COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR

American Chemistry Council Good Chemistry Makes It Possible

September 15, 2003

Dr. Scott A. Masten
Office of Chemical Nomination and Selection
NIEHS/NTP
P.O. Box 12233, MD A3-07
Research Triangle Park, NC 27709

RE: National Toxicology Program: Request for Public Comments on Substances Nominated to the National Toxicology Program for Toxicological Studies and Study Recommendations Made by the NTP Interagency Committee for the Chemical Evaluation and Coordination; Dimethylethanolamine [108-01-0]

Dear Dr. Masten:

The Amines Panel[1] (Panel) of the American Chemistry Council appreciates the opportunity to submit comments to National Toxicology Program's (NTP) recent *Request for Public Comments on Substances Nominated to the National Toxicology Program for Toxicological Studies and Study Recommendations Made by the NTP Interagency Committee for the Chemical Evaluation and Coordination.* The Panel, composed of manufacturers and importers of amines, was formed to address available health and safety test data under the U.S. HPV Challenge Program and also addresses a variety of issues related to the production and use of other amines.

The Request for Public Comments published on July 16, 2003 includes a URL that provides documentation used to support the nomination of listed substances. The documentation for Dimethylethanolamine (DMEA), *Review of Technical Literature,* was performed in 1997 and it does not appear to provide the most current information on this substance. Unmentioned in the Review of Technical Literature is the European Chemicals Bureau IUCLID for DMEA (copy attached), which was updated in 2000. It is suggested that an additional technical literature search be performed in the NTP evaluation of this substance.

The Amines Panel member companies have a great deal of experience and knowledge of DMEA and related amines. This knowledge is being offered to NTP to assist in the evaluation of DMEA, particularly in the areas of study design and data interpretation. Panel members' knowledge of DMEA and other amines can help NTP in its efforts to

[1] Panel member companies are Air Products and Chemicals, Inc., Akzo Nobel Chemicals Inc., ATOFINA Chemicals, Inc., BASF Corporation, Celanese, Crompton Corporation, Dow, DuPont, Ertisa, S.A., Huntsman Corporation, and UCB Chemicals Corporation.

select representative material for testing, establish an effective study design, and put the resulting data into the proper context.

The contact for the Panel is John DiLoreto. As Panel Manager, he will coordinate requests for information from the Panel. He can be reached by phone at (703) 741-5615 or via email at john_diloreto@americanchemistry.com.

Sincerely yours,

Courtney Price
Vice President, CHEMSTAR

Attachment: IUCLID Data Sheet, October 2, 2000

cc: Amines Panel Members

I U C L I D

Data Set

Existing Chemical	:	ID: 108-01-0
CAS No.	:	108-01-0
EINECS Name	:	2-dimethylaminoethanol
EC No.	:	203-542-8
TSCA Name	:	Ethanol, 2-(dimethylamino)-
Molecular Formula	:	C4H11NO

Producer related part

Company	:	EUROPEAN COMMISSION - European Chemicals Bureau
Creation date	:	10.02.2000

Substance related part

Company	:	EUROPEAN COMMISSION - European Chemicals Bureau
Creation date	:	10.02.2000
Status	:	
Memo	:	
Printing date	:	30.07.2003
Revision date	:	10.02.2000
Date of last update	:	10.02.2000
Number of pages	:	84
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
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 APPLICANT AND COMPANY INFORMATION

Type	:	
Name	:	AGFA - Gevaert N.V.
Contact person	:	
Date	:	
Street	:	Septestraat 27
Town	:	B-2640 Mortsel-België
Country	:	Belgium
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	Allied Colloids Ltd.
Contact person	:	
Date	:	
Street	:	PO Box 38, Low Moor
Town	:	BD12 0JZ Bradford
Country	:	United Kingdom
Phone	:	0274 671267
Telefax	:	0274 606499
Telex	:	51646
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	BASF AG
Contact person	:	
Date	:	
Street	:	Karl-Bosch-Str
Town	:	67056 Ludwigshafen
Country	:	Germany
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	ELF ATOCHEM
Contact person	:	
Date	:	
Street	:	4, cours Michelet - Cedex 42
Town	:	92091 Paris la defense 10
Country	:	France

Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	Henkel KGaA
Contact person	:	
Date	:	
Street	:	Henkelstr. 67
Town	:	40589 Duesseldorf
Country	:	Germany
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	ICI C&P France SA
Contact person	:	
Date	:	
Street	:	
Town	:	62920 Chocques
Country	:	France
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	ICI Chemicals & Polymers Limited
Contact person	:	
Date	:	
Street	:	PO Box 14, The Heath
Town	:	WA7 4QF Runcorn, Cheshire
Country	:	United Kingdom
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	Roehm GmbH
Contact person	:	
Date	:	

Street	:	
Town	:	64275 Darmstadt
Country	:	Germany
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	Shell Nederland Chemie B.V.
Contact person	:	
Date	:	
Street	:	Vondelingenweg 601
Town	:	3196 KK Rotterdam
Country	:	Netherlands
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

Type	:	
Name	:	Union Carbide Benelux
Contact person	:	
Date	:	
Street	:	Norderlaan 147
Town	:	2030 Antwerpen
Country	:	Belgium
Phone	:	
Telefax	:	
Telex	:	
Cedex	:	
Email	:	
Homepage	:	

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :
Substance type : organic
Physical status : liquid
Purity :
Colour :
Odour :

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

(2-Hydroxyethyl)dimethylamine

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

(Dimethylamino)ethanol

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

(N,N-Dimethylamino)ethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

.beta.-(Dimethylamino)ethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

.beta.-Dimethylaminoethyl alcohol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

.beta.-Hydroxyethyldimethylamine

Source : ICI C&P France SA Chocques

ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

2-(Dimethylamino)-1-ethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

2-(Dimethylamino)ethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

2-(Dimethylamino)ethyl alcohol

Source : Henkel KGaA Duesseldorf

2-(N,N-Dimethylamino)ethanol

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

2-(N,NODimethylamino)ethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire

2-Dimethylaminoaethanol

Source : Henkel KGaA Duesseldorf

2-dimethylaminoethanol

Source : Shell Nederland Chemie B.V. Rotterdam

2-Dimethylaminoethanol

Source : Henkel KGaA Duesseldorf

Amietol M 21

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Amietol M21

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire

Bimanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

deanol

Source : Union Carbide Benelux Antwerpen

Deanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Dimethol

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Dimethyl(2-hydroxyethyl)amine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

Dimethyl(hydroxyethyl)amine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

Dimethylaethanolamin

Source : Henkel KGaA Duesseldorf

Dimethylethanolamin

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

dimethylethanolamine

Source : Shell Nederland Chemie B.V. Rotterdam

Dimethylethanolamine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen

Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

Dimethylmonoethanolamine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

Dimethyol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire

DMAE

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

DMAE, beta-Dimethylaminoethanol, N-Dimethylaminoethanol, N,N-Dimethylaminoethanol, Dimethylethanolamine, N,N-Dimethylethanolamine, beta-Dimethylaminoethyl alcohol, N,N-Dimethyl-N-(2-Hydroxyethyl)amine, N,N-Dimethyl-2-hydroxyethylamine.

Source : Allied Colloids Ltd. Bradford

DMEA

Source : Union Carbide Benelux Antwerpen
ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
Roehm GmbH Darmstadt

Ethanol, 2-(dimethylamino)-

Source : Henkel KGaA Duesseldorf

Ethanol, 2-(Dimethylamino)-

Source : Henkel KGaA Duesseldorf

Ethanol, 2-(dimethylamino)- (8Cl, 9Cl)

Source : BASF AG Ludwigshafen
Roehm GmbH Darmstadt

Kalpur P

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Liparon

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Morlex DMEA

Source : Henkel KGaA Duesseldorf

N,N-Dimethyl(2-hydroxyethyl)amine

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-Dimethyl(2hydroxyethyl)amine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire

N,N-Dimethyl-.beta.-hydroxyethylamine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-Dimethyl-2-aminoethanol

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-Dimethyl-N-(.beta.-hydroxyethyl)amine

Source : BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-Dimethyl-N-(2-hydroxyethyl)amine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-dimethylaminoethanol

Source : Union Carbide Benelux Antwerpen

N,N-Dimethylaminoethanol

Source : Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N,N-dimethylethanolamine

Source : Shell Nederland Chemie B.V. Rotterdam
Union Carbide Benelux Antwerpen

N,N-Dimethylethanolamine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

N-(2-Hydroxyethyl)dimethylamine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf
Roehm GmbH Darmstadt

Norcholine

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Propamine A

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Rexolin

Source : Henkel KGaA Duesseldorf

Texacat DME

Source : ICI C&P France SA Chocques
ICI Chemicals & Polymers Limited Runcorn, Cheshire
BASF AG Ludwigshafen
Henkel KGaA Duesseldorf

Texacat ZF-51

Source : Henkel KGaA Duesseldorf

Thancat DME

Source : Henkel KGaA Duesseldorf

1.3 IMPURITIES

1.4 ADDITIVES

1.5 TOTAL QUANTITY

Quantity : 50000 - 100000 tonnes in

1.6.1 LABELLING

Labelling : as in Directive 67/548/EEC
Specific limits : yes
Symbols : C, , ,
Nota : , C,
R-Phrases : (10) Flammable
(20/21/22) Harmful by inhalation, in contact with skin and if swallowed
(34) Causes burns
S-Phrases : (1/2) Keep locked up and out of reach of children
(25) Avoid contact with eyes
(26) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
(36/37/39) Wear suitable protective clothing, gloves and eye/face protection
(45) In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

1.6.2 CLASSIFICATION

Classified : as in Directive 67/548/EEC
Class of danger : corrosive
R-Phrases : (20/21/22) Harmful by inhalation, in contact with skin and if swallowed
Specific limits :

Classified : as in Directive 67/548/EEC
Class of danger : corrosive
R-Phrases : (34) Causes burns
Specific limits :

Classified : as in Directive 67/548/EEC
Class of danger :
R-Phrases : (10) Flammable
Specific limits :

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use : type
Category : Non dispersive use

Type of use : type
Category : Use in closed system

Type of use : type
Category : Wide dispersive use

Type of use : industrial
Category : Chemical industry: used in synthesis

Type of use : industrial
Category : Paints, lacquers and varnishes industry

Type of use : industrial
Category : Personal and domestic use

Type of use : industrial
Category : Photographic industry

Type of use : industrial
Category : Polymers industry

Type of use : industrial
Category : Textile processing industry

Type of use : industrial
Category : other: coating industry

Type of use : industrial
Category : other: pharmaceutical industry

Type of use : industrial
Category : other: water treatment industry

Type of use : industrial

Category : other: waxes and polishes

Type of use : use
Category : Corrosive inhibitors

Type of use : use
Category : Intermediates

Type of use : use
Category : pH-regulating agents

Type of use : use
Category : Pharmaceuticals

Type of use : use
Category : Photochemicals

Type of use : use
Category : Process regulators

Type of use : use
Category : other: component for personal care products

Type of use : use
Category : other: emulsifying and dispersing agent

Type of use : use
Category : other

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : MAK (DE)
Limit value :

Remark : Kein MAK-Wert festgelegt.

