; 1000 mg/kg/day (64.1% test substance in water equivalent to 160, 320 and 640 mg/kg/day as 100% substance)
Control group : yes
NOAEL Maternal : 640 mg/kg bw
NOAEL Teratogen : 640 mg/kg bw
Method : OECD Guide-line 414 "Teratogenicity"
Year : 1998
GLP : yes
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8), 64% in water
Remark : 23 mated females/group
Result : There were no deaths during the study. No clinical signs were observed in any of the animals. Body weights and food consumption were not affected by the administration of the test compound. No compound-related effects were observed at necropsy of the animals. Gravid uterus weights, crown-rump lengths, litter size, sex ratios, fetal and transplacental weights remained unaffected by the administration of the test compound. There

5. Toxicity

Id 68411-81-4
Date 29.10.2001

was no increase in the number of early or late conceptuses undergoing resorption. Morphological examination of the fetuses did not reveal any compound-related effect.

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (except reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (18)

5.10 OTHER RELEVANT INFORMATION

Type : Toxicokinetics
Test substance : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8)
Remark : Patches of fabric soaked with ¹⁴C-labelled test substance were applied to the dorsal skin of White New Zealand rabbits for 48 hours. 0.09 - 2.61% of the total ¹⁴C labeling were retrieved in skin samples taking into consideration occlusion (1 - 1.4% after occlusive, ca. 0.1% after semi-occlusive), type of fabric and the specific perspiration of the skin. Perspiration almost doubled skin incorporation of radioactivity (ca. 2.6%) of the total dose in the cloth patches under occlusive conditions. Only < 0.02% was detectable in expired air as ¹⁴C-CO₂. Only 0.001 to 0.006% of the activity was detected in muscle (back or thigh), fat, gonad, spleen, or brain. Higher levels were found in liver (0.117 - 0.205 % of dose), blood (0.058 - 0.095% at 4 hrs), and kidney (0.043- 0.070% of dose).

Reliability : (2) valid with restrictions. Test material was a related chemical.

28.12.01 (27) (28)

Type : Toxicokinetics
Test substance : Dimethyloldihydroxy-ethylene-urea
Remark : (¹⁴C)-Dimethyloldihydroxy-ethylene-urea (¹⁴C-DMDHEU) was stable to blood and skin (air) and was essentially unmetabolized (identity of HPLC radiograms of the composition of the test substance applied and the profile found after excretion). More than 95% of a 50 mg/kg intravenous dose to male F344 rats was excreted unchanged in the urine in 24 hr (85 % in 6 hr). Minor amounts were found in feces (2.2% in 24 hrs). Less than 0.2% was exhaled as ¹⁴CO₂ in 48 hrs. Tissues containing significant fractions of the dose after 0.5 hr were skin, muscle, blood, liver and kidney. By 72 hours, less than 0.5% of the dose remained in the tissues, mainly in muscle (0.3%).

After administration by gavage, the oral absorption of ¹⁴C-DMDHEU increased with increasing dose over the dose range of 500-2000 mg/kg. An average of 17% of an approximately 500 mg/kg dose, 28% of an approximately 1000 mg/kg dose and 38% of an approximately 2000 mg/kg dose was absorbed. The distribution pattern was similar to that of i.v. injection. More than 90% of the radioactivity that was recovered in the urine was excreted within 24 hr. After 72 hours, residual quantities of radioactivity (< 10 micrograms DMDHEU equivalents/g tissue) were left in most tissues (higher amounts in intestine and cecum).

Dermal absorption of ¹⁴C-DMDHEU from a non-occluded dose site over 144 h exposure period was approximately 5% of the applied dose (for doses of 13 and 3.5 mg/cm²) and 1% of the applied dose (for a dose of 0.3 mg/cm²). Partial occlusion of the dose site resulted in a more than 4-fold increase in dermal absorption, probably due to increased hydration of the skin. Distribution of ¹⁴C in tissues following dermal exposure was

5. Toxicity

Id 68411-81-4

Date 29.10.2001

Reliability : somewhat different than that observed following oral or intravenous dosing, with larger amounts of ¹⁴C being found in adipose and smaller amounts in the muscles.
: (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000, and SIDS initial assessment report for CAS No. 1854-26-8 9 (Reviewed at SIAM 10).

28.12.01 (22)

Type : Toxicokinetics
Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : A further study was conducted in the rhesus monkey, which is according to the investigator "the model more closely resembling human skin". Fabrics (96 cm²) treated with ¹⁴C-DMDHEU (prepared from ¹⁴C-formaldehyde) were applied onto back skin of monkeys for 48 hours (either dry or with artificial perspiration). Even though the level of radioactivity used was low, essentially all of the ¹⁴C-activity remained on the textile fabric (the level transferred to the skin was almost indistinguishable from background). An average of 0.12 microcuries of ¹⁴C activity (equivalent to 0.029 %) could be detected in or on the skin lying underneath the fabric. No radioactivity (at or near background level) were detected in expired CO₂, urine, feces, blood, muscle, adipose, liver, lung, kidneys, spleen, brain and testes.