Source : BASF AG Ludwigshafen

(108)

Type of limit : MAK (DE)
Limit value :

Remark : Does not exist.
Source : Roehm GmbH Darmstadt

(36)

Type of limit : TLV (US)
Limit value :

Remark : Union Carbide established the following internal exposure standard for 2-dimethylaminoethanol:
TLV-TWA: 5 ppm
STEL : 25 ppm
Source : Union Carbide Benelux Antwerpen
Union Carbide Benelux Antwerpen
ECB - Existing Chemicals Ispra (VA)
Roehm GmbH Darmstadt

Remark : Supplier recommends 5ppm TWA, 25ppm STEL (USA).
Source : Allied Colloids Ltd. Bradford

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

Classified by : KBwS (DE)
Labelled by : KBwS (DE)
Class of danger : 1 (weakly water polluting)

Source : BASF AG Ludwigshafen

Classified by : KBwS (DE)
Labelled by : KBwS (DE)
Class of danger : 1 (weakly water polluting)

Source : BASF AG Ludwigshafen

(26)

Classified by : KBwS (DE)
Labelled by : KBwS (DE)
Class of danger : 1 (weakly water polluting)

Source : Roehm GmbH Darmstadt

(23)

1.8.4 MAJOR ACCIDENT HAZARDS

Legislation	:	Stoerfallverordnung (DE)
Substance listed	:	no
No. in Seveso directive	:	
Source	:	BASF AG Ludwigshafen BASF AG Ludwigshafen ECB - Existing Chemicals Ispra (VA) Roehm GmbH Darmstadt

(100)

1.8.5 AIR POLLUTION

Classified by	:	TA-Luft (DE)
Labelled by	:	TA-Luft (DE)
Number	:	3.1.7 (organic substances)
Class of danger	:	III
Remark	:	Zuordnung durch VCI
Source	:	BASF AG Ludwigshafen

Classified by	:	TA-Luft (DE)
Labelled by	:	TA-Luft (DE)
Number	:	3.1.7 (organic substances)
Class of danger	:	III
Remark	:	Zuordnung durch VCI
Source	:	BASF AG Ludwigshafen

(26)

Classified by	:	TA-Luft (DE)
Labelled by	:	TA-Luft (DE)
Number	:	3.1.7 (organic substances)
Class of danger	:	III
Remark	:	Zuordnung durch VCI
Source	:	Roehm GmbH Darmstadt

(23)

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

Remark	:	As the quantities of this substance placed on the EU market by Union Carbide Benelux N.V. are normally sourced from the

manufactruing facilities of its U.S. parent company, no exposure can arise within the EU from the manufacture of these quantities. The comments below on exposure are restricted to uses for which Union Carbide believes its customers use this substance.

Major use(s): As chemical intermediate and additive to certain consumer products.

Sources of human exposure: In industrial uses, negligible if appropriate industrial hygiene and personal protective precautions are observed. Consumer uses may result in some exposure via skin. No quantitative estimates are available.

Sources of environmental exposure: Releases to the water compartment via use in consumer products. Substance biodegrades completely in sewage treatment systems.

Source : Union Carbide Benelux Antwerpen

Remark : Bought from a UK supplier, imported using Inward Processing Relief and used at a single site for chemical synthesis.

Source : Allied Colloids Ltd. Bradford

Remark : As the quantities of this substance placed on the EU market by Union Carbide Benelux N.V. are normally sourced from the manufacturing facilities of its U.S. parent company, no exposure can arise within the EU from the manufacture of these quantities. The comments below on exposure are restricted to uses for which Union Carbide believes its customers use this substance.

Major use(s): As chemical intermediate and additive to certain consumer products.

Sources of human exposure: In industrial uses, negligible if appropriate industrial hygiene and personal protective precautions are observed. Consumer uses may result in some exposure via skin. No quantitative estimates are available.

Sources of environmental exposure: Releases to the water compartment via use in consumer products. Substance biodegrades completely in sewage treatment systems.

Source : Union Carbide Benelux Antwerpen
ECB - Existing Chemicals Ispra (VA)
Roehm GmbH Darmstadt

1.11 ADDITIONAL REMARKS

Remark : Molecular formula: (CH3)2NC2H4OH; Brutoformula: C4H11NO

Source : Shell Nederland Chemie B.V. Rotterdam

Remark : Disposal: incinerate in a furnace where permitted under national and local regulations.
Laboratory tests indicate that this product is biodegraded at very low concentrations (approximately 10 ppm) in water.
If spilled material cannot be collected, it may be possible to neutralize with dilute hydrochloric acid, then dispose ofthe neutral salt in accordance with appropriate national andlocal regulations.

Transport: 2-dimethylaminoethanol is currently classified asa category 3 product according the ADR/RID/IMDG/ICAO regulations, although Union Carbide feels that a class 8 classification would be more appropriate (see also comments made in point 1.6.2.).
This product is shipped in road/rail tankcars, tankcontainers/ISOtanks and smaller packages (e.g. drums).

Source : Union Carbide Benelux Antwerpen

Remark : Delivered on a regular basis.
Source : Allied Colloids Ltd. Bradford

Remark : Incinerate in a furnace where permitted under national and local regulations.
Laboratory tests indicate that this product is biodegraded at very low concentrations (approximately 10 ppm) in water.
If spilled material cannot be collected, it may be possible to neutralise with dilute hydrochloric acid, then dispose of the neutral salt in accordance with appropriate national and local regulations.

Transport: 2-dimethylaminoethanol is currently classified as a category 3 product according the ADR/RID/IMDG/ICAO regulations, although Union Carbide feels that a class 8 classification would be more appropriate (see also comments made in point 1.6.2.).
This product is shipped in road/rail tankcars, tankcontainers/ISOtanks and smaller packages (e.g. drums).

Source : Union Carbide Benelux Antwerpen
ECB - Existing Chemicals Ispra (VA)
Roehm GmbH Darmstadt

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value : -59 °C
Decomposition : no, at °C
Sublimation : no
Method : other
Year :
GLP : no
Test substance :

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(64)

Value : = -59 °C

Source : BASF AG Ludwigshafen
(25)

2.2 BOILING POINT

Value : = 133.5 - 135.5 °C at

Source : BASF AG Ludwigshafen
(25)

Value : 134 °C at 10.13 hPa
Decomposition : no
Method : other
Year :
GLP : no
Test substance :

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(39)

2.3 DENSITY

Type : density
Value : .886 g/cm_ at 20 °C
Method : other
Year :
GLP : no
Test substance :

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(46)

Type : density
Value : = .887 g/cm_ at 20 °C

Source : BASF AG Ludwigshafen
(25)

Method : other
Year :
GLP :

Test substance :

Remark : Vapour density (air = 1) : 3.1
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(47)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : .05 hPa at 20 °C
Decomposition :
Method :
Year :
GLP : no
Test substance :

Remark : "Historical" value from literature
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(47)

Value : = 6.12 hPa at 20 °C

Source : BASF AG Ludwigshafen
(25)

Value : .06 hPa at 25 °C
Decomposition :
Method :
Year :
GLP : no
Test substance :

Remark : "Historical" value from literature
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(47)

2.5 PARTITION COEFFICIENT

Partition coefficient :
Log pow : = -.727 at °C
pH value :
Method : other (calculated): Compudrug Ltd Computer Programme
Year :
GLP :
Test substance :

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(11)

Partition coefficient :
Log pow : = -.727 at °C
pH value :
Method : other (calculated): Inkrementenmethode von Rekker mit Computerprogramm der Fa. CompuDrug Ltd.
Year :
GLP :

Test substance	:	
Source	:	BASF AG Ludwigshafen (19)
Partition coefficient	:	
Log pow	:	= -.55 at 23 °C
pH value	:	
Method	:	OECD Guide-line 107 "Partition Coefficient (n-octanol/water), Flask-shaking Method"
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (6)
Partition coefficient	:	
Log pow	:	= -.55 at 23 °C
pH value	:	
Method	:	OECD Guide-line 107 "Partition Coefficient (n-octanol/water), Flask-shaking Method"
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen (17)
Partition coefficient	:	
Log pow	:	.53 at °C
pH value	:	
Method	:	other (calculated)
Year	:	
GLP	:	no
Test substance	:	
Remark	:	No temperature given in the reference Low bioaccumulation potential
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (57)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	
Value	:	at °C
pH value	:	
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	miscible
Stable	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (73)
Solubility in	:	
Value	:	at 20 °C
pH value	:	10.5 - 11

concentration	:	100 g/l at 20 °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	miscible
Stable	:	
Source	:	BASF AG Ludwigshafen

(25)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

Value	:	= 39 °C
Type	:	
Method	:	other: DIN 51 755
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(30)

Value	:	= 39 °C
Type	:	
Method	:	other: DIN 51 755
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen

(25)

Value	:	41 °C
Type	:	closed cup
Method	:	other
Year	:	
GLP	:	no
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Method TAG closed cup ASTM D56-87

(47)

2.8 AUTO FLAMMABILITY

Value	:	= 245 °C at
Method	:	other: IDN 51 794
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(30)

Value	:	= 245 °C at

Method : other: DIN 51 794
Year :
GLP :
Test substance :

Source : BASF AG Ludwigshafen

(25)

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

Result : other: Explosionsgrenzen in Luft: 1.4 - 12.2 Vol. %

Source : BASF AG Ludwigshafen

(25)

Result : other: Explosive limit in air: 1.4 - 12.2 Vol. %

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire

(30)

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

Remark : pH in Water at 1000,000 mg/l = 12
pKa = 9.3
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire

Remark : Gefaehrliche Reaktionen: Exotherme Reaktion mit Saeuren.
Source : BASF AG Ludwigshafen

(25)

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	
Rate constant	:	cm_/(molecule*sec)
Degradation	:	% after
Deg. product	:	
Method	:	other (measured)
Year	:	
GLP	:	
Test substance	:	
Remark	:	Rate constant: 103 (+/- 20) *10^-12 cm^3/molecule*sec at 293K
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(3)

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	500000 molecule/cm_
Rate constant	:	cm_/(molecule*sec)
Degradation	:	= 50 % after .2 day(s)
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(3)

Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	3000000 molecule/cm_
Rate constant	:	cm_/(molecule*sec)
Degradation	:	% after
Remark	:	The rate of the reactions of OH-radicals with 2-(Dimethylamino) ethanol has been determined by using a flash photolysis-resonance fluorescence technique to be 4.7 +/- 1.2*10^-11 cm^3/mol*sec at 300 +/- 2 K. Taking the average OH-concentration in the urban atmosphere to be 3*10^6 mol/cm^3 leads to estimated lifetimes (l/e) for DMAE of approximately 2 h under such conditions, for oxidation by OH-radicals.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(40)

Type	:	air
Light source	:	
Light spectrum	:	nm

Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	
Rate constant	:	cm_/(molecule*sec)
Degradation	:	% after
Deg. product	:	
Method	:	other (measured)
Year	:	
GLP	:	
Test substance	:	
Remark	:	Rate Constant: 103 (+/- 20)*10^-12 cm^3/molecule*sec bei 293 K
Source	:	BASF AG Ludwigshafen (4)
Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	3000000 molecule/cm_
Rate constant	:	cm_/(molecule*sec)
Degradation	:	% after
Remark	:	The rate of the reactions of OH-radicals with 2-(Dimethyl-amino)ethanol has been determined by using a flash photo-lysis-resonance fluorescence technique to be 4.7 +/- 1.2 *10^-11 cm^3/mol*sec at 300 +/- 2 K. Taking the average OH-concentration in the urban atmosphere to be 3*10^6 mol/cm^3 leads to estimated lifetimes (l/e) for DMAE of approximately 2 h under such conditions, for oxidation by OH-radicals.
Source	:	BASF AG Ludwigshafen (41)
Type	:	air
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
INDIRECT PHOTOLYSIS		
Sensitizer	:	OH
Conc. of sensitizer	:	500000 molecule/cm_
Rate constant	:	cm_/(molecule*sec)
Degradation	:	= 50 % after .2 day(s)
Remark	:	Rate Constant: 90.0*10^-12 cm^3/molecule*sec at 25 deg C
Source	:	BASF AG Ludwigshafen (5)
Type	:	other
Light source	:	
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
Remark	:	Method based on that described by R Atkinson. "Estimation of gas- phase hydroxyl radical rate constamts for organic chemicals". Environmental Toxicology and Chemistry, 7, 435-442 1988

Result : Calculated half life in air - 0.94 days
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire

(58)

3.1.2 STABILITY IN WATER

Deg. product :
Method : other
Year :
GLP :
Test substance :

Remark : no data are available
Source : BASF AG Ludwigshafen

3.1.3 STABILITY IN SOIL

Type : other
Radiolabel :
Concentration :
Soil temperature : °C
Soil humidity :
Soil classification :
Year :

Remark : no data are available
Source : BASF AG Ludwigshafen

3.2.1 MONITORING DATA

Type of measurement : other
Media :
Concentration :
Method :

Remark : no data are available
Source : BASF AG Ludwigshafen

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : other
Media :
Air : % (Fugacity Model Level I)
Water : % (Fugacity Model Level I)
Soil : % (Fugacity Model Level I)
Biota : % (Fugacity Model Level II/III)
Soil : % (Fugacity Model Level II/III)
Method :
Year :

Remark : no data are available
Source : BASF AG Ludwigshafen

3.3.2 DISTRIBUTION

Media : air - biota - sediment(s) - soil - water
Method : Calculation according Mackay, Level I
Year :

Remark : Water 56% Air 44% at 10 degree C

Water 39% Air 61% at 20 degree C
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(58)

Media : other
Method :
Year :

Remark : no data are available
Source : BASF AG Ludwigshafen

3.4 MODE OF DEGRADATION IN ACTUAL USE

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire

Remark : no data are available
Source : BASF AG Ludwigshafen

3.5 BIODEGRADATION

Type : aerobic
Inoculum : activated sludge
Concentration : 1000 mg/l related to COD (Chemical Oxygen Demand)
related to
Contact time :
Degradation : 90 (±) % after 13 day(s)
Result : readily biodegradable
Deg. product :
Method : Directive 87/302/EEC, part C, p. 99 "Biodegradation: Zahn-Wellens test"
Year :
GLP : no data
Test substance : no data

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire
(120)

Type : aerobic
Inoculum : activated sludge, non-adapted
Concentration : 1000 mg/l related to COD (Chemical Oxygen Demand)
related to
Contact time :
Degradation : > 90 (±) % after 13 day(s)
Result :
Deg. product :
Method : OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"

Year	:	
GLP	:	
Test substance	:	
Remark	:	Lag phase of 3 days.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (121)
Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Concentration	:	1000 mg/l related to COD (Chemical Oxygen Demand) related to
Contact time	:	
Degradation	:	> 90 (±) % after 13 day(s)
Result	:	
Deg. product	:	
Method	:	OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"
Year	:	
GLP	:	
Test substance	:	
Remark	:	Lag-Phase = 3 Tage
Source	:	BASF AG Ludwigshafen (122)
Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	30 - 100 (±) % after 14 day(s)
Result	:	
Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	No further information available
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Test method - Japanese MITI - BOD 100 mg/l in 30g/l activated sludge - temp 25 degree C (86)
Type	:	aerobic
Inoculum	:	domestic sewage
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	60.5 (±) % after 14 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Japanese MITI. 100 mg/l in 30 g/l sewage

Temperature - 25 degree C

(52)

Type	:	aerobic
Inoculum	:	domestic sewage, non-adapted
Contact time	:	
Degradation	:	= 85 (±) % after 20 day(s)
Result	:	readily biodegradable
Kinetic of testsubst.	:	5 day(s) = 4 % 10 day(s) = 67 % 20 day(s) = 85 % % %
Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	The data show DMEA biograde rapidly after a short (approx 5 days) lag period in the river-simulating biochemical oxygen demand (BOD) test using nonacclimated domestic sewage microorganisms. Any prior contact of the bacteria to DMEA would be expected to increase the initial rate of biodegradation. Nitrification, and the associated oxygen demand, was not indicated in this test due to the lack of any nitrite or nitrate detected in the test solutions.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Dilution bottle bichemical oxygen demand test The theoretical carbonaceous oxygen demand was calculated based on the oxygen required to oxidize the carbon content to carbon dioxide and water. The calculation assumes the nitrogen reaches ammonia and remains in that form. The biochemical oxygen demand was measured in dilution bottle biochemical oxygen demand test published in Standard Methods for the Examination of Water and Wastewater, Am. Public Health Assoc., 17th ed., Washington, DC (1989). Bioxidation calculated as percentage ration of BOD to ThOD (BOD/ThOD x 100).

(59)

Type	:	aerobic
Inoculum	:	industrial sewage
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	79.9 (±) % after 14 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Ammonia was the end product.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Japanese MITI. 100 mg/l in 30 g/l sewage Temperature - 25 degree C

(51)

Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	= 60.5 (±) % after 14 day(s)
Result	:	
Deg. product	:	
Method	:	other: MITI-Test (BOD of THOD)
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen
Test condition	:	Concentration of sludge: 30 mg/l

(31)

Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	100 mg/l related to Test substance related to
Contact time	:	
Degradation	:	= 60.5 (±) % after 14 day(s)
Result	:	
Deg. product	:	
Method	:	other: MITI-Test (BOD of ThOD)
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Concentration of sludge: 30 mg/l.

(31)

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Contact time	:	
Degradation	:	> 30 (±) % after 14 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other: MITI-Test (BOD of ThOD)
Year	:	
GLP	:	
Test substance	:	other TS: 30 ppm activated sludge/100 ppm test substance specific and non-specific analysis.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(85)

Type	:	aerobic
Inoculum	:	activated sludge, non-adapted
Contact time	:	
Degradation	:	> 30 (±) % after 14 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other: MITI-Test (BSB des THSB)
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen

Test condition	:	30 ppm Belebtschlamm / 100 ppm Testsubstanz; substanzspezifische und -unspezifische Analytik
		(87)
Type	:	aerobic
Inoculum	:	
Contact time	:	
Degradation	:	> 60 (±) % after
Result	:	
Deg. product	:	
Method	:	other: Standard TOC Test
Year	:	
GLP	:	
Test substance	:	
Remark	:	Good elimination, essentially through biodegredation.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
		(24)
Type	:	aerobic
Inoculum	:	
Contact time	:	
Degradation	:	> 60 (±) % after
Result	:	
Deg. product	:	
Method	:	other: Standversuch (TOC)
Year	:	
GLP	:	
Test substance	:	
Remark	:	Gut eliminierbar, im wesentlichen durch biologischen Abbau.
Source	:	BASF AG Ludwigshafen
		(24)

3.6 BOD5, COD OR BOD5/COD RATIO

BOD5		
Method	:	other
Year	:	
Concentration	:	related to
BOD5	:	mg/l
GLP	:	
Remark	:	no data are available
Source	:	BASF AG Ludwigshafen

3.7 BIOACCUMULATION

Species	:	other
Exposure period	:	at °C
Concentration	:	
Remark	:	no data are available
Source	:	BASF AG Ludwigshafen

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	other: oral (force-fed)
Species	:	Cyprinus carpio (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	
Limit test	:	
Analytical monitoring	:	no
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Dosis ohne Letalitaet wurde mit 88 bis 167 mg/kg angegeben
Source	:	BASF AG Ludwigshafen

(61)

Type	:	static
Species	:	Cyprinus carpio (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC0	:	107 - 167
Limit test	:	
Analytical monitoring	:	no data
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Practically non-toxic to fish. No analysis of test water.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Percentage mortality measured in fresh water. Temperature 18.3 Deg C (acclimated 8.3 Deg C).