Conclusion : No appreciable penetration of test material from treated fabric was demonstrated

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

(21)

5.11 EXPERIENCE WITH HUMAN EXPOSURE

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : One case of sensitization to dimethylol-dihydroxy-ethyleneurea was reported. Additional information is found in Section 5.3

Reliability : (2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.

28.12.01 (16)

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)
Remark : Thirty-seven substances which may be used in finishing textiles (including DMDHEU) were patch-tested in 66 patients who, anamnestically and/or clinically, were suspected of suffering from a textile finish contact eczema. In 27 patients, positive patch-test reactions to various textile finishes and additives were observed after 48-hr contact. Eight out of 24 patients tested for DMDHEU gave a positive response to DMDHEU (50 % in aqueous solution). Six out of these 8 patients also showed a positive response to formaldehyde (5 % in aqueous solution).

Reliability : Additional information is found in Section 5.3
: (2) valid with restrictions. Test material was a related chemical.

28.12.01 (23)

5. Toxicity

Id 68411-81-4
Date 29.10.2001

- Test substance** : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
- Remark** : Three different resins containing test material in 10% petrolatum [Calaroc PK (43-47% aqueous solution); Calaroc PG (50% aqueous solution), and Fixapret CPNS] were patch tested on ten of 15 subjects with allergic textile dermatitis. Formaldehyde (2% in aqueous solution) was tested on all 15. The Calaroc PG and PK (not currently available) induced a positive reaction in 3/10 and 1/10 of the subjects with allergic textile dermatitis, respectively. None responded to the Fixapret CPNS. All 15 responded to formaldehyde.
- Reliability** : Additional information is found in Section 5.3
(2) valid with restrictions. Test material was a related chemical. Formaldehyde content of the different resins was not determined.
- 25.10.2001 (1)(12)(17)
-
- Test substance** : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
- Remark** : One patient who showed hypersensitivity to non-ironed sheets and pillow cases gave a positive response to the test substance; the patch test was negative to other textile finishes and formaldehyde.
- Reliability** : Additional information is found in Section 5.3
(2) valid with restrictions. Test material was a related chemical. Original reference (16) was not consulted.
- 25.10.2001 (16)(17)
-
- Test substance** : 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CAS No. 1854-26-8).
- Remark** : One out of 6 subjects reacted to the test substance; none responded to formaldehyde.
- Test condition** : Twenty five subjects with contact dermatitis suspected to have arisen from permanent-pressed colored sheets were subjected to further clinical investigations. Patch test concentrations and further details were not given.
- Reliability** : Additional information is found in Section 5.3
(2) valid with restrictions. Test material was a related chemical. Original reference was not consulted. Information (including reliability code) came from IUCLID data set for CAS No. 1854-26-8, dated 04-FEB-2000.
- 25.10.2001 (31)
-
- Test substance** : Dimethyloldihydroxy-ethylene-urea (DMDHEU; 4.5% in aqueous solution); Fixapret CPN
- Remark** : In the 1960's the use of test material in fabrics yielded fabrics with approximately 500 ppm of free formaldehyde. Fabrics treated with the latest modified resins (as of 1998) predictably contain less than 75 ppm free formaldehyde. These levels are unlikely to cause contact allergy in formaldehyde-allergic individuals.
- Result** : All ten subjects reacted to Fixapret CPN and formaldehyde (only 2 reacted slightly). Three reacted slightly to the newer low-formaldehyde resins. One out of the three reacted slightly to the product that did not contain formaldehyde (and no other resins), another reacted to all of the low-formaldehyde resins, and the other reacted to most of the resins tested and formaldehyde.
- Test condition** : Ten out of 12 subjects with positive patch-test reactions to older

5. Toxicity

Id 68411-81-4
Date 29.10.2001

formaldehyde resins were patch-tested with standard commercial allergens, formaldehyde (1% in aqueous solution), test substance (4.5% in aqueous solution), and 6 resins with low formaldehyde content (< 200 ppm).

Conclusion : Additional information is found in Section 5.3
: New resins containing < 200 ppm of formaldehyde are less likely to cause dermatitis than older resins

Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (29)

Test substance : Dimethyloldihydroxy-ethylene-urea (DMDHEU)

Remark : Case report of a 10-year-old boy with eczema on both shins wearing protective shin pads. He was patch tested with a standard series and a textile series. He showed positive reactions to DMDHEU (+/+, 4.5% in aqueous), formaldehyde (+/+/+), the formaldehyde releasing preservatives quaternium 15 +/+/+ and imidazolidinyl urea (+/+/+), carba mix (+), dimethylol propylene urea (+/+), tetramethylol acetylenediurea (+/+), ethylene urea melaminie-formaldehyde resin (+/+/+, 5%), urea-formaldehyde resin 10% pet (+/+/+) and the epoxy hardener hexamethylenetetramine . He did not react to the sample of his shin pads.

Reliability : (2) valid with restrictions. Test material was a related chemical.
25.10.2001 (30)

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Id 68411-81-4
Date 29.10.2001

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