(60)

Type	:	static
Species	:	Cyprinus carpio (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC0	:	88 - 131
Limit test	:	
Analytical monitoring	:	no data
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	no data
Remark	:	Practically non-toxic to fish. No analysis of test water.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Percentage mortality measured in fresh water. Temperature 18.3 Deg C (acclimated 8.3 Deg C).

(60)

Type	:	static
Species	:	Leuciscus idus (Fish, fresh water)
Exposure period	:	48 hour(s)
Unit	:	mg/l
Limit test	:	

Analytical monitoring : no
Method : other: BASF-Test
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Ergebnisse:

Konzentr. (mg/l)	einges. Fische	tote Fische nach 4 h	24 h	48 h
0	10	0	0	0
10	3	0	0	0
100	3	0	0	0
500	3	0	0	0
500	10	0	0	0
1000	3	0	0	1
1500	3	0	0	1
2500	3	0	0	3
4000	3	-	1	3
6300	3	-	3	3
10000	3	-	3	3

Source : BASF AG Ludwigshafen

(12)

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : 100
LC0 : 100
LC50 : 100 - 200
Limit test :
Analytical monitoring : yes
Method : other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN 38412, Teil 15
Year : 1982
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Time trend data for the LC50 value.

All figures are mg/ml

1 h > 460 < 1000
4 h about 460
24 h > 100 < 220
48 h > 100 < 220
72 h > 100 < 220
96 h > 100 < 220

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire

(9)

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
NOEC : 100
LC0 : 100
LC50 : 100 - 220
LC100 : 220

Limit test	:	
Analytical monitoring	:	no
Method	:	other: Bestimmung der Wirkung von Wasserinhaltsstoffen auf Fische, DIN38412 Teil 15
Year	:	1982
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(14)

Type	:	static
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
LC50	:	81
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The aquatic toxicity data on DMEA indicates only moderate toxicity to fathead minnows with a 96-hour LC50 of 81 mg/L. The pH of the test solutions was not adjusted so some toxicity may be the result of the higher pH due to free ammonia formation. The study was designed to evaluate the toxicity associated with direct spills into waterways without any benefit of prior treatment. The bioassay was conducted by recommended procedures available in 1973-74. Ten minnows were used for each test concentraion in 5-gallon test vessels. Current procedures recommend 20 fish per test concentration and utilise less than 90-day old minnows. Generally, the younger fish will show a small increase in sensitivity to chemicals, but not over 10 percent.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(59)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC0	:	62.5
EC50	:	98.77
EC100	:	250
Analytical monitoring	:	no data
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	1989
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(27)

Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	24 hour(s)
Unit	:	mg/l
EC0	:	= 62.5

EC50	:	= 105.42
EC100	:	= 250
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (22)
Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	24 hour(s)
Unit	:	mg/l
EC0	:	= 62.5
EC50	:	= 105.42
EC100	:	= 250
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen (21)
Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC0	:	= 62.5
EC50	:	= 98.37
EC100	:	= 250
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (22)
Type	:	
Species	:	other aquatic arthropod: Daphnia magna Straus
Exposure period	:	48 hour(s)
Unit	:	mg/l
EC0	:	= 62.5
EC50	:	= 98.37
EC100	:	= 250
Method	:	Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen (21)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus sp. (Algae)
Endpoint	:	
Exposure period	:	72 hour(s)

Unit	:	mg/l
EC50	:	35
EC20	:	18
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	In contrast to the non-neutrilised test (100 mg/l = 94% inhibition), the neutrilised test showed a reduction in toxicity (100 mg/l = 74% inhibition).
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (28)
Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	
Exposure period	:	72 hour(s)
Unit	:	mg/l
EC50	:	= 35
EC20	:	= 18
Method	:	other: Scenedesmus-Zellvermehrungs-Hemmtest, DIN 38412 Teil 9, Bestimmung der Hemmwirkung von Wasserinhaltsstoffen auf Gruenalgen
Year	:	
GLP	:	
Test substance	:	
Remark	:	EC90(72h)=87 mg/l. Im Gegensatz zur nicht neutralisierten Probe (100 mg/l = 94% Hemmung) zeigte die neutralisierte Probe (100 mg/l = 74% Hemmung) eine Toxizitaetsreduktion.
Source	:	BASF AG Ludwigshafen (20)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type	:	
Species	:	activated sludge
Exposure period	:	
Unit	:	
Remark	:	If dimethylaminoethanol is introduced into an adapted sewage system, no adverse effects would be expected on the sludge.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (76)
Type	:	
Species	:	activated sludge
Exposure period	:	
Unit	:	
Remark	:	Bei sachgemaesser Einleitung in adaptierte biologische Klaeranlagen sind keine Stoerungen der Abbauaktivitaet des Belebtschlamms zu erwarten.
Source	:	BASF AG Ludwigshafen (24)
Type	:	
Species	:	Pseudomonas putida (Bacteria)
Exposure period	:	
Unit	:	mg/l

EC10	:	> 8000
Method	:	other: Cell inhibition test
Year	:	
GLP	:	
Test substance	:	
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (29)
Type	:	
Species	:	Pseudomonas putida (Bacteria)
Exposure period	:	
Unit	:	mg/l
EC10	:	> 8000
Method	:	other: Zellvermehrungshemmtest
Year	:	
GLP	:	
Test substance	:	
Source	:	BASF AG Ludwigshafen (18)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species	:	other
Endpoint	:	
Exposure period	:	
Unit	:	
Remark	:	no data are available
Source	:	BASF AG Ludwigshafen

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

Method	:	other
Year	:	
GLP	:	
Test substance	:	
Remark	:	no data are available
Source	:	BASF AG Ludwigshafen

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

Type	:	other
Species	:	
Endpoint	:	
Exposure period	:	
Unit	:	

Remark : no data are available
Source : BASF AG Ludwigshafen

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

Species : other
Endpoint :
Exposure period :
Unit :

Remark : no data are available
Source : BASF AG Ludwigshafen

4.7 BIOLOGICAL EFFECTS MONITORING

Remark : no data are available
Source : BASF AG Ludwigshafen

4.8 BIOTRANSFORMATION AND KINETICS

Type : other
Deg. product :

Remark : no data are available
Source : BASF AG Ludwigshafen

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	2340 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	no data
Remark	:	No clinical information given
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(96)

Type	:	LD50
Value	:	2000 - 2170 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	
GLP	:	no
Test substance	:	
Remark	:	No clinical Information given
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test substance	:	Dimethylaminoethanol as 20% w/v dilution in drinking water

(91)

Type	:	LD50
Value	:	6000 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	
GLP	:	no
Test substance	:	
Remark	:	No clinical information given
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test substance	:	Dimethylaminoethanol (neutralised)

(42)

Type	:	LD50
Value	:	1803 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	
GLP	:	no
Test substance	:	
Remark	:	No further information given
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(102)

Type	:	LD50
Value	:	ca. 2130 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: BASF test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(7)

Type	:	LD50
Value	:	ca. 2130 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LD50 ca. 2400 ul/kg
Source	:	BASF AG Ludwigshafen

(16)

Type	:	LD50
Value	:	= 2000 - 2170 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other
Year	:	
GLP	:	no

Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Angabe von 2000 mg/kg bezieht sich auf maennliche Tiere; fuer weibliche Tiere wurde ein Wert von 2170 mg/kg angegeben.
Source	:	BASF AG Ludwigshafen

(80) (92)

Type	:	LD50
Value	:	= 2340 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(93)

Type	:	LD50
Value	:	= 6000 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Dimethylaminoethanol-Hydrochlorid
Remark	:	mit HCl neutralisiert
Source	:	BASF AG Ludwigshafen

(43)

Type	:	LD50
Value	:	= 2600 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Dimethylaminoethanol-Tartrat
Source	:	BASF AG Ludwigshafen

(74)

Type	:	LD50
Value	:	1242 - 1597 mg/kg bw
Species	:	rat
Strain	:	

Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LD50 = 1.4 ml/kg (weibl. Tiere); 1.8 ml/kg (maennl. Tiere)
Source	:	BASF AG Ludwigshafen (109)
Type	:	LD50
Value	:	1803 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (103)
Type	:	LD50
Value	:	= 3100 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Diethylaminoethanol-Tartrat
Source	:	BASF AG Ludwigshafen (74)
Type	:	LD50
Value	:	= 3500 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	neutralisiert
Source	:	BASF AG Ludwigshafen

(35)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	LC50
Value	:	1641 ppm
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	4 hour(s)
Method	:	
Year	:	
GLP	:	no
Test substance	:	
Remark	:	5 rats (Wistar Albino) exposed for 4 hours at each exposure concentration (1668, 2408 and 3311 ppm). Maintained for a further 14 day observation period before sacrifice. Clinical signs, observed in all exposure groups, included lacrination, excess in salivation, ocular, oral and nasal discharge and encrustation, respiratory difficulties, co-ordination loss, decreased motor activity, and swelling and bleeding of extremities (feet and nose) from excessive preening (highest concentraion only). Substantial body weight losses occurred for all but one survivor on postexposure Day 7, with only two males of the 1668 ppm group surpassing the preexposure body weight by Day 14. Discoloured lungs, livers, kidneys and spleens were seen at the necropsy of animals which died on study as well as in the two survivors of the 3311 ppm group. Survivors of the 2408 and 1668 groups did not have exposure-related macroscopic lesions at the end of the 14-day postexposure observation period.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire
Test condition	:	Dimethylaminoethanol Vapour

(55)

Type	:	LC50
Value	:	= 6.1 mg/l
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	4 hour(s)
Method	:	other: nach Carpenter, C.P. et al.: Toxicol. Appl. Pharmacol. 32, 246-262
Year	:	1975
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LC50 = 1641 ppm / 4 h
Source	:	BASF AG Ludwigshafen

(53) (80)

Type	:	other

Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	4 hour(s)
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Letalitaet bei 4-stuendiger Einwirkung von 4.5 mg/l
Source	:	BASF AG Ludwigshafen (62)
Type	:	other: IRT
Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	8 hour(s)
Method	:	other: BASF test
Year	:	
GLP	:	
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	There was no lethality after 10 minutes exposure to a saturated atmosphere at 20 deg C. Lethality After Longer Exposures --- 1/6 after 30 minutes 2/6 after 1 hour 5/6 after 3 hours 6/6 after 8 hours
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (7)
Type	:	other: IRT
Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	8 hour(s)
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Keine Letalitaet nach 10 min Exposition in einer mit Dampf bei 20 Grad C gesaettigten Atmosphaere; Letalitaet nach laengerer Exposition: 1/6 nach 30 Minuten, 2/6 nach 1 Stunde, 5/6 nach 3 Stunden, 6/6 nach 8 Stunden.

Source	:	BASF AG Ludwigshafen

(16)

Type	:	other: IRT
Value	:	
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	8 hour(s)
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Keine Todesfaelle nach 8 h Exposition in einer mit Dampf gesaettigten Atmosphaere
Source	:	BASF AG Ludwigshafen

(93)

Type	:	LC50
Value	:	= 3.25 mg/l
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	unspecified
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(62) (80)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD50
Value	:	1220 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	
GLP	:	no
Test substance	:	
Remark	:	Range finding LD50 No clinical data available.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(97)

Type	:	LD50

Value	:	3135 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Remark	:	No further information
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(106)

Type	:	LD50
Value	:	= 1220 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LD50 = 1370 ul/kg
Source	:	BASF AG Ludwigshafen

(80) (94)

Type	:	LD50
Value	:	1685 - 2368 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LD50 = 1900 ul/kg (maennliche Tiere), 2100 ul/kg (weibliche Tiere)
Source	:	BASF AG Ludwigshafen

(109)

Type	:	LD50
Value	:	3135 mg/kg bw
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(107)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type	:	LD50
Value	:	= 1080 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Dimethylaminoethanol-Hydrochlorid
Source	:	BASF AG Ludwigshafen

(43) (80)

Type	:	LD50
Value	:	ca. 140 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Originalangabe lautet: LD50 ca. 160 ul/kg
Source	:	BASF AG Ludwigshafen

(16)

Type	:	LD50
Value	:	= 210 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(63)

Type	:	LD50
Value	:	= 234 mg/kg bw
Species	:	mouse
Strain	:	

Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(81)

Type	:	LD50
Value	:	= 1020 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(90)

Type	:	LC50
Value	:	142 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: BASF test
Year	:	
GLP	:	
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(7)

Type	:	LDLo
Value	:	= 450 mg/kg bw
Species	:	guinea pig
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.p.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4

Source	:	BASF AG Ludwigshafen

(83)

Type	:	LD50
Value	:	= 961 mg/kg bw
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	s.c.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(82)

Type	:	other
Value	:	= 1000 mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.v.
Exposure time	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Im Fehlen eines signifikanten Unterschiedes der Hexobarbital-Seitenlagezeit nach Gabe von Dimethylethanolamin sehen die Autoren einen Hinweis darauf, dass dieser Substanz keine wesentliche akute Hepatotoxizitaet zukommt.
Source	:	BASF AG Ludwigshafen

(92)

Type	:	other
Value	:	= 40 mg/kg bw
Species	:	cat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.v.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	40 mg/kg ohne Effekt auf Atmung und Zirkulation
Source	:	BASF AG Ludwigshafen

(35)

Type	:	other

Value	:	= 30 mg/kg bw
Species	:	dog
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Route of admin.	:	i.v.
Exposure time	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	blutdrucksenkende Wirkung
Source	:	BASF AG Ludwigshafen

(72)

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	corrosive (causes burns)
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	1981
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Corrosive after 1 hour under occlusive or semiocclusive dressing. No further information
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(77)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	highly irritating
Classification	:	irritating
Method	:	Draize Test
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	Highly irritating/corrosive. No further information.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(102)

Species	:	rabbit
Concentration	:	
Exposure	:	

Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	corrosive (causes burns)
Method	:	Draize Test
Year	:	
GLP	:	no
Test substance	:	

Remark : Highly irritating/corrosive
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (97)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	Draize Test
Year	:	
GLP	:	
Test substance	:	as prescribed by 1.1 - 1.4

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (10)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	corrosive (causes burns)
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (8)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	other: BASF test
Year	:	
GLP	:	no

Test substance	:	as prescribed by 1.1 - 1.4
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (7)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (16)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	1981
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (13)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (78) (79)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	

Vehicle	:	
PDII	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	offene Applikation, 445 mg (500 ul): - 4 Stunden Applikation: starke Erythem-, Oedem- und Nekrosenbildung, Schuppung, Ulzeration. Nach 14 Tagen zeigten drei Tiere noch Erytheme, fuenf zeigten Oedeme, bei allen wurden Nekrosen und Schuppung beobachtet. - 1 Stunde Applikation: starke Reizung mit Nekrosen und Ulzeration bei der Haelfte der Tiere. - 3 Minuten Applikation: geringgradig bis mittelgradige Ulzeration bei einem drittel der Tiere; keine Reizung bei den restlichen Tieren.
Source	:	BASF AG Ludwigshafen (84) (109)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	irritating
Classification	:	
Method	:	other: Smyth Carpenter
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (93)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	Draize Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (15)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	

Vehicle	:	
PDII	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (109)
Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	corrosive
Classification	:	
Method	:	Draize Test
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Score: 6.6 bis 8.0 von maximal 8.0
Source	:	BASF AG Ludwigshafen (104)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	highly irritating
Classification	:	irritating
Method	:	
Year	:	
GLP	:	no data
Test substance	:	
Remark	:	No further information
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (97)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	highly irritating
Classification	:	
Method	:	

Year	:	
GLP	:	no data
Test substance	:	
Remark	:	No further information
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (102)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: BASF test
Year	:	
GLP	:	
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (7)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (16)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: Smyth Carpenter
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (80) (94)
Species	:	rabbit
Concentration	:	

Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen (62)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	5 ul der unverduennten Substanz fuehrten zu starken cornealen Schaeden, Iritis, Schaeden der Konjunktiven und zu Nekrosen. Es wurde Verkleinerung der Pupillen bis zu 24 Stunden nach der Instillation festgestellt ("pinpoint pupils"). Die Schaeden der Konjunktiven waren zwischen 1 und 24 Stunden nach der Instillation am staerksten; die Hornhauttruebung erreichte nach 48 Stunden ihr Maximum und persistierte auf dem Maximalwert fuer sieben Tage. Bei den meisten Tieren traten die Augaepfel hervor und es zeigten sich Unregelmaessigkeiten der Hornhautoberflaeche im Zeitraum von 24 bis 72 Stunden nach der Instillation. Corneale Vaskularisation zeigte sich nach sieben Tagen. Obwohl sich die Augen von zwei Tieren nach 14 Tagen erholten, blieben bei vier Tieren signifikante Augenleiden bis zum Ende der 21taegigen Beobachtung bestehen.
Source	:	BASF AG Ludwigshafen (109)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Remark	:	Die Instillation von 500 ul einer 15%igen Loesung in Propylenglykol fuehrte zu starken Augenschaeden. Eine 5%ige Loesung zeigte schwaechere, jedoch immer noch deutliche Schaedigung.
Source	:	BASF AG Ludwigshafen (109)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure time	:	
Comment	:	
Number of animals	:	
Vehicle	:	
Result	:	irritating
Classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Score: 80/110/110, extremely irritating
Source	:	BASF AG Ludwigshafen (105)

5.3 SENSITIZATION

Type	:	Mouse local lymphnode assay
Species	:	mouse
Number of animals	:	
Vehicle	:	
Result	:	sensitizing
Classification	:	
Method	:	other: Local Lymph Node Screening Assay
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Substanz wurde in den Konzentrationen 0, 3, 10 und 30% w/v untersucht. Das Ergebnis ausgedrueckt als Verhaeltnis von Testgruppe zu Kontrollgruppe lautete 0, 1.93, 2.13 und 14.5, wobei ein Wert > 3.0 auf eine Sensiblisierung hinweist. Daten aus Humanversuchen ergaben jedoch keine Hinweise auf ein sensibilisierendes Potential der Testsubstanz unter Beachtung der ueblichen Sicherheitsvorkehrungen fuer reizende Stoffe.
Source	:	BASF AG Ludwigshafen (49)
Type	:	
Species	:	mouse
Number of animals	:	
Vehicle	:	
Result	:	
Classification	:	
Method	:	
Year	:	1989
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Remark	:	LOCAL LYMPH NODE SCREENING ASSAY A potential skin sensitiser. Tested at 0, 3, 10 and 30% w/v. Test /control ratio 0, 1.93, 2.13 and 14.50 respectively. (>3.0 is considered an indication of a potential sensitiser). (However, human experience to data has not given rise to a sensitisation problem with the usual handling precautions associated with irritant materials).
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

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5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	11 days
Frequency of treatm.	:	daily
Post exposure period	:	
Doses	:	98, 228, 586 ppm
Control group	:	yes
Method	:	other
Year	:	1987
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Remark :

10 rats/sex, approximately 8 weeks old, with mean body weights of 167g for males and 121g for females, were randomly assigned to all study groups to be used for clinical and anatomic pathology evaluations. Additionaly, 5 male rats were assigned to the control, middle and high concentraion groups for possible ultrastructural (electron microscopic) evaluation of nerve tissue (not performed since no behavioural abnormalities or light microscopic lesions of nerve tissues were observed). Rats were exposed for 6 hr/day, 5 days/week, for 9 exposures during an 11 day period (2 days without exposure between Exposure Days 5 and 6). All animals were sacrificed on the morning after the ninth exposure. Necropsies were performed on all rats.

Results:
Rats exposed to 98, 288 or 586 ppm DMEA for 9 days (6hr/day) during an 11-day period also exhibited signs of respiratory and ocular irritation (except the 98 ppm group). All animals of the 586 ppm group and 4 of 15 male rats of the 288 ppm group died. Body weight values for the 288 ppm group were reduced to about 75% of preexposure values, while the 98 ppm group gained 35% less weight than controls. Decreases in weight of brain, kidney and testes were seen at the 288 ppm level. Statistically significant differences in clinical pathology parameters (288 ppm group) and in organ weight values (288 and 98 ppm groups) probably resulted from the decreased food consumption and not from specific target organ toxicity. In the groups evaluated histologically (the 98 and 288 ppm groups) the eye and nasal mucosa were the primary target organs. Although the nervous system was a

suspect target organ, microscopic lesions of the central (brain) or peripheral (sciatic nerve) nervous systems were not observed.
The only effect seen in the 98 ppm group was reduced weight gain, most likely due to decreased food consumption.

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (54)

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	90 days
Frequency of treatm.	:	6 hr/day 5 days/week
Post exposure period	:	
Doses	:	0, 8, 25, 75 ppm
Control group	:	yes
Method	:	other
Year	:	1987
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Remark : RATS F344
20 rats/sex, approximately 9 weeks old, with mean body weights of 180 g for males and 130 g for females, were randomly assigned to each of four study groups. Additionally, 10 male rats were assigned to the control, middle, and high concentraion groups for possible ultrastructural evaluation of nerve tissue (not performed since no behavioural abnormalities or light microscopic lesions of nerve tissue were observed). Rats were exposed for 6hr/day, 5 days/week, for 13 weeks. One half of all rats per sex per group were sacrificed after at least 2 days of exposure during the 14th week of the study: the remaining rats were sacrificed after 5 complete weeks of recovery. The study was conducted in 4320-litre stainless steel and glass chambers at airflows of 800-1000 litres/min. The target concentrations of DMEA vapour were 0, 8, 25 and 75 ppm. (Actual 8, 24 and 96 ppm).
24 and 76 ppm groups showed transient corneal opacity. In addition the 76 ppm group showed decreased body weight gain and lesions of respiratory and olfactory epithelium.
Dose or concentraion at which no toxic effects were observed: 24 ppm.

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (54)

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	13 Wochen
Frequency of treatm.	:	6 h / Tag; 5 Tage / Woche
Post exposure period	:	5 Wochen
Doses	:	8; 24; 76 ppm (0.03; 0.09; 0.28 mg/l)
Control group	:	yes, concurrent no treatment
NOAEL	:	.09 mg/l
Method	:	other
Year	:	

GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	76 ppm: Verminderte Gewichtszunahme. In der Histologie Schaedigungen des Respirationstraktes und des olfaktorischen Epithels der vorderen Nasenhoehle, bei weiblichen Tieren histologisch nachweisbare Korneaschaeden als Folge der lokalen Reizwirkung von Dimethylethanolamin. Bei Tieren, die nach 5-woechiger Nachbeobachtung untersucht wurden, zeigten sich bei der histologischen Auswertung nur noch leichte Schaedigungen des Nasengewebes. 24 ppm: Voruebergehend Korneatruebung. Keine Hinweise auf Neurotoxizitaet.
Source	:	BASF AG Ludwigshafen (53) (56)
Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	2 Wochen
Frequency of treatm.	:	6 h / Tag; 5 Tage / Woche
Post exposure period	:	keine
Doses	:	98; 288; 586 ppm (0.36; 1.07; 2.17 mg/l)
Control group	:	yes, concurrent no treatment
Method	:	other
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	In den oberen Dosierungen Schleimhautreizung (Augen und Atemwege). Alle 25 Tiere der 586 ppm-Gruppe starben, sowie 4 der 15 maennlichen Tiere der 288 ppm-Gruppe. Verminderte Gewichtszunahme in der 98 ppm-Gruppe und Gewichtsabnahme in der 288 ppm-Gruppe. In der 288 ppm-Gruppe Thymus-Atrophie. Statistisch signifikante Unterschiede zu den Kontrollen in klin.-chemischen Parametern (288 ppm; keine Einzelbefunde aufgefuehrt) bzw. in den Organgewichten (288; 98 ppm) werden von den Autoren als Folge verminderter Futteraufnahme gewertet. Bei der histologischen Untersuchung fanden sich als Folge der lokalen Reizwirkung Schaedigungen des oberen Respirationstraktes (288 ppm: Degeneration des respiratorischen und olfaktorischen Epithels; 98 ppm: Rhinitis, Epithelmetaplasie und Ulzerationen der Nasenmucosa) sowie Korneaschaeden (288 ppm). Keine histologisch nachweisbare Schaedigung des zentralen oder peripheren Nervensystems.
Source	:	BASF AG Ludwigshafen (53) (56)
Type	:	
Species	:	rat
Sex	:	no data
Strain	:	no data
Route of admin.	:	inhalation
Exposure period	:	5 Monate
Frequency of treatm.	:	4 h / Tag
Post exposure period	:	keine Angaben
Doses	:	0.67 mg/l
Control group	:	yes, concurrent no treatment

Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Verzoegerte Gewichtszunahme. Nach 3 Versuchsmonaten erniedrigte Serum-Katalase-Aktivitaet. Gestoerte Ascorbinsaeure-Synthese. Unauffaelliges Blutbild. Die beobachtete Nebennierenhyperplasie wird in Verbindung mit einem verringerten Ascorbinsaeure-Gehalt der Nebennieren von den Autoren als Hinweis auf eine Nebennieren-Ueberfunktion gesehen. Ferner werden Leber- und Nierendystrophien berichtet. Die Untersuchung entspricht in Versuchsdurchfuehrung und Ergebnisdarstellung nicht heutigen Kriterien und kann daher fuer eine Substanzbewertung nur unterstuetzend zu anderen Befunden herangezogen werden.
Source	:	BASF AG Ludwigshafen (62)

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	no data
Route of admin.	:	inhalation
Exposure period	:	9 Tage
Frequency of treatm.	:	6 Stunden pro Tag: 5 Tage, 2 Tage Pause, dann nochmals 4 Tage
Post exposure period	:	keine Angaben
Doses	:	100, 300 bzw. 600 ppm (0.37, 1.11 bzw. 2.22 mg/l)
Control group	:	yes, concurrent no treatment
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Vollstaendige Mortalitaet war bei 600 ppm, teilweise bei 300 ppm festzustellen. Koerpergewichtsverminderung wurde bei 300 ppm, verminderte Gewichtszunahme bei 100 ppm beobachtet. Klinische Anzeichen einer Schleimhautreizung (Auge, Atemwege) wurden bei 300 ppm festgestellt. Es waren keine Anzeichen neurologischer Effekte, keine histologischen Schaeden im Gehirn und sciatischen Nerv feststellbar. Gewebelaesionen am Auge wurden bei 300 ppm und im Nasalgewebe bei 100 ppm beobachtet.
Source	:	BASF AG Ludwigshafen (109)

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	
Route of admin.	:	oral feed
Exposure period	:	90 days
Frequency of treatm.	:	daily
Post exposure period	:	
Doses	:	0.45 to 0.89 gm/kg
Control group	:	
NOAEL	:	.18
LOAEL	:	.89
Method	:	other
Year	:	1951
GLP	:	no

Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	No microsomal changes were observed in liver, kidneys, spleen or testes even at the max dose but at this level liver/kidney weights increased.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(97)

Type	:	
Species	:	rat
Sex	:	no data
Strain	:	no data
Route of admin.	:	oral feed
Exposure period	:	90 Tage
Frequency of treatm.	:	kontinuierlich im Futter
Post exposure period	:	keine Angaben
Doses	:	45 - 890 mg/kg
Control group	:	no data specified
NOAEL	:	180 mg/kg
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Bei einer Dosis von 890 mg/kg wurden Veraenderungen des Lebergewichts sowie ein erhoehtes relatives Nierengewicht beobachtet. Die histologische Untersuchung der Niere war unauffaellig. Es handelt sich um einen Range-finding Versuch mit 10 Ratten/Dosisgruppe. Die Versuchsergebnisse sind lediglich summarisch kurz dargestellt.
Source	:	BASF AG Ludwigshafen

(95)

Type	:	
Species	:	rabbit
Sex	:	male/female
Strain	:	no data
Route of admin.	:	dermal
Exposure period	:	11 Tage
Frequency of treatm.	:	9 Applikationen, 6 Stunden pro Tag
Post exposure period	:	keine Angaben
Doses	:	50, 250 und 500 mg/kg/d als 50%ige waessrige Loesung
Control group	:	no data specified
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Es wurde keine Mortalitaet und keine veraenderte Futteraufnahme beobachtet. An den Applikationsstellen wurden Hautlaesionen (Oedeme, Erytheme, Nekrosen) bei allen Dosierungen beobachtet. Weiterhin wurde verminderter Harnstoffgehalt im Serum, erhoehtes Leber-, Nieren- und Nebennierengewicht und verminderte Haemoglobinkonzentration festgestellt.
Source	:	BASF AG Ludwigshafen

(109)

Type	:	
Species	:	mammal
Sex	:	no data

Strain	:	no data
Route of admin.	:	oral unspecified
Exposure period	:	6 Monate
Frequency of treatm.	:	taeglich
Post exposure period	:	keine Angaben
Doses	:	50; 100; 500 mg/kg/Tag
Control group	:	no data specified
NOAEL	:	100 mg/kg
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Spezies: Ratte, Maus Vereinzelt Todesfaelle nach Kraempfen. Die gleichen Autoren beobachteten bei Maeusen eine erniedrigte Krampfschwelle auch nach 2-woechiger peroraler Gabe von taeglich 1000 mg bzw. 31-taegiger Zufuhr mit dem Trinkwasser (0.03M). (Von den Autoren werden keine naeheren Angaben zur Versuchsdurchfuehrung gemacht, nur summarische Ergebnisdarstellung ohne Einzelbefunde)
Source	:	BASF AG Ludwigshafen (33) (71) (75)

Type	:	
Species	:	mammal
Sex	:	no data
Strain	:	no data
Route of admin.	:	unspecified
Exposure period	:	20 Tage
Frequency of treatm.	:	keine Angaben
Post exposure period	:	keine Angaben
Doses	:	175; 350 mg/kg
Control group	:	yes, concurrent no treatment
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Spezies: Ratte, Maus ZNS-stimulierender Effekt (erhoehte Spontanaktivitaet und Reflexantwort) und erhoehter Muskeltonus bei Ratte und Maus. (Angaben aus dem Abstract einer polnischen Arbeit)
Source	:	BASF AG Ludwigshafen (35)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Salmonella typhimurium reverse mutation assay
System of testing	:	TA100
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	:	no data
Result	:	negative
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Ames et al, Mutat Res 31 347-364. 1975

Not mutagenic to bacteria
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (67)

Type : Salmonella typhimurium reverse mutation assay
System of testing : TA100, TA1537, TA98
Test concentration :
Cycotoxic concentr. :
Metabolic activation :
Result : negative
Method : other
Year :
GLP : yes
Test substance :

Remark : Ames et al
Not a bacterial mutagen
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (124)

Type : Salmonella typhimurium reverse mutation assay
System of testing : TA98, TA100, TA1535, TA1537, TA1538
Test concentration :
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :
Year :
GLP : yes
Test substance :

Remark : Ames et al, Mutat Res 31 347-364 (1975)
The test substance did not produce a positive or dose-dependent mutagenic response in any of the bacterial strains tested with or without a metabolic activation system.
Not a bacterial mutagen.
Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (118)

Type : Mammalian cell gene mutation assay
System of testing : CHO/HGPRT Gene Mutation Test
Test concentration : 0.1 - 0.3 mg/ml
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :
Year :
GLP : yes
Test substance :

Remark : The lowest concentration producing cell toxicity
with metabolic activation: >3mg/ml
without metabolic activation: 1mg/ml
The test substance did not produce any statistically significant increases in the incidence of mutations of CHO cells at concentrations between 0.1 to 0.3 mg/ml in tests without an S9 metabolic activation system. However, three of the five lowest doses produced increased frequencies of mutants which were 2 to 3 times greater than the concurrent controls. These increases were not repeatable in a

duplicate culture at the same respective doses and no dose-related trend in the mutation index was observed at higher doses. Since similar random variability was observed during recent CHO/HGPRT tests at BRRC, the random increases were not judged to be a positive test result. With S9 activation, no statistically significant or dose-related trend in the numbers of mutants was observed. All of the mutant indices for the dosed cultures were within the typical range of variation for this test based upon historical negative control variability at BRRC. DMEA was judged to lack significant mutagenic potential under the conditions of the CHO/HGPRT test system.

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (117)

Type : Mammalian cell gene mutation assay
System of testing : Sister Chromatid Exchange Assay
Test concentration : 0.1 - 0.3 mg/ml
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method :
Year :
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Remark : The test substance was concluded to lack clastogenic potential under the conditions of the SCE test system.
Lowest concentration producing cell toxicity
with metabolic activation: >3mg/ml
without metabolic activation: 1mg/ml
Not a clastogen

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (115)

Type : Ames test
System of testing : Salmonella typhimurium; TA98 TA100
Test concentration : 100 ul/Platte
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method : other: nach Ames, B.N. et al.: Mutation Research 31, 347-364
Year : 1975
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : BASF AG Ludwigshafen (66)

Type : Ames test
System of testing : Salmonella typhimurium TA97, TA 98, TA100, TA1535, TA1537
Test concentration : bis zu 10 mg/Platte
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method : other: nach Haworth, S. et al.: Environ. Muatgen. 5, Suppl. 1, 3-142
Year : 1983
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Source : BASF AG Ludwigshafen

(69) (125)

Type	:	Ames test
System of testing	:	Salmonella typhimurium
Test concentration	:	keine Angaben
Cycotoxic concentr.	:	
Metabolic activation	:	no data
Result	:	ambiguous
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(68)

Type	:	Escherichia coli reverse mutation assay
System of testing	:	Escherichia coli SD-4-73
Test concentration	:	10 - 25 ul/Platte ("paper-disk method")
Cycotoxic concentr.	:	
Metabolic activation	:	without
Result	:	negative
Method	:	other: nach Iyer, V.N. und Szybalski, W.: Appl. Microbiol. 6, 23-29
Year	:	1958
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(101)

Type	:	Ames test
System of testing	:	Salmonella typhimurium (5 Staemme, keine Angaben)
Test concentration	:	10 - 20000 ug/Platte
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

(109)

Type	:	HGPRT assay
System of testing	:	Chinese Hamster Ovary Cells (CHO)
Test concentration	:	keine Angaben
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: no data
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Testsubstanz fuehrte nicht zu einer statistisch signifikanten Erhoehung der Mutationen in CHO Zellen zwischen 0.1 und 0.3 mg/ml ohne S9-Aktivierung. Jedoch wurde bei den geringen Konzentrationen teilweise erhoehte Mutationsfrequenz festgestellt, die 2- bis 3-fach ueber dem Kontrollwert lag. Diese Ergebnisse waren jedoch nicht

reproduzierbar und es war keine Dosis-Wirkungsbeziehung zu erkennen. Mit S9-Aktivierung war keine dosisabhaengige, statistisch signifikante Zunahme der Mutationsrate festzustellen.

Source : BASF AG Ludwigshafen

(109) (111)

Type : Sister chromatid exchange assay
System of testing : Chinese Hamster Ovary Cells (CHO)
Test concentration : keine Angaben
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method : other: no data
Year :
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Source : BASF AG Ludwigshafen

(109) (111)

Type : Ames test
System of testing : Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Test concentration : keine Angaben
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method : other: nach Ames, B.N. et al.: Mutation Research 31, 347-364
Year : 1975
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Source : BASF AG Ludwigshafen

(113)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : Drosophila SLRL test
Species : Drosophila melanogaster
Sex : no data
Strain : no data
Route of admin. : unspecified
Exposure period : keine Angaben
Doses : keine Angaben
Result :
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4

Result : Keine mutagene Wirkung
Source : BASF AG Ludwigshafen

(70)

Type : Micronucleus assay
Species : mouse
Sex : male/female
Strain : Swiss Webster
Route of admin. : i.p.
Exposure period : keine Angaben

Doses	:	270, 540, 860 mg/kg
Result	:	
Method	:	other: EPA-Guideline 560/5-83-001; nach Schlegel und MacGregor, Mutation Research 104, 367-369
Year	:	1982
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	negativ
Source	:	BASF AG Ludwigshafen (109) (112)
Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	Swiss Webster
Route of admin.	:	i.p.
Exposure period	:	
Doses	:	0,270,540,860mg/kg
Result	:	
Method	:	
Year	:	
GLP	:	yes
Test substance	:	
Remark	:	Chromosome damage was measured by quantifying the incidence of micronuclei in peripheral blood polychromatic erythrocytes (PCE) at three sampling intervals following injection. Procedures used for this study were consistent with the general recommendations in the Environmental Protection Agency - Health Effect Test Guidelines, EPA Report 560/5-83-001. The specific test system employed peripheral blood erythrocytes from mice following improved procedures for the micronucleus test suggested by Schlegel and MacGregor (Mutation Research, 104, 367-369, 1982). Test results for this study showed that DMEA was not an active agent in producing treatment - related increases in numbers of micronuclei in PCE's of Swiss-Webster mice. Relatively high dose levels of DMEA were tested, up to 80% of the LD50 (860mg/kg) with no indication of significant induction of micronuclei. Test substance does not possess clastogenic activity in vitro under the conditions of the micronucleus test system.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire (116)

5.7 CARCINOGENICITY

Species	:	mouse
Sex	:	female
Strain	:	other: C3H/HeN; C3H/HeJ(+)
Route of admin.	:	drinking water
Exposure period	:	105 bzw. 123 Wochen
Frequency of treatm.	:	kontinuierlich im Trinkwasser
Post exposure period	:	keine Angaben
Doses	:	10 (C3H/HeN-Maeuse) bzw. 15 (C3H/HeJ(+)-Maeuse) mM im Trinkwasser (entspr. 890 bzw. 1340 mg/l / entspr. ca. 200-300 mg/kg KG/d)
Result	:	
Control group	:	yes, concurrent no treatment
Method	:	other: no data

Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Kein signifikanter Unterschied in den Ueberlebensraten von Kontrollen und behandelten Tieren. Keine erhoehte Tumorinzidenz. Bei den behandelten Tieren war der Gehalt an Lipofuscin in der Leber erniedrigt. Bei beiden Maeusestaemmen handelt es sich um Traeger von Brustdruesen-Tumor-Proviren.
Source	:	BASF AG Ludwigshafen

(98)

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	6-15 days
Frequency of treatm.	:	daily
Duration of test	:	
Doses	:	0,10,30,100ppm Gestational days 6-15
Control group	:	
NOAEL maternal tox.	:	10 ppm
NOAEL teratogen.	:	100 ppm
Method	:	other
Year	:	1986
GLP	:	yes
Test substance	:	
Remark	:	Timed-pregnant Fischer 344 rats were exposed to N,N-dimethylethanolamine (DMEA) by inhalation of vapour on gestational days (gd) 6 through 15 at exposure target concentrations of 0, 10, 30 or 100ppm. The mean analytical values were 0.1, 10.4, 29.8 and 100ppm, respectively. Clinical observations were performed daily, and maternal body weights were determined on gd 0, 6, 9, 12, 15 and 18. At scheduled necropsy on gd 21, dams were evaluated for body weight and liver weight, gravid uterine weight and status of implantation sites (ie, resorptions, dead fetuses, liver fetuses). Live fetuses were dissected from the uterus, counted, weighted, sexed and examined for external abnormalities. Approximately one-half of the live fetuses in each litter were examined for visceral malformations by the method of Staples (Teratology 9, A-37, 1974). These fetuses were then decapitated and the heads fixed in Bouin's solution and examined for soft tissue craniofacial malformations according to the techniques of Wilson (Teratology Principles and Techniques 251-277, 1965, Environment and Birth defects, 1973) and van Julsingha and Bennett (Methods of Prenatal Toxicology, 126-144 1977). The remaining intact fetuses in each litter were eviscerated, fixed in alcohol, stained with alizarin red S and examined for skeletal defects and deficits. Dose levels: 0, 10, 30, 100ppm Gestational days 6-15

No of animals: 25 per exposure group
No of litters examined: Oppm: 22, 10ppm: 23, 30ppm: 22, 100ppm: 23
There was no maternal mortality. Maternal toxicity was observed: reduced body weight at 100ppm during and after exposures, reduced weight gain during but no after the exposure period, and ocular changes, more profound at 30 and 100ppm, minimal and transient at 10ppm. At sacrifice, maternal body weight was reduced at 100ppm but there were no treatment-related changes in gravid uterine weight, body weight corrected for gravid uterine weight or absolute or relative liver weight.
There were no effects of treatment on any reproductive parameters including pre-and postimplantation loss or sex ratio. Fetal body weights per litter (for males and females but not for total) were increased at 100ppm relative to controls.
There were no concentration-related increases in individual malformations, malformations by category (external visceral or skeletal) or total malformations. The incidence of fetal variations did not indicate a consistent pattern indicative of fetal toxicity. One fetal variation, split (bipartite) cervical centrum, was elevated at 100ppm relative to controls in the absence of any other indications of delayed ossification or of any indications of reduced fetal body weights.
There was no evidence of embryonic or fetal toxicity (including teratogenicity) at any exposure concentrations employed, including those which produced maternal toxicity.

Source : ICI Chemicals & Polymers Limited Runcorn, Cheshire (114)

Species	:	rat
Sex	:	female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	6. bis 15. Tag der Traechtigkeit
Frequency of treatm.	:	taeglich, 6 Stunden pro Tag
Duration of test	:	21 Tage
Doses	:	10, 30 bzw. 100 ppm (0.04, 0.11 bzw. 0.37 mg/l)
Control group	:	yes, concurrent no treatment
Method	:	other
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4

Result : Je Dosisgruppe wurden 25 Tiere eingesetzt. Verminderte maternale Gewichtszunahme waehrend, jedoch nicht nach der Expositionszeit, reversibel in der 10 und 30 ppm Gruppe. Veraenderungen an den Augen und makroskopische Veraenderungen der Leber. Keine Veraenderung des relativen Uterus- und Lebergewichtes. Es wurde keine Mortalitaet beobachtet und keine Anzeichen von reproduktiven Effekten, Teratogenitaet, fetaler bzw. embryonaler Toxizitaet festgestellt.

Source : BASF AG Ludwigshafen (109) (110)

Species	:	rat
Sex	:	female
Strain	:	Sprague-Dawley

Route of admin.	:	oral feed
Exposure period	:	15 Tage ante partum - 15 Tage post partum
Frequency of treatm.	:	kontinuierlich im Futter
Duration of test	:	keine Angaben
Doses	:	1% in Cholin-defizientem Futter (ca. 833 mg/kg/d)
Control group	:	other: 1) Cholin-defizientes Futter; 2) Cholin-substituiertes Futter
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Maternale Tox: nicht beobachtet
Result	:	Unauffaellige Gestationsperiode, keine Mortalitaet bei den Muttertieren; jedoch hohe postnatale Mortalitaet der Nachkommen (Ueberlebensrate nach 36 h: 8 %). Im Vergleich zu den Kontrolltieren bei den Muttertieren keine Unterschiede im Phospholipid-Gehalt des Gehirns, dagegen bei den Jungtieren erhoehte Cholin- und Acetylcholin-Spiegel in Gehirn und Leber bei gleichzeitigem Rueckgang der Phosphatidylcholin und Phosphatidylaminoethanol-Konzentration im Gehirn. Histologisch keine Veraenderungen im Gehirn der Jungtiere. Ferner war bei den Jungtieren ein erniedrigter Surfactant-Gehalt der Lunge auffaellig (in geringem Masse wurde dies auch unter Cholin-defizienter Diaet beobachtet). Die hohe postnatale Mortalitaet wird von den Autoren auf eine gestoerte Surfactant-Bildung zuruckgefuehrt.
Source	:	BASF AG Ludwigshafen

(50) (123)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

Remark	:	A single dose of 2500 mg taken in a suicide attempt resulted in no adverse effects.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(38)

Remark	:	Progressively severe sneezing, rhinorrhea, cough, wheezing and dyspnea development was reported in a spray painter. No analytical data on concentration of dimethylaminoethanol is given.
Source	:	ICI Chemicals & Polymers Limited Runcorn, Cheshire

(119)

Remark	:	Es liegen keine Untersuchungsberichte der BASF vor.
Source	:	BASF AG Ludwigshafen

5.11 ADDITIONAL REMARKS

Type : Biochemical or cellular interactions

Remark : Bei Maeusen wurde nach i.p.-Injektion von 267 mg Dimethylethanolamin/kg eine erhoehte Cholinkonzentration in Serum und Nieren beobachtet. Von den Autoren wird vermutet, dass Dimethylethanolamin den Cholin-Metabolismus im Gewebe hemmt und so zu einem erhoehten Serum-Spiegel an freiem Cholin fuehrt, welches die Blut-Hirn-Schranke ueberwindet und zentralnervoese Wirkung hat.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(44)

Type : Biochemical or cellular interactions

Remark : Dimethylethanolamin kann sowohl in vitro als auch in vivo die Cholinesterase-Aktivitaet hemmen.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(43)

Type : Biochemical or cellular interactions

Remark : Dimethylethanolamin ist ein Zwischenprodukt der endogenen Cholinsynthese; es zeigt zentral-stimulierende Wirkung.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(72)

Type : Biochemical or cellular interactions

Remark : Dimethylethanolamin hat keinen inhibitorischen Effekt auf die Cholinphosphotransferase-Aktivitaet in Meerschweinchenlungen-Mitochondrien bzw. -Mikrosomen.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(99)

Type : Biochemical or cellular interactions

Remark : Die intravenoese Infusion von Dimethylethanolamin (0,3 mg/kg/min ueber 15 Std.) in maennliche Wistar Ratten verbesserte die durch Oestradiol 17 beta-D-Glukuronid induzierte Cholestase. Der Nachweis erfolgte biochemisch, biophysikalisch und ultrastrukturell.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(1)

Type : Chemobiokinetics general studies

Remark : Nach intracerebraler Injektion (Ratte) wurde 14C-Dimethylethanolamin schnell aus dem Gehirn eliminiert (nach 0.5; 1; 7 h waren nur noch 30; 27; bzw. 16% der Radioaktivitaet nachweisbar). Der Phosphodimethylethanolaminspiegel erreichte 1-2 h nach der Injektion sein Maximum, die Konzentration von Phosphatidylethanolamin stieg waehrend der gesamten

7stuendigen Beobachtungsperiode an. Auch nach intraperitonealer Gabe von radioaktiv markiertem Dimethylethanolamin stieg der Gehalt an Phosphatidylethanolamin im Gehirn an; die Spiegel waren 10-40fach hoeher als jene von Phosphodimethylethanolamin.

Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(2)

Type : Chemobiokinetics general studies

Remark : Beim Kaninchen fuehrte die 3-woechige Gabe von zunaechst 15, dann 30 mM Dimethylethanolamin im Trinkwasser (entsprechend 245 bzw. 420 mg/kg/d) zu erhoehtem Cholin-Spiegel im Plasma und Liquor, wahrscheinlich aufgrund vermehrter endogener Cholin-Bildung. Die Plasma-Spiegel der Acetylcholin Vorlaeufer Lecithin, Lysolecithin und Sphingomyelin blieben von der Substanzgabe unbeeinflusst.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(32)

Type : Distribution

Remark : Nach intravenoeser Gabe von 14C-Dimethylethanolamin (Maus) wurden im Gehirn Phosphoryldimethylethanolamin und Phosphatidyldimethylethanolamin, sowie Cholinderivate nachgewiesen.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(65)

Type : Excretion

Remark : Verglichen mit der Trimethylaminbildung nach Cholin-Gabe, fuehrte Dimethylethanolamin (Ratte, 15 nmol/kg = 1340 mg/kg p.o.) nur zu einem minimalen Anstieg von Dimethylamin im Harn.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(126)

Type : Metabolism

Remark : Nach Inkubation von Dimethylethanolamin mit Mikrosomen aus Rattenleber bzw. -nasenhoehle fand sich keine Metabolisierung zum Formaldehyd.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(34)

Type : Metabolism

Remark : Die intrazerebrale Umwandlung in Acetylcholin wird vermutet, konnte jedoch im Tierversuch bisher nicht bestaetigt werden.
Source : BASF AG Ludwigshafen
Test substance : Dimethylaminoethanol

(88)

Type : Metabolism

Remark	:	Bei Untersuchungen an Ratten mit radioaktiv markiertem Dimethylethanolamin-Maleat wurde beobachtet, dass Dimethylethanolamin im Phospholipid-Zyklus metabolisiert wird und als Metaboliten u.a. Phosphoryldimethylaminoethanolamin und Glycerophosphatidylcholin entstehen.
Source	:	BASF AG Ludwigshafen
Test substance	:	Dimethylaminoethanol

(37)

Type	:	other
Remark	:	Dimethylethanolamin wirkt als OH-Radikal-Faenger
Source	:	BASF AG Ludwigshafen
Test substance	:	Dimethylaminoethanol

(127)

Type	:	other
Remark	:	Dimethylethanolamin - als Acetamidobenzoat verabreicht - erhoehte die Ueberlebenszeit seniler A/J-Maeuse (3monatige Gabe von taeglich 7 mg Dimethylethanolamin/kg im Trinkwasser).
Source	:	BASF AG Ludwigshafen
Test substance	:	Dimethylaminoethanol

(45)

Type	:	other: zuammenfassende Darstellungen
Remark	:	Zusammenfassende Darstellungen
Source	:	BASF AG Ludwigshafen
Test substance	:	Dimethylaminoethanol

(33) (72) (89)

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT