IUCLID 5

Printing Date 2010-01-27 12 44 30 EST
Restriction of specific regulatory purposes
EU BPD, EU PPP, EU REACH, CA CEPA, CA PCPA, JP CSCL, OECD HPVC, US EPA HPVC, US FIFRA, US TSCA, other
Confidentiality
CBI, IP, no PA
Name 929-06-6_master_2-(2-aminoethoxy)ethanol (IUC4 DSN 504)
Legal entity owner The Acta Group EU, Ltd / Runcorn / United Kingdom

Substance: 929-06-6_master_2-(2-aminoethoxy)ethanol (IUC4 DSN 504)

UUID IUC4-8389eda9-c5e7-36ff-b35a-82b61fe6ef9c
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-21 21:05:07 EST
Remarks

0 Related Information
0.1 Templates
0.2 Categories
0.3 Mixtures
1 General Information
1.1 Identification
Substance identification

Chemical name 929-06-6_master_2-(2-aminoethoxy)ethanol (IUC4 DSN 504)
US: EPA HPVC
Legal entity The Acta Group EU, Ltd / Runcorn / United Kingdom

Role in the supply chain

Role: (X) Manufacturer (X) Importer ( ) Only representative ( ) Downstream user

Reference substance

Reference substance 2-(2-aminoethoxy)ethanol

EC number	EC name
213-195-4	2-(2-aminoethoxy)ethanol

CAS number **CAS name**

IUPAC name

Type of substance

Composition mono constituent substance
Origin organic

Trade names

Name 2,2'-Aminoethoxyethanol
Name Ethanol, 2-(2-aminoethoxy)- (7CI, 8CI, 9CI)
Name .beta.-Hydroxy-.beta.'-aminoethyl ether
Name .beta.-(.beta.-Hydroxyethoxy)ethylamine
Name 2-Hydroxyethyloxyethylamine
Name Ethanol, 2-(2-aminoethoxy)-
Name 2-(2-Aminoethoxy)ethanol
Name b-(b-Hydroxyethoxy)ethylamine
Name b-Hydroxy-b'-aminodiethyl ether
Name 1-Amino-2-(2-hydroxyethoxy)ethane
Name 2-(2-Hydroxyethoxy)ethylamine
Name 2-(Hydroxyethoxy)ethylamine
Name 2-Amino-2'-hydroxydiethyl ether
Name 2-Aminoethyl 2-hydroxyethyl ether
Name 5-Amino-3-oxapentan-1-ol
Name 5-Hydroxy-3-oxapentylamine
Name Diethylene glycol amine
Name Diethylene glycol monoamine
Name Diglycolamine
Name (2-hydroxyaethyl)-(2-aminoaethyl)-aether

Contact person

Person flags **US: EPA HPVC**
Organisation The AEE Consortium
Department BASF Corporation
Title Chair
First name Jodi
Last name Visco
Phone 973 245 6124
E-mail jodi.visco@basf.com
Address 100 Campus Drive
Postal code 07932
Town Florham Park
Region / State NJ
Country United States of America

1.2 Composition
Substance composition

Name ethanol, 2-(2-aminoethoxy)

Degree of purity

> 95

1.3 Identifiers
Identifiers

1.4 Analytical information
1.5 Joint submission
1.6 Sponsors

Sponsors

Name	The AEE Consortium
Type	consortium

Contact information

Address	BASF Corporation
Address	100 Campus Drive
Postal code	07932
Town	Florham Park
Region / State	NJ
Country	
Phone	973 245 6124
E-mail	jodi.visco@basf.com

Name	The AEE Consortium
Type	consortium

Contact information

Address	The Huntsman Corporation
Address	8600 Gosling Road
Postal code	77381
Town	The Woodlands
Region / State	TX
Country	
Phone	(281) 719-3017
E-mail	ray_papciak@huntsman.com

Contact persons

Appearance/physical state/colour, IUC4#2/Ch.1.1.1

UUID	IUC4-fa3673c4-f0e2-39d1-8d7b-3eb85e3f0465
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-11-10 23:53:50 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Data are from peer reviewed published data base

Data source

Reference

Reference type	review article or handbook		
Author	Hazardous Substances Data Bank - HSDB (through 2003/12)	Year	2003
Title	Hazardous Substance Data Bank		
Bibliographic source			
Testing laboratory		Report no.	
Owner company			
Company study no.		Report date	

Reference type	review article or handbook		
Author	Hawley, G.G.	Year	1981
Title	The Condensed Chemical Dictionary. 10th ed. New York: Van Nostrand Reinhold Co., 51		
Bibliographic source			
Testing laboratory		Report no.	
Owner company			
Company		Report	

study no. | date

Data access

data published

Materials and methods

Test guideline

Qualifier

Guideline other guideline:

Deviations

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number

Identity 929-06-6

Identifier EC number

Identity 213-195-4

Identifier EC name

Identity 2-(2-aminoethoxy)ethanol

Results and discussion

Physical state at 20ºC and 1013 hPa

liquid

Form

other: slightly viscous

Colour

colorless [R2]

Odour

other: mild amine odor [R2]

Overall remarks, attachments

Overall remarks

GESTIS. Appearance/physical state/colour.001

UUID IUC5-de065465-db2e-4b6f-b65f-8bd8e2fc552c
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:14:40 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type secondary source
Author GESTIS **Year** 2008
Title Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source online query 29 Sep 2008
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other: visual inspection

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussion

Physical state at 20ºC and 1013 hPa

liquid

Colour

colourless

Odour

other: amine-like

Substance type

organic

Appearance/physical state/colour, IUC4#1/Ch.1.1.1

UUID IUC4-9e1c98c6-08ad-39a2-9f11-259c9640e84f
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-10 23:47:21 EST
Remarks

Administrative Data

Purpose flag supporting study ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 4 (not assignable)
Rationale for reliability Company Material Safety Data Sheet

Data source

Reference

Reference type company data
Author BASF AG **Year** 2003
Title Safety data sheet 2-(2-Aminoethoxy)Ethanol, 06.06.2003 (30036979
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4
Identifier EC name
Identity 2-(2-aminoethoxy)ethanol

Results and discussion

Physical state at 20°C and 1013 hPa

liquid

Colour

colourless to slightly yellow

Odour

other: amine-like

4.2 Melting point/freezing point

Melting point/freezing point

UUID	IUC5-56b442a5-da15-4917-ae34-93d309d319ce
Dossier UUID	0
Author	jaeckhc / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-05-08 03:14:50 EDT
Remarks	

Administrative Data

Short description of key information

-12.5

HSDB_Hawley. Melting point/freezing point.key

UUID	IUC5-a3c11ea1-7b4d-41a0-bf5d-4ec1d6afd8d9
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 15:23:54 EST
Remarks	

Administrative Data

[]

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	other:
Reliablility	2 (reliable with restrictions)
Rationale for reliability	peer reviewed data base

Data source

Reference

Reference type	secondary source		
Author	Hawley, G.G.	**Year**	1981
Title	The Condensed Chemical Dictionary. 10th ed.		
Bibliographic source	New York: Van Nostrand Reinhold Co., 1981., p. 51. cited in HSDB 21 Sep 2006		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Melting / freezing point

Melt./Freez. pt.	-12.5 °C
Atm. pressure	
Decomposition	
Decomp. temp.	
Sublimation	
Subl. temp.	
Remarks	

Overall remarks, attachments

Overall remarks

Knovel Solvents. Melting point/freezing point.002

UUID IUC5-6a34b343-492f-4a1c-ac3a-462cd26d4cec
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:36:48 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type other: authoritive database
Author Wypych, George **Year** 2000
Title Knovel Solvents - A Properties Database
Bibliographic source © 2008 Knovel Corporation. All rights reserved; © 2000 ChemTec Publishing
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Type of method

other:

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Melting / freezing point

Melt./Freez. pt. -12.5 °C
Atm. pressure
Decomposition
Decomp. temp.
Sublimation
Subl. temp.
Remarks

GESTIS. Melting point/freezing point.003

UUID IUC5-281b28f6-ee62-4dde-a636-7425f478018e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-10 23:58:51 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type secondary source
Author GESTIS **Year** 2007
Title Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source query date 05 June 2007
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Melting / freezing point

Melt./Freez. pt. -11 °C
Atm. pressure
Decomposition
Decomp. temp.
Sublimation
Subl. temp.
Remarks

Overall remarks, attachments

Overall remarks

Knovel_DIPPR. Melting point/freezing point.004

UUID IUC5-225a34d3-f32b-4be3-afde-5eb2aca0572b
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:32:39 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: Peer reviewed database
Author AIChE **Year** 2008
Title Design Institute for Physical Properties, Sponsored by AIChE © 2005 Design Institute for Physical Property Data/AIChE; DIPPR Project 801 - Full Version; online query 29 Sep 2008
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Melting / freezing point

Melt./Freez. pt. -13 °C
Atm. pressure
Decomposition
Decomp. temp.
Sublimation
Subl. temp.
Remarks

4.3 Boiling point

Boiling point

UUID	IUC5-04249152-8624-4c77-8177-3a29aa07891c
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:23:44 EST
Remarks	

Administrative Data

Short description of key information

222.5 - 223.8 at 1013 hPa

BASF AG (1996). Boiling point.key

UUID	IUC5-6a4d5037-c757-446d-8e53-09f63af879bc
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-11-11 00:08:47 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	scientifically acceptable

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1996
Title	Bestimmung des Siedeverlaufs von Aminodiglykol bei 1013 mbar		
Bibliographic source			
Testing laboratory	BASF AG, Technische Entwicklung Verfahrenstechnik	**Report no.**	FE 96.355
Owner company	BASF SE, D-67056 Ludwigshafen		
Company study no.		**Report date**	1996-07-15

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier	
Guideline	other guideline: DIN 53406, resp. ASTM D 850
Deviations	

Principles of method if other than guideline

other: measured based on DIN 53406, resp. ASTM D 850

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: purity 98.2 %

Any other information on materials and methods incl. tables

Results and discussions

Boiling point

Boiling pt.	222.5 — 223.8 °C
Atm. pressure	1013 hPa
Decomposition	
Decomp. temp.	
Remarks	

Remarks on results including tables and figures

```
RS-Freetext:
Distillation range: 222.5 - 223.8 °C (1013 hPa)
Initial Boiling Point (IBP): 222.5 °C (1013 hPa)
Dry point temperature (DPT): 223.8 °C (1013 hPa)
```

BASF AG (1978). Boiling point.002

UUID IUC5-26deb1fb-ab36-4e73-a7ff-c620e3be3a5f
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-11 00:10:00 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable

Data source

Reference

Reference type study report
Author BASF AG **Year** 1978
Title
Bibliographic source
Testing laboratory BASF AG. Analytisches Labor **Report no.** PH 6666
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1978-07-16

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Boiling point

Boiling pt. 222.3 °C
Atm. pressure 1013 hPa
Decomposition
Decomp. temp.
Remarks

HSDB_Hawley. Boiling point.003

UUID IUC5-fb700b6a-3095-4964-b727-998231ce1b0c
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:44:39 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable; peer reviewed data base

Data source

Reference

Reference type other: peer reviewed database
Author Hawley, G.G. **Year** 1981
Title The Condensed Chemical Dictionary. 10th ed. New York: Van Nostrand Reinhold Co.,p. 51. cited in HSDB 21 Sep 2006
Bibliographic source HSDB
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Boiling point

Boiling pt. 221 °C
Atm. pressure 1013 hPa
Decomposition
Decomp. temp.
Remarks

Overall remarks, attachments

Overall remarks

GESTIS. Boiling point.004

UUID IUC5-6e8a533a-3c4a-40ad-850c-8edbba41b4f7
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-11 00:14:31 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type secondary source
Author GESTIS **Year** 2007
Title - Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA), query date 05 June 2007
Bibliographic source data base
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Boiling point

Boiling pt. 218 — 224 °C
Atm. pressure 1013 hPa
Decomposition
Decomp. temp.
Remarks

Overall remarks, attachments

Overall remarks

4.4 Density

Density

UUID	IUC5-13ab664a-399b-44ea-a685-f07d99bf0c73
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:23:48 EST
Remarks	

Administrative Data

Key parameter (optional)

Density in g/L (= kg/m³) at 20°C

1060

HSDB_Hawley. Density

UUID IUC5-1872f76c-4ba0-41a6-ac72-80ff744664fe
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:46:03 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification (X) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base; scientifically database

Data source

Reference

Reference type other: peer reviewed database
Author Hawley, G.G. **Year** 1981
Title The Condensed Chemical Dictionary
Bibliographic source New York: Van Nostrand Reinhold Co., 1981., p. 51. cited in HSDB 21 Sep 2006
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Reference type review article or handbook
Author Beilstein **Year** 1988
Title Registry No. 906728
Bibliographic source Beilstein Institut zur Foerderung der Chemischen Wissenschaften licensed to Beilstein GmbH and MDL Information Systems GmbH. Registry No. 906728, query dat2 25 Oct 2006
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Reference type secondary source
Author BGIA - Institute for Occupational Safety **Year** 2009
Title GESTIS - Database on hazardous substances query Nov 2009
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other: measured

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussion

Density

Type relative density
Density 1.06 g/cm³
Temp. 20 °C

Overall remarks, attachments

Overall remarks

Knovel_Yaws. Density.004

UUID	IUC5-3204f8d1-2a78-4dba-ab18-8046e1a37dc3
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-11-11 22:58:14 EST
Remarks	

Administrative Data

Purpose flag	supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	authoritative handbook

Data source

Reference

Reference type	review article or handbook		
Author	Yaws, Carl L.	**Year**	2008
Title	Yaws' Handbook of Physical Properties for Hydrocarbons and Chemicals		
Bibliographic source	© 2008 Knovel Corporation. All rights reserved.		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussion

Density

Type	density
Density	1051 kg/m³
Temp.	25 °C

4.6 Vapour pressure

Vapour pressure

UUID	IUC5-3658ac1d-67d1-4967-8b40-de17bf3960d5
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:23:53 EST
Remarks	

Administrative Data

Short description of key information

0.002 hPa at 25 °C

HSDB_Daubert. Vapour pressure.001

UUID IUC5-7484ad97-59f3-4ab8-8065-eb3c1884ba09
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 15:52:54 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: cited in peer reviewed database
Author DAUBERT,TE & DANNER,RP **Year** 1989
Title no data
Bibliographic source cited in SRC PhysProp Database, 04 Jun 2007
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other (measured)

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Vapour pressure

0.002 hPa **at** 25 °C

Remarks

Overall remarks, attachments

Overall remarks

BASF AG (1982). Vapour pressure.002

UUID IUC5-690ac8c9-2fd6-41ed-8db0-41aa5b041f03
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-11 23:13:15 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable although not conducted at standard temperature.

Data source

Reference

Reference type study report
Author BASF AG **Year** 1982
Title
Bibliographic source
Testing laboratory BASF AG, Physikalische Chemie **Report no.** BRU 82.23
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1982-02-23

Data access

data submitter is data owner

Materials and methods

Principles of method if other than guideline

other (measured): dynamisch

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Vapour pressure

0.5 hPa **at** 58.5 °C

Remarks

Overall remarks, attachments

Overall remarks

```
Year: 1982 (unclear if "Year of test guideline" or "Year of study completion".)
RM-Freetext:
Temperatur in Grad C/Druck in hPa: 58.5/0.500; 67.9/1.00;
77.9/2.00; 92.5/5.00; 117.8/20.0; 137.0/50.0; 153.5/100.0;
171.4/200.0; 198.5/500.0; 222.3/988.7
```

GESTIS. Vapour pressure.003

UUID IUC5-499cac9c-171a-46a4-90f6-f2573edb048e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 16:03:36 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type other: authoritative database
Author GESTIS **Year** 2007
Title Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source query date 05 June 2007
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Principles of method if other than guideline

Method: other (measured)

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Vapour pressure

< 0.1 hPa **at** 20 °C

Remarks reported as mbar in original reference

Overall remarks, attachments

Overall remarks

BASF AG (1977). Vapour pressure.004

UUID IUC5-887149a7-61ec-45d0-929a-a897b48f42af
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 16:10:21 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability well conducted study eventhough not recorded at standard temperature

Data source

Reference

Reference type study report
Author BASF AG **Year** 1977
Title
Bibliographic source
Testing laboratory BASF AG, TET/VF3 **Report no.** Job No. 33/740
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1977-07-10

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other (measured)

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Vapour pressure

1.18 hPa **at** 70 °C
Remarks

847.4 hPa **at** 215.1 °C
Remarks color of the substance shifts to brown

Transition / decomposition

Transition / decomposition ambiguous
at < 215 °C
Vapour pressure at 10° C above transition temperature
Vapour pressure at 20° C above transition temperature

Remarks on results including tables and figures

Temperature in Grad C/in hPa: 70.0/1.18; 79.0/2.12; 90.4/4.38; 105.2/10.30; 124.3/26.77; 144.7/70.17; 164.1/153.7; 182.8/312.4; 206.4/661.8; 215.1/847.4

Overall remarks, attachments

Overall remarks

BASF AG (1978_07). Vapour pressure.005

UUID IUC5-fc9474ec-2e55-4c42-8d39-c70d3be443f1
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-11 23:15:24 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable although not conducted at standard temperature

Data source

Reference

Reference type study report
Author BASF AG **Year** 1978
Title
Bibliographic source
Testing laboratory BASF AG, Analytisches Labor **Report no.** PH 6666
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1978-07-16

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

other (measured)

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: 99.3 %

Results and discussions

Vapour pressure

1.3 hPa **at** 70 °C

Remarks

Overall remarks, attachments

Overall remarks

```
Year: 1978 (unclear if "Year of test guideline" or "Year of study completion".)
RM-Freetext:
Temperatur in Grad C/Dampfdruck in hPa: 70/1.3; 80/2.7;
90/4.8; 100/8.5; 110/14.5; 120/24.1; 130/39.1; 140/61.5;
150/92.9; 160/137; 170/197; 180/281; 190/389; 200/532;
210/707; 220/931; 223.3/1013
```

4.7 Partition coefficient

Partition coefficient

UUID	IUC5-c8c0c014-76be-41e3-9215-43fc5cd03f09
Dossier UUID	0
Author	jaeckhc / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-05-08 02:51:51 EDT
Remarks	

Administrative Data

Short description of key information

-1.89 at 20 °C

EPISuite 4.0 (2009). Partition coefficient.key

UUID IUC5-bda020c7-83ab-4fbd-af23-f1e74b5d64c6
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 16:35:16 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation **Study period** 12-12-2009
Reliablility 2 (reliable with restrictions)
Rationale for reliability Accepted calculation method

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title KOWWINv1.67; Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB).
Bibliographic source EPISuite v4.0 model performed
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

data published

Materials and methods

Partition coefficient type

octanol-water

Type of method

other:

Principles of method if other than guideline

other (calculated): EPISuite 4.0 (EPIWEB); KOWWIN v1.67 (2009)

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier other:
Identity uncharged molecule

Results and discussions

Partition coefficient

Type log Pow
Partition coefficient -1.89
Temp.
pH

Remarks on results including tables and figures

The estimation does not take into consideration adjustment of pH value.

Overall remarks, attachments

Overall remarks

BASF_QSAR (2007). Partition coefficient

UUID IUC5-c20e8c92-414c-4dd0-a1f1-f12572419c36
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 16:38:43 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Scientifically accpetable calculation method.

Data source

Reference

Reference type other: QSAR
Author BASF AG **Year** 2007
Title unpublished Log D calculation for pH values of 4, 7 and 9
Bibliographic source
Testing laboratory BASF AG , Department of Product Safety **Report no.**
Owner company
Company study no. **Report date**

Data access

not applicable

Materials and methods

Partition coefficient type

octanol-water

Principles of method if other than guideline

Method: other (calculated)

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Any other information on materials and methods incl. tables

```
logD(alkaline) = log P - log [1 + 10^(pKa-pH)]
```

Results and discussions

Partition coefficient

Type log Pow
Partition coefficient -7.07
Temp.
pH 4

Type log Pow
Partition coefficient -4.07
Temp.
pH 7

Type log Pow
Partition coefficient -2.29
Temp.
pH 9

Remarks on results including tables and figures

```
pH      Log D
4.0     -7.07
7.0     -4.07
9.0     -2.29
```

Overall remarks, attachments

Overall remarks

4.8 Water solubility

Water solubility

UUID	IUC5-a22ede43-1bfe-405b-90a0-5e8a26f4926d
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 16:55:34 EST
Remarks	

Administrative Data

Short description of key information

miscible

Key parameter (optional)

Water solubility	**mg/L at the temperature (in°C) of**	25

Discussion

1.0E+06

1000000

EPISuite 4.0 WSKOWv1.41. key

UUID IUC5-6eaf04a0-9012-4c40-a604-b4726cebf85e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 09:23:47 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability reliable and acceptable estimation method

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 3.20 (EPIWEB4.0) - WSKOWv 1.41 Waternet
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

data published

Materials and methods

Type of method

other: calculated

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Details on methods

Estimated using default values in EPISUITEv4.0 (EPIWEB4.0)

Results and discussions

Water solubility

1000000 mg/L
Temp. 25 °C
pH

Details on results

1.0E+6 mg/L at 25C

Applicant's summary and conclusion

Interpretation of results

miscible

SRC Data Base. Water solubility

UUID IUC5-2f4f8d37-fe70-4cad-96c7-925f906d3f9e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 16:48:53 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: peer reviewed database
Author MEYLAN,WM ET AL. **Year** 1996
Title no data
Bibliographic source cited in SRC PhysProp Database, 04 Jun 2007
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

other: calculated

Principles of method if other than guideline

other: calculated

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Details on results

miscible

Remarks on results including tables and figures

Study was performed without adjustment of pH value.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Interpretation of results

miscible

HSDB_Hawley. Water solubility

UUID IUC5-8604f3cd-5bd9-46c6-890d-fef8bd3cf36e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-11-11 23:44:56 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type review article or handbook
Author Hawley, G.G. **Year** 1981
Title The Condensed Chemical Dictionary. 10th ed.
Bibliographic source New York: Van Nostrand Reinhold Co., 1981., p. 51. cited in HSDB 21 Sep 2006
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

other: Unknown

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Details on results

miscible in all proportions

Remarks on results including tables and figures

Study was performed without adjustment of pH value.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Interpretation of results

miscible

GESTIS. Water solubility

UUID IUC5-8cf7c438-1ee4-489f-8903-b386b8f3e368
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:04:30 EST
Remarks

Administrative Data

Purpose flag supporting study ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type other: authoritative database
Author GESTIS **Year** 2007
Title Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source query date 05 June 2007
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Water solubility

Temp. 20 °C
pH 10.2

Details on results

pH Concentration: 10 g/l, miscible

Remarks on results including tables and figures

Study was performed without adjustment of pH value.

Applicant's summary and conclusion

Interpretation of results

miscible

4.11 Flash point

Flash point

UUID	IUC5-5751fa49-0d0c-42a2-9321-eb882635e7d2
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:24:16 EST
Remarks	

Administrative Data

Short description of key information

127 °C (cc)

BASF AG (1988). Flash point.001

UUID IUC5-3690b826-66b0-496d-b38c-203be9e8266f
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:09:22 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable

Data source

Reference

Reference type study report
Author BASF AG **Year** 1988
Title Flammpunkt nach DIN EN 22719
Bibliographic source
Testing laboratory BASF AG **Report no.** SIK-Nr. 88/1183
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1987-12-31

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier equivalent or similar to
Guideline ISO 2719:2002 (Determination of flash point - Pensky-Martens closed cup method)
Deviations

Type of method

closed cup

Principles of method if other than guideline

DIN EN 22719, Verfahren nach Pensky-Martens

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

127 °C
at

BASF AG (1977). Flash point.002

UUID IUC5-ed46652e-48a0-43d6-a7f7-836680857c32
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:11:00 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable

Data source

Reference

Reference type study report
Author BASF AG **Year** 1977
Title Sicherheitstechnische Kenndaten
Bibliographic source
Testing laboratory BASF AG, TLM/SIK - B 14 **Report no.** 77/1477
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1978-01-09

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier equivalent or similar to
Guideline ISO 2719:2002 (Determination of flash point - Pensky-Martens closed cup method)
Deviations

Type of method

closed cup

Principles of method if other than guideline

DIN 51758, Pensky-Martens

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

117 °C
at

BASF AG (1980). Flash point.003

UUID IUC5-82684362-dc2d-4e7f-ab42-495419fae254
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:12:08 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable

Data source

Reference

Reference type study report
Author BASF AG **Year** 1980
Title Sicherheitstechnische Kenndaten
Bibliographic source
Testing laboratory BASF AG **Report no.** 80/0928
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1980-11-04

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier equivalent or similar to
Guideline ISO 2719:2002 (Determination of flash point - Pensky-Martens closed cup method)
Deviations

Principles of method if other than guideline

DIN 51758, Pensky-Martens

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

112 °C
at

HSDB_Hawley. Flash point.004

UUID IUC5-34756e5c-d961-492c-8af0-2b38eeadae6f
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:14:53 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: cited in peer reviewed database
Author Hawley, G.G. **Year** 1981
Title The Condensed Chemical Dictionary. 10th ed.
Bibliographic source New York: Van Nostrand Reinhold Co., 1981., p. 51. cited in HSDB 21 Sep 2006
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

closed cup

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

126.6 °C
at

Overall remarks, attachments

Overall remarks

GESTIS. Flash point.005

UUID IUC5-a742b573-2572-401e-8807-f7c53fd1866c
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:18:54 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type other: authoratative database
Author BGIA **Year** 2007
Title GESTIS - Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2008-06-05

Data access

data published

Materials and methods

Principles of method if other than guideline

data located in database are stated to be measured;

query date 05 June 2007

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

127 °C
at

Overall remarks, attachments

Overall remarks

Knovel_DIPPR. Flash point.006

UUID	IUC5-6d60c5a5-0b15-4b36-b379-da741dce6ef2
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 17:20:38 EST
Remarks	

Administrative Data

Purpose flag	supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	other:
Reliablility	2 (reliable with restrictions)
Rationale for reliability	peer reviewed data base

Data source

Reference

Reference type	other: peer reviewed database		
Author	AICHE	**Year**	2005
Title	Design Institute for Physical Properties,		
Bibliographic source	Sponsored by AIChE © 2005 Design Institute for Physical Property Data/AIChE; DIPPR Project 801 - Full Version; online query 29 Sep 2008		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods

Principles of method if other than guideline

As cited in database: other: experimental

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Flash point

124 °C

at

4.12 Auto flammability

Auto flammability

UUID	IUC5-a6a3d0dd-3a49-44ac-9e5c-5a45b84d031a
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:24:19 EST
Remarks	

Administrative Data

Short description of key information

370 °C

BASF AG (1977). Auto flammability.001

UUID IUC5-f01136e5-f529-421d-b2a7-dccaa1f90d5c
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:27:44 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability scientifically acceptable

Data source

Reference

Reference type study report
Author BASF AG **Year** 1977
Title Sicherheitstechnische Kenndaten
Bibliographic source
Testing laboratory BASF AG , TLM/SIK - B 14 **Report no.** 77/1477
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1978-01-09

Reference type study report
Author BASF AG **Year** 1980
Title Sicherheitstechnische Kenndaten
Bibliographic source
Testing laboratory BASF AG, TLM/SIK-B14 **Report no.** 80/0928
Owner company BASF SE, D-67056 Ludwigshafen
Company study no. **Report date** 1980-11-04

Data access

data submitter is data owner

Materials and methods

Principles of method if other than guideline

DIN 51794

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Autoflammability / Self-ignition temperature

370 °C
at

4.13 Flammabilit

Flammability

UUID	IUC5-32d4e0ba-f372-4837-b7c4-6dade95b584d
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 17:32:21 EST
Remarks	

Administrative Data

Short description of key information

Non flammable upon ignition.
The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.

Discussion

Flammability derived from flash point (and boilling point).
Based on chemical structure pyrophoric properties and flammability in contact with water are not to be expected.

Justification for classification or non-classification

GESTIS. Flammability.001

UUID IUC5-1a9f20a5-0bba-4a4e-9b0a-8c8da8cfe4e2
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:35:22 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 2 (reliable with restrictions)
Rationale for reliability authoritative data base

Data source

Reference

Reference type other: authoratative database
Author BGIA **Year** 2008
Title GESTIS - Substance database of 'Berufsgenossenschaftlichen Instituts für Arbeitsschutz' (BGIA)
Bibliographic source GESTIS
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2008-09-29

Data access

data published

Materials and methods

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Solid/liquid: Ignition on contact with air

no

Remarks on results including tables and figures

not easy to ignite

Applicant's summary and conclusion

Interpretation of results

non flammable

HSDB_Emergency Response Guidebook. Flammability.002

UUID	IUC5-864dc836-2e67-47a1-9fbf-fa896a475c7c
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 17:38:01 EST
Remarks	

Administrative Data

Purpose flag	supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	other:
Reliablility	2 (reliable with restrictions)
Rationale for reliability	peer reviewed data base

Data source

Reference

Reference type	other: peer reviewed database		
Author	U.S. Department of Transportation.	**Year**	2004
Title	2004 Emergency Response Guidebook. A Guide book for First Responders During the Initial Phase of a Dangerous Goods/Hazardous Materials Incident. Washington, D.C. 2004. cited in HSDB		
Bibliographic source	HSDB		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods

Principles of method if other than guideline

other

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Solid/liquid: Ignition on contact with air

no

Remarks on results including tables and figures

Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes

Applicant's summary and conclusion

Interpretation of results

non flammable

4.14 Explosiveness

Explosiveness.001

UUID	IUC5-3f587c14-aa64-4654-8301-ab8fa9790864
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:30:57 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Reliablility	2 (reliable with restrictions)
Rationale for reliability	authoritative database

Data source

Reference

Reference type	other: authoritative database		
Author	BGIA	Year	2007
Title	GESTIS		
Bibliographic source	Substance Database of "Berufsgenossenschaftlichen Instituts fur Arbeitsschutz" BGIA		
Testing laboratory		Report no.	
Owner company			
Company study no.		Report date	2007-06-05

Data access

data published

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

Results and discussions

Remarks on results including tables and figures

Explosive limits: lower 2% vol%; upper 15.5% vol%

4.21 Dissociation constant

Dissociation constant

UUID	IUC5-f7525569-a248-43a0-a810-702069adb007
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:24:33 EST
Remarks	

Administrative Data

Short description of key information

9.62 at 23 °C

SRC Data Base. Dissociation constant.001

UUID IUC5-2814cd81-a200-4853-9883-a2c89e27bc9e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:49:20 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: peer reviewed database
Author LITTEL,RJ ET AL. **Year** 1990
Title as cited in SRC PhysProp Database
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2007-06-04

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Dissociating properties

yes

Dissociation constant

No. **pKa** 9.62 **at** 23 °C

Remarks

Overall remarks, attachments

Overall remarks

Beilstein. Dissociation constant

UUID IUC5-9da8eed8-44f7-4789-b1ee-4253e868a9b6
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:52:58 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: cited in peer reviewed database
Author Barth, Danielle; Rubini, Patrice; Delpuech, Jean-Jacques **Year** 1984
Title no data
Bibliographic source Bull. Soc. Chim. Fr.; FR; 1; 1984; 227-230. cited in Beilstein Data: Copyright (c) 1988-2006, Registry No. 906728
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2006-10-25

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Dissociating properties

yes

Dissociation constant

No. **pKa** **at**

Remarks Acid-base constant: pKa = 9.42 at 25°C; |solvent: H2O|method: potentiometric|type: a1 apparent

No. **pKa** 9.24 **at** 33.6 °C

Remarks

Remarks on results including tables and figures

```
9.24 at 33.6°C;
9.11 at 39.8°C;
8.95 At 49.1°C;
8.77 at 60.9°C;
8.62 at 69.5°C;
8.55 at 70.5°C;
8.59 at 71.8°C;
8.51 at 75.9°C
```

Overall remarks, attachments

Overall remarks

BASF_SPARC (2007). Dissociation constant.003

UUID IUC5-11211276-483f-44ef-813a-52b5dec697cf
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:54:10 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Accepted calculation method

Data source

Reference

Reference type other: QSAR
Author BASF AG **Year** 2007
Title unpublished SPARC-calculation
Bibliographic source
Testing laboratory BASF AG, Department of Product Safety **Report no.**
Owner company
Company study no. **Report date**

Data access

not applicable

Materials and methods

Principles of method if other than guideline

other: calculated with SPARC software

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Dissociating properties

yes

Dissociation constant

No. **pKa** **at**

Remarks Acid-base constant: 9.18

Remarks on results including tables and figures

```
Two different molecular species of the substance will occur
(shown as smiles codes):
1 OCCOCCN   (uncharged molecule)
2 OCCOCC[N+1] (charged molecule)
Depending on pH, the substance will exist to following parts as species 1  and 2:
   pH          Species 1       Species 2
 1.00            0.00            1.00
 2.00            0.00            1.00
 3.00            0.00            1.00
 4.00            0.00            1.00
 5.00            0.00            1.00
 6.00            0.00            1.00
 7.00            0.01            0.99
 7.20            0.01            0.99
 7.40            0.02            0.98
 7.60            0.03            0.97
 7.80            0.04            0.96
 8.00            0.06            0.94
 8.20            0.09            0.91
 8.40            0.14            0.86
 8.60            0.21            0.79
 8.80            0.29            0.71
 9.00            0.40            0.60
 9.20            0.51            0.49
 9.40            0.62            0.38
 9.60            0.72            0.28
 9.80            0.81            0.19
10.00            0.87            0.13
10.20            0.91            0.09
10.40            0.94            0.06
10.60            0.96            0.04
10.80            0.98            0.02
11.00            0.98            0.02
12.00            1.00            0.00
13.00            1.00            0.00
14.00            1.00            0.00
The pKa of the substance (9.18) indicates that except in
environments with high pH (e.g. pH > 9.0), the
substance will exist predominantly in the protonated form. However,  between pH 8 and 9 the substance may occur to significant parts also as  uncharged species.
```

Overall remarks, attachments

Overall remarks

% ionisation.Dissociation constant.004

UUID IUC5-0095f4b4-197b-4729-9925-27da9d4762b1
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:56:33 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliability 2 (reliable with restrictions)
Rationale for reliability Acceptable calculation method

Data source

Reference

Reference type other: Calculation for % ionisation
Author BASF SE **Year** 2009
Title Calculation of percentage of ionisation from pKa value
Bibliographic source
Testing laboratory Department of Product Safety **Report no.**
Owner company BEASF SE
Company study no. **Report date**

Reference type publication
Author Mark Earll **Year** 1999
Title Percentage ionisation from pKa value
Bibliographic source http://www.raell.demon.co.uk/chem/calcs/LogP/perion.htm
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

not applicable

Materials and methods

Principles of method if other than guideline

other: calculated

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4
Identifier IUPAC name
Identity 2-(2-aminoethoxy)ethanol

Results and discussions

Dissociating properties

yes

Remarks on results including tables and figures

Using a pKa of 9.62 the percentage of ionisation at the environmental relevant pH values was calculated.

pH	% ionised
5	100
6	100
7	100
8	98
9	81

4.22 Viscosity

Viscosity

UUID	IUC5-6876b49b-fe4c-4b2a-9bae-4cd6f8ae89ee
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:00:05 EST
Remarks	

Administrative Data

Short description of key information

48.699 mPa_s at 25 °C

Knovel_Yaws. Viscosity.001

UUID IUC5-70c9a123-1550-4bcd-8a1e-5b523a4f3f80
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 17:58:40 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability authoritative handbook

Data source

Reference

Reference type review article or handbook
Author Yaws, Carl L. **Year** 2003
Title Yaws' Handbook of Thermodynamic and Physical Properties of Chemical Compounds
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Principles of method if other than guideline

other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Viscosity

48.688 mPa s (dynamic)
Temp. 25 °C
Remarks

Knovel_DIPPR. Viscosity.002

UUID IUC5-80581bcb-e694-45bf-a675-cc5078196995
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 18:02:53 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: peer reviewed database
Author Design Institute for Physical Properties, Sponsored by AIChE **Year** 2008
Title DIPPR Project 801 - Full Version
Bibliographic source © 2005 Design Institute for Physical Property Data/AIChE
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2008-09-29

Data access

data published

Materials and methods

Principles of method if other than guideline

data in database cited as being : other: measured

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Viscosity

43.9 mPa s (dynamic)
Temp. 25 °C
Remarks

17.5 mPa s (dynamic)
Temp. 40 °C
Remarks

Beilstein. Viscosity

UUID IUC5-f5a7ce30-543b-47c3-8d61-79370524114f
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 18:06:27 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliablility 2 (reliable with restrictions)
Rationale for reliability peer reviewed data base

Data source

Reference

Reference type other: peer reviewed database
Author Henni, Amr; Tontiwachwuthikul, Paitoon;|Chakma, Amit; Mather, Alan E.; JCEAAX; J. **Year** 2001
Title Chem. Eng. Data;|EN; 46; 1; 2001; 56 - 62. cited in Beilstein Data: Copyright (c) 1988-2006,
Bibliographic source Beilstein Institut zur Foerderung der Chemischen Wissenschaften licensed to Beilstein GmbH and MDL Information Systems GmbH. Registry No. 906728
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

other: other

Principles of method if other than guideline

other

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Analytical purity: pure

Results and discussions

Viscosity

25.66 mPa s (dynamic)
Temp. 20 °C
Remarks

4.9 mPa s (dynamic)
Temp. 70 °C
Remarks

Remarks on results including tables and figures

4.23 Additional physico-chemical information

BASF AG (1981). Additional physico-chemical information

UUID	IUC5-479f8c73-0ae7-487c-9499-558310f20d41
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:08:16 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	scientifically acceptable

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1981
Title			
Bibliographic source			
Testing laboratory	BASF AG, Analytisches Labor	**Report no.**	J.Nr. K 651
Owner company	BASF SE, D-67056 Ludwigshafen		
Company study no.		**Report date**	1981-08-25

Data access

data submitter is data owner

Materials and methods

Endpoint investigated

other: specific heat

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
2-(2-aminoethoxy)ethanol, pure

Results and discussions

Results

Memo: Specific heat c = 2.527 J/g*°C +/- 2 %

gem. at 50 °C

BASF AG (1978). Additional physico-chemical information

UUID	IUC5-16d7c3c1-1762-48e5-b9ae-19db5d03e8ed
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:11:50 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	scientifically acceptable

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1978
Title	Analytisches Labor,		
Bibliographic source	unpublished study No.|J.Nr. PH 6666, 17 Jul 1978		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data submitter is data owner

Materials and methods

Endpoint investigated

other: Verdampfungswärme (Heat of Vaporization)

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
2-(2-aminoethoxy)ethanol, pure

Results and discussions

Results

Memo: Verdampfungswärme (Heat of Vaporization) 54.1 kJ/mol (gemessen beim Siedepunkt)(measured with the boiling point)

BASF AG (1969_01). Additional physico-chemical information

UUID	IUC5-bec78e1d-548a-4aaa-96ce-0f5eafeae248
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:13:39 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	scientifically acceptable

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1969
Title	Analytisches Labor		
Bibliographic source	unpublished study No.|J.Nr. K 284, 24 Jan 1969		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data submitter is data owner

Materials and methods

Endpoint investigated

other: specific heat

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
2-(2-aminoethoxy)ethanol, pure

Results and discussions

Results

Memo: Specific heat c = 0.595 cal/g*°C at 20 °C

BASF AG (1969). Additional physico-chemical information

UUID	IUC5-f8b6e32d-7d4e-460d-89d0-975a8b8192b9
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:15:08 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	scientifically acceptable

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1969
Title	Ingenieurwesen Prüf- und Versuchsbetriebe,|		
Bibliographic source	unpublished study		
Testing laboratory		**Report no.**	
Owner company			
Company study no.	No. 369.015.1	**Report date**	1969-01-15

Data access

data submitter is data owner

Materials and methods

Endpoint investigated

other: Wärmeleitzahl (thermal conductivity)

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
2-(2-aminoethoxy)ethanol, pure

Results and discussions

Results

Memo: Wärmeleitzahl (thermal conductivity) 0.234 W/m*grd bei 21.1 Grad C

5 Environmental fate and pathways
5.1 Stability
Stability

UUID	IUC5-fd562f88-f48a-4879-9121-9f2bd64162b6
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:06:55 EST
Remarks	

Administrative Data

Discussion

After evaporation or exposure to the air, 2-(2-aminoethoxy)ethanol will be rapidly degraded by photochemical processes with OH-radicals. Based on the calculation according the EPISuite 4.0 (AOP v1.92), AEE is indirectly photodegraded by reaction with hydroxyl radicals in the atmosphere with a half-life (t1/2) of about 0.154 days (1.845 hours) taking inot account a 12 -h day with a mean OH radical concentration of 5.0E+05 molecules per cm3.

Hydrolysis is not expected to be an important fate path in the environment because the substance lacks hydrolysable functional groups.
According to Kollig et al. (1993), Boethling and Mackay (2000) and Harris (1990) hydrolysis is not an important fate path in the environment due to the fact that the molecule lacks hydrolysable functional groups. Therefore, no test on hydrolysis is performed.

5.1.1 Phototransformation in air

Phototransformation in air

UUID	IUC5-1e8d6604-244f-4249-9143-71e36f2c7b1f
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 18:52:55 EST
Remarks	

Administrative Data

Short description of key information

After evaporation or exposure to the air, the product will be rapidly degraded by photochemical processes with OH-radicals.

Discussion

Based on the calculation according to SRC AOP v1.92, 2-(2-aminoethoxy)ethanol is indirectly photodegraded by reaction with hydroxyl radicals in the atmosphere with a half-life (t1/2) of about 0.154 days (1.845 hours) taking into account a 12-h day and a mean OH radical concentration of 5.0E+05 molecules per cm^3 .

Key BASF SRC AOP v1.92 2009.Phototransformation in air. key

UUID IUC5-c129eda4-6481-43e9-bdd1-91ef43823b2a
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 09:34:31 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Accepted calculation method

Data source

Reference

Reference type other: estimation software
Author United states Environmental Protection Agency, Washingtod DC, USA **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0) Washington, DC, USA.
Bibliographic source EpiSuite v4.0; AOP v1.92
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Test guideline

Qualifier no guideline required
Guideline

Deviations

Principles of method if other than guideline

Method: other (calculated): EPIWEB 4.0; AOP v1.92
Input: default parameters of CAS number 929-06-6

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

TS-Freetext:
2-(2-aminoethoxy)-ethanol

Results are related to the uncharged molecule

Study design

Estimation method (if used)

PHOTOCHEMICAL REACTION WITH OH RADICALS
- Concentration of OH radicals: 500000 molecules/cm³
- Degradation rate constant: 69.5782 E-12 cm3/molecule-sec
- Computer programme: SRC AOP v1.91

Details on test conditions

Sensitiser (for indirect photolysis): OH
Sensitiser concentration: 500000 molecule/cm³

Results and discussions

Dissipation half-life of parent compound

DT50 1.84 h
Test condition based on a 12 -hr day (1.5E6 OH/cm3)

Remarks on results including tables and figures

Overall remarks, attachments

Overall remarks

assumed data: 24-hr day, 0.5E6 OH/cm³

Hydroxyl radical 1/2 life = 0.154 days (1.84 hours) based on a 12 -hr day (1.5E6 OH/cm3)

5.1.2 Hydrolysis

Hydrolysis

UUID	IUC5-a15a9fb6-2d39-4fd5-8928-a628e4c6fec9
Dossier UUID	0
Author	endlwek / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-09-01 04:25:02 EDT
Remarks	

Administrative Data

Short description of key information

According to structural properties, hydrolysis is not expected/probable.

Discussion

According to Kollig et al. (1993), Boethling and Mackay (2000) and Harris (1990) hydrolysis is not an important fate path in the environment due to the fact that the molecule lacks hydrolysable functional groups. Therefore, no test on hydrolysis is performed.

Hydrolysis. Key

UUID IUC5-92137154-43ca-412c-baf2-3fdbb52a5fed
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 09:40:32 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type other:
Reliability 2 (reliable with restrictions)
Rationale for reliability Data from reliable published literature

Data source

Reference

Reference type publication
Author Kollig, HP et al. **Year** 1993
Title Environmental fate constantsfor organic chemicals under consideration for EPA's hazardous waste identification projects
Bibliographic source EPA/600/R-93/132
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Reference type publication
Author Boethling R and Mackay D **Year** 2000
Title Handbook of Property Estimation Methods for Chemicals.
Bibliographic source CRC Press, Boca Raton, FL, USA. cited in Neoacids C5 to C28 Category Analysis Report-IUCLID datasheet
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Reference type publication
Author Harris JC **Year** 1990
Title Rate of hydrolysis
Bibliographic source in: Lyman WJ et al., Handbook of chemical property estimation methods, 3rd edition, ACS Washington.
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4
Identifier IUPAC name
Identity 2-(2-aminoethoxy)ethanol

Study design

Estimation method (if used)

According to Kollig et al. (1993), Boethling and Mackay (2000) and Harris (1990) hydrolysis is not an important fate path in the environment due to the fact that the molecule lacks hydrolysable functional groups. Therefore, no test on hydrolysis is performed.

Results and discussion

Details on results

According to Kollig et al. (1993), Boethling and Mackay (2000) and Harris (1990) hydrolysis is not an important fate path in the environment due to the fact that the molecule lacks hydrolysable functional groups. Therefore, no test on hydrolysis is performed.

Applicant's summary and conclusion

Conclusions

According to Kollig et al. (1993), Boethling and Mackay (2000) and Harris (1990) hydrolysis is not an important fate path in the environment due to the fact that the molecule lacks hydrolysable functional groups. Therefore, no test on hydrolysis is performed.

5.2 Biodegradation

Biodegradation

UUID	IUC5-f313f4c3-f70f-4f3e-a7a3-e1e5c8cfa563
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-05 01:00:06 EST
Remarks	

Administrative Data

Discussion

2-(2-aminoethoxy)ethanol is readily biodegradable (according to OECD criteria).

5.2.1 Biodegradation in water: screening tests

Biodegradation in water: screening tests

UUID	IUC5-e77c8b8e-71cc-42b5-8f6c-73ed8288ef27
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:11:37 EST
Remarks	

Administrative Data

Short description of key information

Readily biodegradable (according to OECD criteria)

Discussion

Existing data are available on the sponsored substance 2 -(2 -aminoethoxy)ethanol following "inherent biodegradation" test protocols. In order to further support 2 -(2 -aminoethoxy) ethanol as being "readily" biodegradable and in lieu of performing additional testing, read-across is performed to the structure analog 2 -ethoxyethylamine, CAS number 110 -76 -9, in which existing studies are available following "ready biodegradation" test protocols. Read-across is supported as both substances are considered structure analogs of one another. Each substance contains a comparable molecular structure with similar functional groups and physical chemical properties. Additional data are provided to further support a classification of ready biodegradation using a weight-of-evidence approach for the sponsored test substance.

A test according to OECD guideline 301A (Die away test, ready biodegradation) was performed with 2-Ethoxyethylamin, CAS 110-76-9. A non-adapted municipal sludge inoculum was used in which after 17 days a DOC removal of 90 -100% was measured (BASF, 1996).

In an OECD 302B test guideline study (Zahn-Wellens test, inherent biodegradation) using industrial activate sludge, the sponsored substance, AEE, was found to have a DOC removal rate of 84% after 28 days (BASF 1980). In addition, in a Die Away test, AEE, was considered biodegradable (Emtiazi and Knapp, 1994).

Several model estimates were performed. Using the OASIS Catalogic v5.10.5 progamme, a QSAR estimation using the OECD 301C model and the 301F kinetic model revealed biodegradation rates > 70% [BOD/ThOD] and >80% [BOD/ThOD], respectively (BASF SE 2008). According to a second QSAR model for predicting biodegradation (Biowin v4.10), AEE, is readily biodegradable (BASF SE 2009).

Conclusion: Based on data provided on the structural analog and from the sponsored substance (AEE), the substance is considered to be readily biodegradable.

Key.BASF96/0079/21/1.Biodegradation in water: screening tests.001

UUID IUC5-32a8acd8-2fd8-44b7-91a3-9e29486aadeb
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-05 01:27:33 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 05.03 - 22.03.1996
Reliability 1 (reliable without restriction)
Rationale for reliability Guideline study, GLP

Data source

Reference

Reference type study report
Author BASF AG **Year** 1996
Title Prüfung der biologischen Abbaubarkeit von 2-Ethoxyethylamin im DOC-Abnahme (Die-Away) Test
Bibliographic source
Testing laboratory Department of Ecology **Report no.**
Owner company BASF AG
Company study no. 96/0079/21/1 **Report date** 1996-04-15

Data access

data submitter is data owner

Materials and methods

Test type

ready biodegradability

Test guideline

Qualifier according to
Guideline OECD Guideline 301 A (new version) (Ready Biodegradability: DOC Die Away Test)
Deviations

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier CAS number
Identity 110-76-9

Details on test material

- Name of test material (as cited in study report): 2-Ethoxyethylamin
- Molecular weight: 89
- Physical state: liquid
- Analytical purity: >99 %

Study design

Oxygen conditions

aerobic

Inoculum or test system

activated sludge, domestic, non-adapted

Details on inoculum

- Source of inoculum/activated sludge (e.g. location, sampling depth, contamination history, procedure): Municipal activated sludge taken from a laboratory wastewater treatment plant fed with municipal sewage and synthetic wastewater.
- Laboratory culture: yes
- Concentration of sludge: 5 ml

Duration of test (contact time)

17 d

Initial test substance concentration

Initial conc. 37.3 mg/L
Based on test mat.
Initial conc. 20 mg/L
Based on DOC

Parameter followed for biodegradation estimation

DOC removal

Details on study design

TEST CONDITIONS
- Composition of medium:

500 ml dest. water
13 ml anorganic medium
64 ml test substance solution
482 ml water
= Total test volume: 1000 ml

- Aeration of dilution water: yes

TEST SYSTEM
- Method used to create aerobic conditions: aeration

SAMPLING
- Sampling frequency: day 0, 1, 3, 5, 7, 11, 14, 16 and 17

CONTROL AND BLANK SYSTEM
- Inoculum blank: yes

- Toxicity control: yes

Reference substance

aniline

Any other information on materials and methods incl. tables

Assay to examine the phys.-chem. elimination: activated sludge, including mercury chloride to avoid biodegradation.

Results and discussions

% Degradation of test substance

% Degr.	90 — 100
St. dev.	
Parameter	DOC removal
Sampling time	17 d
Remarks	

Details on results

BOD5 / COD results

Results with reference substance

90-100 % degradation after 7 days

Overall remarks

Adaptation phase: 5 days

Degradation phase: 6 days

Phys.-Chem. elimination (% DOC): <10 after 17 days

Elimination (adsorption) (% DOC): < 10 after 7 days

Applicant's summary and conclusion

Interpretation of results

readily biodegradable

BASF 1980 OECD 302B.Biodegradation in water: screening tests.002

UUID IUC5-fc05e1c4-4530-492f-9d96-fa3d762a9c53
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-05 01:31:15 EST
Remarks

Administrative Data

[]

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability Comparable to guideline study with acceptable restrictions; no GLP

Data source

Reference

Reference type study report
Author BASF SE **Year** 1980
Title Test protocol "Standversuch"
Bibliographic source unpublished report
Testing laboratory Laboratory of Ecology **Report no.**
Owner company BASF SE
Company study no. 79/318/I **Report date** 1980-12-09

Data access

data submitter is data owner

Materials and methods

Test type

inherent biodegradability

Test guideline

Qualifier equivalent or similar to
Guideline OECD Guideline 302 B (Inherent biodegradability: Zahn-Wellens/EMPA Test)
Deviations

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

- Test substance: Amino-Di-Glykol

- Purity: no data on purity

Study design

Oxygen conditions

aerobic

Inoculum or test system

activated sludge, industrial (adaptation not specified)

Details on inoculum

- Source of inoculum/activated sludge: BASF industrial STP

Duration of test (contact time)

28 d

Details on study design

Test conditions:
- number of replicates: test substance = 2, blank = no blank flask was tested in parallel but a statistically obtained mean value of 17 mg/l DOC was used to calculate the elimination
- reference substance: no reference substance was tested in parallel

Inoculum:
- activated sludge from BASF sewage works
- concentration: 1000 mg/l dry weight

Test system:
- 5 l-glass bottle
- closed vessel w/o O2 determination
- 278 ml stock solution
- 15 ml nutrient stock solution
- 2607 ml water
- 100 ml activated sewage sludge (not adapted)
- total liquid volume: 3000 ml Incubation:
- at room temperature (20-25 °C) on a magnetic stirrer, aerated with air (sparging)

Measurements:
- DOC (dissolved organic carbon)

Remark: In the report, the elimination is related to the TOC (total organic carbon), but the determination of the organic carbon in the culture broth was performed after the removal of the activated sludge. Therefore, the elimination should read as DOC-elimination instead of TOC-elimination.

Any other information on materials and methods incl. tables

Results and discussions

% Degradation of test substance

% Degr. 84
St. dev.

Parameter DOC removal

Sampling time 28 d

Remarks

Details on results

RS-Freetext:
Time TOC TOC pH
measured elimination
(mg/l) (%)
0 400 7.0
3 h 409 0
1 d 369 11 6.8
3 d 347 15 6.6
6 d 287 29 6.4
10 d 258 35 6.5
13 d 260 34 6.6
17 d 153 62 6.8
21 d 95 78 7.0
27 d 76 83 7.0
28 d 70 84 7.1

- TOC elimination: 84 %

- adsorption of TOC at start: 2 %

- elimination predominantly by biodegradation

Kinetic of test substance (in %):
= 0 after 3 hour(s)
= 11 after 1 day(s)
= 62 after 17 day(s)
= 78 after 21 day(s)
= 84 after 28 day(s)
Degradation products: not measured

BOD5 / COD results

Overall remarks

Applicant's summary and conclusion

Interpretation of results

inherently biodegradable

Biowin.EPISuite4.0.2009.Biodegradation in water: screening tests.003

UUID IUC5-c399648d-cfd5-492b-977a-204a75f184e0
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 19:27:48 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliability 2 (reliable with restrictions)
Rationale for reliability Scientifically acceptable estimation method

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title EPISuite (v4.0) (EPIWEB 4.0) (BIOWIN)
Bibliographic source Estimation Programs Interface Suite,™. for Microsoft® Windows, v 4.0.
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Test type

other: calculated biodegradation

Test guideline

Qualifier no guideline required
Guideline
Deviations

Principles of method if other than guideline

Calculation using Biowin v4.10; default values

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier CAS number
Identity 929-06-6

Results and discussions

BOD5 / COD results

Overall remarks

Biowin1 (Linear Model Prediction): Biodegrades Fast

Biowin2 (Non-Linear Model Prediction): Biodegrades Fast
Biowin3 (Ultimate Biodegradation Timeframe): Weeks
Biowin4 (Primary Biodegradation Timeframe): Days
Biowin5 (MITI Linear Model Prediction): Biodegrades Fast
Biowin6 (MITI Non-Linear Model Prediction): Biodegrades Fast
Biowin7 (Anaerobic Model Prediction): Biodegrades Fast
Ready Biodegradability Prediction: YES
Ready Biodegradability Prediction: (YES or NO)

Criteria for the YES or NO prediction: If the Biowin3 (ultimate survey model) result is "weeks" or faster (i.e. "days", "days to weeks", or "weeks" AND the Biowin5 (MITI linear model) probability is >= 0.5, then the prediction is YES (readily biodegradable). If this condition is not satisfied, the prediction is NO (not readily biodegradable). This method is based on application of Bayesian analysis to ready biodegradation data (see Help). Biowin5 and 6 also predict ready biodegradability, but for degradation in the OECD301C test only; using data from the Chemicals Evaluation and Research Institute Japan (CERIJ) database.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Interpretation of results

readily biodegradable

BASF QSAR Catalogic.Biodegradation in water: screening tests.004

UUID	IUC5-cb4e9166-b173-47a0-a619-c6a8f1019dde
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-05 01:48:23 EST
Remarks	

Administrative Data

Purpose flag	supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	(Q)SAR
Reliability	2 (reliable with restrictions)
Rationale for reliability	Acceptable calculation method

Data source

Reference

Reference type	other: model calculation report		
Author	BASF SE	**Year**	2009
Title	OASIS Catalogic v5.10.5 OECD 301C & OECD 301F model		
Bibliographic source	unpublished data		
Testing laboratory	Department of Product Safety	**Report no.**	
Owner company	BASF SE		
Company study no.		**Report date**	

Data access

not applicable

Materials and methods

Test type

ready biodegradability

Test guideline

Qualifier	no guideline required
Guideline	
Deviations	

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4
Identifier	IUPAC name
Identity	2-(2-aminoethoxy)ethanol

Study design

Oxygen conditions

other: model calculation

Inoculum or test system

other: model calculation

Duration of test (contact time)

28 d

Results and discussions

% Degradation of test substance

% Degr.	> 70
St. dev.	
Parameter	O2 consumption
Sampling time	28 d
Remarks	OECD 301C model, the substance is within the applicability domain at a threshold of 100%
% Degr.	> 80
St. dev.	
Parameter	O2 consumption
Sampling time	28 d
Remarks	301F kinetic model, the substance is within the applicability domain at a threshold of 57.14%

Applicant's summary and conclusion

Interpretation of results

readily biodegradable

Emtiazi&Knapp.1994.Biodegradation in water: screening tests.005

UUID IUC5-a680834e-d71b-4c4d-9313-75db072ef61e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-05 01:33:33 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability Acceptable well-documented publication which meets basic scientific principles

Data source

Reference

Reference type publication
Author Emtiazi, G. & Knapp JS **Year** 1994
Title The biodegradation of piperazine and strucutrally-related linear and cyclic amines
Bibliographic source Biodegradation 5: 83-92
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test type

other: biodegradation

Test guideline

Qualifier no guideline followed
Guideline
Deviations

Principles of method if other than guideline

die-away test

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4
Identifier IUPAC name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
- Analytical purity: no data
- Other: obtained from Aldrich Chemical Co. Ltd

Study design

Oxygen conditions

aerobic

Inoculum or test system

other: microbial population from River Aire in central Leeds

Initial test substance concentration

Initial conc. 1 mmol/L
Based on test mat.
Initial conc. 105.14 mg/L
Based on test mat.

Parameter followed for biodegradation estimation

DOC removal

Details on analytical methods

The test substance was analysed spectrophotometrically.

Details on study design

Test method:

Die-Away test

Inoculum:

- water from the River Aire in central Leeds (UK)
At sampling the river was classified as grade 3/4, and was recovering from serious pollution by treated domestic and industrial effluents from a large conurbation.

Medium / initial test concentration:
---
25 ml of water were added to 50 ml of a sterile solution of the amine/mineral salts medium (pH 7.0). Further on, 25 ml of sterile distilled water was added to give a final amine

concentration of 1 mM.

Incubation:

- cultures were incubated at 27 °C with shaking (100 rpm)

Sampling and analysis:

Samples were removed at regular intervals and the supernatant fluids were spectrophotometrically analysed for the amine.

Adsorption control:

- control flasks contained 20 mg HgCl as a biostat.
Under the conditions employed all amines remained in aqueous

solution and did not adsorb to any significant extent.

Results and discussions

% Degradation of test substance

% Degr.	100
St. dev.	
Parameter	DOC removal
Sampling time	21 d
Remarks	Degradation time varried from 14 to 28 days

Details on results

Lag period ranged from 3 to 16 days

Applicant's summary and conclusion

Interpretation of results

other: biodegradable

Biodegradation in water: screening tests.006

UUID IUC5-a5208987-b4c8-4b53-8d68-c1a09bd7f135
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-05 01:25:01 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability Test procedure in accordance with national standard methods with acceptable restrictions (i.e. detailed documentation missing)

Data source

Reference

Reference type company data
Author BASF AG. **Year** 1980
Title TUU/W 3, Report on ecological testing of|substances and sewage.
Bibliographic source Unpublished data
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 1980-12-10

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier according to
Guideline other guideline: DIN 38409, Part 51
Deviations

Qualifier according to
Guideline other guideline: DIN 38409, Part 43
Deviations

Principles of method if other than guideline

BOD and COD

GLP compliance

no GLP for COD method: no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
Amino-di-glykol

Study design

Any other information on materials and methods incl. tables

- BOD:

German Industrial Standard DIN 38409, Part 51

- COD:

German Industrial Standard DIN 38409, Part 43

Results and discussions

Details on results

RS-Freetext:
- COD:
1316 mg/g test substance

- BOD5:
< 2 mg/g test substance

- BOD5*100/COD:
< 1 % degradation

BOD5 / COD results

BOD5 / COD

BOD5

COD

BOD5*100/COD

Overall remarks

Inoculum: effluent from industrial sewage treatment plant

TOC: 418 mg/g

5.3 Bioaccumulation

Bioaccumulation

UUID	IUC5-66554b6a-6120-4b55-a813-7df2dc5ee619
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:39:39 EST
Remarks	

Administrative Data

Discussion

Based on the low logPow (-1.89) AEE is not expected to accumulate in organisms. The estimated Log BCF is 0.500 and the BCF is 3.162 based on default input parameters in EPISUITE web 4.0

5.3.1 Bioaccumulation: aquatic / sediment

Bioaccumulation: aquatic / sediment

UUID	IUC5-12b3328c-9b3a-479a-9816-028b03d1feb2
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:41:33 EST
Remarks	

Administrative Data

Short description of key information

Accumulation in organisms is not to be expected.

Discussion

Based on the low logPow (-1.89) of the uncharged molecule, AEE is not expected to accumulate in organisms. The estimated Log BCF is 0.500 and the BCF is 3.162 based on default input parameters in EPISUITE web 4.0. Furthermore, the substance is mainly present in its charged, cationic form under environmental conditions.

Bioaccumulation: aquatic / sediment.001

UUID	IUC5-bd69ff67-70ae-4ef8-acc9-5bbb10e32e1a
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:38:03 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	estimated by calculation
Reliability	2 (reliable with restrictions)
Rationale for reliability	data are from reliable estimation software

Data source

Reference

Reference type	other: estimation software		
Author	United States Environmental Protection Agency	**Year**	2009
Title	Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)		
Bibliographic source			
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	2009-12-12

Data access

not applicable

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

Study design

Test type

other: calculated

Water media type

freshwater

Test conditions

Details on estimation of bioconcentration

BIOWIN 4.10, default parameters

Results and discussions

Bioaccumulation factor

Conc. in environment / dose	
Type	BCF
Value	3.162
Basis	
Time of plateau	
Calculation basis	
Remarks	

Details on results

The log BCF is predicted to be 0.500 and the BCF is 3.162 based on default input parameters in EPISUITE 4.0.

Applicant's summary and conclusion

Conclusions

Not bioaccumulative

5.4 Transport and distribution

Transport and distribution

UUID	IUC5-a7547bf0-16a4-4751-906b-3174e6f3fc09
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 19:51:59 EST
Remarks	

Administrative Data

Discussion

After exposure to soil, significant adsorption to solid soil phase (e.g. clay) is not expected. From the water surface 2-(2-aminoethoxy)ethanol will not evaporate into the atmosphere. The distribution of the substance between the environmental compartments was calculated by use of the EPISuite v4.0 (EPIWEB 4.0) LEVEL III Fugacity model. Due to the results of the Mackay LEVEL III the primary compartment of distribution of the uncharged molecule is the soil compartment; however, the log Koc is 0. Any distribution to the soil compartment would not be anticipated to adsorb to the soil. Volatilization from a river and lake is estimated to be 693 and 7562 years, respectively (US EPA., 2009). Removal from water water treatment plant is anticipated to be minimal with a total effluent removal estimated as being 1.85% (US EPA, 2009.) When released to the air compartment, AEE will be rapidly degraded based on half-life of 1.845 hours (US EPA, 2009.)

5.4.1 Adsorption / desorption

Adsorption / desorption

UUID	IUC5-1252d44a-ee6c-4abc-8d44-f1e9dde6ef10
Dossier UUID	0
Author	endlwek / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-09-01 04:37:34 EDT
Remarks	

Administrative Data

Short description of key information

Adsorption to solid soil phase is not expected.

Discussion

A calculated logKoc of 0 is available (BASF SE, SRC PCKOC v1.66, 2007). This value refers to the uncharged molecule (pKa value: 9.62). This pKa value indicates that the molecule will exist primarily as a cation in the environment and cations generally adsorb stronger to soils containing organic carbon and clay than their neutral counterparts. Hence, the PCKOC-model may underestimate adsorption to organic carbon since it does not consider the ionic structure of the molecule. Under environmental conditions (pH from 5 to 9) the test substance is mainly present in its charged form (as calculated by the formula % ionised = 100/(1+10(pKa - pH)): 81% at a pH of 9, 98% at a pH of 8, 100% at lower pH values). In a calculation conducted according to a publication by Franco & Trapp (2008) taking into account a pKa of 9.62 and log Pow of -1.89 a log Koc value of 2.36 were determined.

Key EPISUITE v4.0 KOCWIN 2.0.Adsorption / desorption.001

UUID IUC5-059240bf-178d-4a5a-ba3c-1810923b7579
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 20:06:16 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Accepted calculation method

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0) KOCWIN 2.0
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Study type

adsorption

Media

soil

Type of method

other: model calculation

Principles of method if other than guideline

Method: calculated PCKOCWIN v1.66

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)-ethanol

Results are related to the uncharged molecule

Results and discussions

Adsorption coefficient Koc

1

log Koc

0

Results: Batch equilibrium or other method

Remarks on results including tables and figures

The data refer to the uncharged moelcule (pKa value: 9.62). This pKa value indicates that the molecule will exist mainly as a cation under environmental conditions and cations generally adsorb stronger to solid soil phase (e.g. organic carbon, clay) than their neutral counterparts. Hence, KOCWIN v 2.0 may underestimate adsorption since it does not consider the ionic structure of the molecule. This statement is supported by a calculation estimating the degree of ionisation based on the following formula:

% ionisation = 100/(1 +10(pKa-pH)) (see also IUCLID chapter 4.21)

Overall remarks, attachments

Overall remarks

Calculation according to Franco&Trapp.2008.Adsorption / desorption

UUID IUC5-a305803f-e842-4d96-9cca-4a62edaf7632
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 20:08:44 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Scientifically acceptable calculation method

Data source

Reference

Reference type other: log Koc calculation
Author BASF SE **Year** 2008
Title Calculations of pH-corrected logKoc for acids and bases
Bibliographic source
Testing laboratory Department for Product Safety **Report no.**
Owner company BASF SE
Company study no. **Report date** 2008-12-11

Reference type publication
Author Franco A. & Trapp S. **Year** 2008
Title Estimation of the soil-water partition coefficient normalized to organic carbon for ionizable organic chemicals
Bibliographic source Environmental Toxicology and Chemistry, 27 (10), pages: 1995-2004
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

not applicable

Materials and methods

Study type

other: calculation of log Koc for ionized molecule

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Study design

Batch equilibrium or other method

Any other information on materials and methods incl. tables

The following input parameters were used for the calculation:

1. Test substance is a base

2. log Pow = -1.89 (as stated in chapter 4.7)

3. pKa = 9.62 (as stated in chapter 4.21)

Results and discussions

Adsorption coefficient Koc

231

log Koc

2.36

5.4.2 Henry's Law constant

Henry's Law constant

UUID	IUC5-4f9c5fe6-fd78-42dc-baae-687d04be49b7
Dossier UUID	0
Author	hiddinb / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-03-09 10:18:43 EDT
Remarks	

Administrative Data

Short description of key information

From the water surface the substance will not evaporate into the atmosphere.

Discussion

Henry's law constant was calculated by use of the bond estimation method implemented within the SRC HENRY v3.10 calculation model (BASF 2007). It is calculated to be 0.00000058 Pa*m³/mol.

Key BASF EPISUITE 4.0 HENRYWIN.Henry's Law constant.001

UUID	IUC5-ee872c03-e9ca-4279-a0c8-dccd6eb44878
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 20:25:29 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	estimated by calculation
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Acceptable calculation method

Data source

Reference

Reference type	other: estimation software		
Author	United Stated Environmental Protection Agency	**Year**	2009
Title	Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0) HENRYWIN v3.2		
Bibliographic source			
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	2009-12-12

Data access

not applicable

Materials and methods

Test guideline

Qualifier	no guideline required
Guideline	
Deviations	

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4
Identifier	IUPAC name
Identity	2-(2-aminoethoxy)ethanol

Results and discussions

Henry's Law constant H

H	0
Temp. (°C)	
Atm. press.	

Remarks on results including tables and figures

5.72E-12 atm/m3/mole at 25C

5.79E-007 pa-m3/mole at 25C

5.4.3 Distribution modelling

Distribution modelling.001

UUID IUC5-51fc2c27-bd4c-41b7-a22d-0c8bb646daa2
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 20:31:08 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliability 2 (reliable with restrictions)
Rationale for reliability Acceptable estimation/calculation method

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)
Bibliographic source United States Environmental Protection Agency, Washington, DC, USA.
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Model

Calculation according to Mackay, Level III

Calculation programme

EPIWEB 4.0; Level III Fugacity model

Release year

2009

Media

air - biota - sediment(s) - soil - water

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Test substance input data

Default paramters of CAS number

Results and discussions

Percent distribution in media

Air (%)

0

Water (%)

37.8

Soil (%)

62.1

Sediment (%)

0.07

Other distribution results

Mass Amount Half-Life Emissions
(percent) (hr) (kg/hr)
Air 0.00228 3.69 1000
Water 37.8 360 1000
Soil 62.1 720 1000
Sediment 0.0707 3.24e+003 0

Fugacity Reaction Advection Reaction Advection
(atm) (kg/hr) (kg/hr) (percent) (percent)
Air 9.32e-014 7.54 0.401 0.251 0.0134
Water 3.12e-015 1.28e+003 664 42.6 22.1
Soil 1.76e-013 1.05e+003 0 35 0
Sediment 2.85e-015 0.266 0.0248 0.00885 0.000828

Persistence Time: 585 hr
Reaction Time: 752 hr
Advection Time: 2.64e+003 hr
Percent Reacted: 77.9
Percent Advected: 22.1

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):
Air: 3.689
Water: 360
Soil: 720
Sediment: 3240
Biowin estimate: 3.143 (weeks)

Advection Times (hr):
Air: 100
Water: 1000
Sediment: 5e+004

Remarks on results including tables and figures

Results are for the uncharged molecule

5.4.4 Other distribution data

Other distribution data.001

UUID IUC5-fe18c205-61c8-4204-bd9e-88e0cacf4067
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-13 20:33:54 EST
Remarks

Administrative Data

Purpose flag (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Acceptable method of calculation

Data source

Reference

Reference type other:
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)
Bibliographic source United States Environmental Protection Agency, Washington, DC, USA.
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Type of study

volatility

Media

other: Lake and river

Principles of method if other than guideline

Estimation software - volatiliation from water
Chemical Name: Ethanol, 2-(2-aminoethoxy)-

Molecular Weight : 105.14 g/mole
Water Solubility : -----
Vapor Pressure : -----
Henry's Law Constant: 9.88E-011 atm-m3/mole (Henry experimental database)

RIVER LAKE
--------- ---------
Water Depth (meters): 1 1
Wind Velocity (m/sec): 5 0.5
Current Velocity (m/sec): 1 0.05

HALF-LIFE (hours) : 6.076E+006 6.629E+007
HALF-LIFE (days) : 2.532E+005 2.762E+006
HALF-LIFE (years) : 693.2 7562

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Any other information on materials and methods incl. tables

Results and discussions

Remarks on results including tables and figures

From River:

HALF-LIFE (hours) : 6.076E+006 HALF-LIFE (days) : 2.532E+005 HALF-LIFE (years) : 693.2

From Lake:

HALF-LIFE (hours): 6.629E+007 HALF-LIFE (days): 2.762E+006 HALF-LIFE (years): 7562

Overall remarks, attachments

Overall remarks

Calculation is for the uncharged molecule

Other distribution data.002

UUID	IUC5-1b83ed4a-63be-4f1e-be9b-4fc4a378a8c6
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 20:35:19 EST
Remarks	

Administrative Data

Purpose flag	(X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	estimated by calculation
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Acceptable calculation/estimation method

Data source

Reference

Reference type	other: estimation software		
Author	US EPA	**Year**	2009
Title	Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)		
Bibliographic source	United States Environmental Protection Agency, Washington, DC, USA.		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	2009-12-12

Data access

not applicable

Materials and methods

Type of study

other:

Test guideline

Qualifier	no guideline required
Guideline	
Deviations	

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

Any other information on materials and methods incl. tables

Default parameters for substance used (CAS number)

Calculation is for the uncharged molecule

Results and discussions

Remarks on results including tables and figures

Total removal from waste water treatment plant:

1.85%

Total Biodegradation:

0.09%

Final Water Effluent 98.15%

5.5 Environmental data
5.5.1 Monitoring data
Monitoring data, IUC4#1/Ch.3.2.1

UUID	IUC5-7eade752-fdfc-4170-b37f-21db793d1e94
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 20:41:14 EST
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Reliablility	4 (not assignable)
Rationale for reliability	No additional details available.

Data source
Reference

Reference type	secondary source		
Author	Joseph M et al.	**Year**	1993
Title	Determination of trace amounts of|morpholine and its thermal degradation products in boiler|water by HPLC.		
Bibliographic source	Chromatographia 35(3-4): 173-176.		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods
Type of measurement

other: other

Media

other: boiler water

Test materials
Test material equivalent to submission substance identity

yes

Overall remarks, attachments
Overall remarks

```
RM-Freetext:
2-(2-aminoethoxy)ethanol as thermal degradation product of
morpholine was determined in trace amounts by pre-column
derivatisation of aqueous samples followed by HPLC analysis.
```

5.6 Additional information on environmental fate and behaviour

Additional information on environmental fate and behaviour, IUC4#1/Ch.3.1.2

UUID	IUC5-316bef95-90c2-492a-9f01-b696382e4302
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-13 20:44:06 EST
Remarks	

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS

Reliablility 4 (not assignable)

Rationale for reliability Original reference not yet available

Data source

Reference

Reference type	company data		
Author	Huntsman Corporation	**Year**	1995
Title	Communication to BASF, May 1995.		
Bibliographic source			
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Materials and methods

Principles of method if other than guideline

Method: other

Test materials

Test material equivalent to submission substance identity

yes

Overall remarks, attachments

Overall remarks

RM-Freetext:
Aqueous solutions of this product can be prepared, and under controlled conditions, these solutions can remain stable for periods of greater than 2 years. These controlled conditions prevent the process of biodegradation which is mentioned more fully in section 5.2. From the fact that no significant hydrolysis is expected to occur under these controlled conditions, which are recommended for standard product storage, we can therefore expect that there is no formation of hydrolysis products with any pronounced harmful environmental effect.

6 Ecotoxicological Information

6.1 Aquatic toxicity

Aquatic toxicity

UUID	IUC5-9e25848e-a91b-4ef2-810b-c404e2f7d2ee
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 16:36:00 EST
Remarks	

Administrative Data

Discussion

Acute tests on all three trophic levels were performed to examine the aquatic toxicity of 2-(2-aminoethoxy)ethanol. Algae is considered to be the most sensitive species with an ErC50 (72h) of 202 mg/L (nominal)(non-neutralized). When the test substance is neutralized the 72 hr EC50 is 261 mg/L (nominal). In a study following the German Industrial Standard, DIN 38412 part 15, the 96h LC50 (*Leuciscus idus*) of the non-neutralized substance is 464 mg/L(nominal) while when neutralized then 96 LC50 is 681 mg/L (highest concentration tested) (nominal). In a study with Daphnia magna following EU Method C. 2, the 48 hr EC50 of the non-neutralized test substance is 189 mg/L and that of the neutralized substance is >500 mg/L. Thus, 2-(2-aminoethoxy)ethanol is considered to be of low acute aquatic toxicity regardless of pH adjustment (neutralization).

6.1.1 Short-term toxicity to fish

Short-term toxicity to fish

UUID	IUC5-052b0060-4a8c-4ae5-8e7a-ad79c105ee95
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-16 20:05:18 EST
Remarks	

Administrative Data

Short description of key information

The acute toxicity of the test substance in fresh water aquatic vertebrate species is considered low.

Key parameter (optional)

LC50 for freshwater fish in mg/L	681
LC50 for marine water fish in mg/L	

Discussion

As key study regarding acute toxicity to fish a static non-GLP test according to German Industrial Standard DIN 38412 part 15 using Leuciscus idus was identified (BASF 1981). After 96 hours of exposure a LC50 of ca. 460 mg/L was estimated, related to the nominal concentration and for a non-neutralized sample whereas for a neutralized sample a LC50 > 681 mg/L was found.

The estimated acute toxicity of AEE in fresh water aquatic vertebrate is 96h LC50 = > 500 mg/L (US EPA, 2009).

Key BASF 80/438 1981.Short-term toxicity to fish

UUID IUC5-c6e61e9e-f104-4a80-82c9-7ae9984177f9
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 05:33:32 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability Guideline study with acceptable restrictions (e.g. no analytical verification of the test concentrations)

Data source

Reference

Reference type study report
Author BASF SE **Year** 1981
Title Report on the acute toxicity of 2,2' aminoethoxyethanol to Leuciscus idus L.
Bibliographic source unpublished report
Testing laboratory Department for Toxicology **Report no.**
Owner company BASF SE
Company study no. 80/438 **Report date** 1981-03-11

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier according to
Guideline other guideline: German Industrial Standard DIN 38412 part 15
Deviations

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

- Name of the test substance: 2,2' aminoethoxiethanol

- Purity: 99.7 % purity

Analytical monitoring

no

Vehicle

no

Test organisms

Test organisms (species)

Leuciscus idus

Details on test organisms

- animal species: Leuciscus idus L., golden variety (golden orfe)
- supplier: Fa. P. Eggers, Hohenweststedt, Germany.
- mean body length: 6.5 cm
- mean body weight: 2.7 g
- mean corpulence factor of the batch: 0.87
- duration of adaptation to test water and test temperature: 3 days

Study design

Test type

static

Water media type

freshwater

Limit test

no

Total exposure duration

96 h **Remarks**

Test conditions

Hardness

total hardness of 2.6 mmol/l

Test temperature

20 °C +/- 1 °C

pH

8 +/- 0.1

Dissolved oxygen

> 8 mg/l oxygen

Nominal and measured concentrations

nominal test concentrations: 0.0 (control), 46.4, 68.1, 100.0, 147.0, 215.0, 316.0, 464.0, and 681.0 mg/l

Details on test conditions

- test water: reconstituted freshwater was prepared from fully demineralized tap water (activated charcoal filter + demineralization with "Aquadem", Type 42 DF, WTA, Cologne/Germany)
- fully demineralized tap water was resalted by the addition of 344 mg/l CaSO4*2H2O, 124 mg/l MgSO4*7H2O, 70 mg/l NaHCO3, 3 mg/l KCl - test water had a total hardness of 2.6 mmol/l, an acid capacity (to pH 4.3) of 0.8 mmol/l, 82 mg/l Ca, 12 mg/l Mg, > 8 mg/l oxygen, and pH 8 +/- 0.1
- volume of test water: 10 l
- aeration: continuously with oil-free air
- No. of animals per test concentration: 10
- test vessels: all-glass aquaria (30x22x24 cm)
- temperature: 20 °C +/- 1 °C
- nominal test concentrations: 0.0 (control), 46.4, 68.1, 100.0, 147.0, 215.0, 316.0, 464.0, and 681.0 mg/l
- observations: mortality after 1, 4, 24, 48, 72, and 96 h
- symptoms after 4, 24 and 48 h
- measurements: pH and oxygen content after 1, 24, 48, 72, and 96 h

In addition, a neutralized sample of the highest concentration was tested (concentration 681 mg/L)

- the median lethal concentration (LC50) was calculated using Probit Analysis (Finney D.J., Probit Analysis, Cambr. Univ. Press, 3rd Edition, 1971)

Reference substance (positive control)

yes Chloracetamid

Any other information on materials and methods incl. tables

In the test item concentrations 316 to 681 mg/l, depositions on the glass walls of the aquaria were observed.

Results and discussions

Effect concentrations

Duration	96 h
Endpoint	LC50
Effect conc.	> 681
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	mortality
Remarks (e.g. 95% CL)	neutralized sample (20% H2SO4)
Duration	96 h
Endpoint	LC50
Effect conc.	ca. 460 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	mortality
Remarks (e.g. 95% CL)	non-neutralized sample
Duration	96 h
Endpoint	LC0
Effect conc.	316 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	mortality
Remarks (e.g. 95% CL)	non-neutralized sample

Details on results

The author of the study report stated that in a parallel test of the highest concentration tested (681 mg/L) in which the test substance was neutralized, no symptoms were observed. As a result, the 96 LC50 of the neutralized test substance is 681 mg/L.

Reported statistics and error estimates

Probit Analysis

Any other information on results incl. tables

Main Study:

Mortality:

Nominal conc.(mg/l)	Mortality (cumulated) after					
	1 h	4 h	24 h	48 h	72 h	96 h
0	0	0	0	0	0	0
46.4	0	0	0	0	0	0
68.1	0	0	0	0	0	0
100	0	0	0	0	0	0
147	0	0	0	0	0	0
215	0	0	0	0	0	0
316	0	0	0	0	0	0
464	0	0	1	4	5	5
681	0	1	10	10	10	10

Symptoms:

Nominal conc.(mg/l)	Symptoms after		
	4 h	24 h	48 h
0			
46.4			
68.1			
100			

147			
215			
316		A	A
464	L	ALT	XLA
681	LT		

Legend: A = apathy; L = gasping for breath; T = tumbling; X = opacity of eyes

Oxygen:

Nominal conc.(mg/l)	Oxygen concentrations [mg O2/L] after				
	1 h	24 h	48 h	72 h	96 h
0	8.9	9.0	8.9	9.0	9.0
46.4	8.7	8.7	8.6	8.7	8.8
68.1	8.2	8.1	8.2	8.2	8.3
100	8.5	8.5	8.6	8.6	8.7
147	8.5	8.5	8.6	8.6	8.7
215	8.8	8.9	8.9	8.9	9.0
316	8.5	8.5	8.3	8.5	8.4
464	8.6	8.5	8.7	8.6	8.7
681	8.3	9.1			

pH:

Nominal conc.(mg/l)	pH values after				
	0 h	24 h	48 h	72 h	96 h
0	7.8	7.8	7.8	7.9	7.9
46.4	9.2	7.9	7.9	7.9	7.9
68.1	9.5	8.2	7.8	7.8	7.8
100	9.7	8.7	8.0	7.9	8.0
147	9.9	9.1	8.6	8.1	8.0
215	10.1	8.8	8.1	8.1	8.1
316	10.3	9.3	8.9	8.3	8.0
464	10.4	9.5	9.2	8.9	8.6
681	10.6	9.9			

LC50

---

after 1 hour: > 680 mg/L (1 % significance level)

after 4 hours: > 680 mg/L (5 % significance level)

after 24 hours: > 460 mg/L (5 % significance level)

< 680 mg/L (1 % significance level)

after 48 hours: ca. 460 mg/L

after 96 hours: ca. 460 mg/L

The control with chloracetamide (48-h LC 50: ca. 26 mg/l) corresponds to the normal sensitivity.
In a parallel study of the highest concentration tested (681 mg/L) the test substancce was neutralized. No symptoms were observed. The 96hr LC50 of the neutralized test substance is 681 mg/L.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Validity criteria fulfilled

yes

Conclusions

The 96 hr LC50 for both the neutralized and non-neutralized test substance are > 100 mg/L. The test substance is considered to have low acute aquatic toxicity in Leuciscus idus.

Short-term toxicity to fish.002

UUID IUC5-4443e481-5efb-4c30-9c61-032fc985d254
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 19:52:15 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Acceptable estimation software

Data source

Reference

Reference type other: eestimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

estimation software - input parameters are default values

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Results and discussions

Effect concentrations

Duration 96 h
Endpoint LC50
Effect conc. 4023 mg/L
Nominal/Measured
Conc. based on
Basis for effect mortality
Remarks (e.g. 95% CL)

Applicant's summary and conclusion

Conclusions

The substance is considered to be of low acute toxicity to fish.

6.1.3 Short-term toxicity to aquatic invertebrates

Short-term toxicity to aquatic invertebrates

UUID	IUC5-a4962cd2-e338-4bbc-bb98-718a7399e2e0
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-16 20:03:50 EST
Remarks	

Administrative Data

Short description of key information

Based on available data, the substance is considered to have low acute aquatic toxicity to aquatic invertebrates.

Key parameter (optional)

EC50/LC50 for freshwater invertebrates in mg/L	500
EC50/LC50 for marine water invertebrates in mg/L	

Discussion

To determine the toxicity of 2-(2-aminoethoxy)ethanol to aquatic invertebrates, a static non-GLP study following Directive 79/831/EEC, method C.2 in Daphnia magna is available. In the main study using the non-neutralized test substance the 48 hr EC50 is 189 mg/L (nominal). The calculated EC50 (48h) is greater than the highest concentration tested (500 mg/L) (nominal) for the neutralized test substance. (BASF SE 1990).

After 24 h test duration, 100% mortality was observed in the non-neutralized concentration of 500 mg/l (pH 10.03), whereas in the neutralized concentration of 500 mg/l only 5% mortality occurred. Thus, it is likely that the alkalinity of this test item concentration contributed to the mortality.

The estimated acute aquatic toxicity to aquatic invertebrates is 48h EC50 = 181 mg/L (US EPA, 2009).

Key BASF 1/0506/2/89 1990.Short-term toxicity to aquatic invertebrates

UUID IUC5-6821bb26-c06e-48c0-b110-50669d56f1cb
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 08:30:42 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability Guideline study with acceptable restrictions (e.g. no analytical verification of test concentrations)

Data source

Reference

Reference type study report
Author BASF SE **Year** 1990
Title Report on acute effect of 2,2'-aminoethoxyethanol to Daphnia magna Straus.
Bibliographic source unpublished data
Testing laboratory Laboratory of Ecology, **Report no.**
Owner company BASF SE
Company study no. 1/0506/2/89 **Report date** 1990-06-21

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier according to
Guideline EU Method C.2 (Acute Toxicity for Daphnia)
Deviations

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

- Test substance: 2-2'-aminoethoxyethanol

- Purity: 99.6%

Analytical monitoring

no

Test organisms

Test organisms (species)

Daphnia magna

Details on test organisms

TEST ORGANISM
- Common name: water flea
- Source: Institut National de Recherche Chimique Appliquée, France, received in 1970 an bread since that time in the laboratories of the BASF

Study design

Test type

static

Water media type

freshwater

Limit test

no

Total exposure duration

48 h

Remarks

Test conditions

Hardness

2.7 mM
Acid capacity to pH 4.3: 0.9 mM

Test temperature

19.5 - 21.2 °C

pH

8.09 - 10.03

Dissolved oxygen

8.57 - 9.04

Details on test conditions

Test conditions:
- test medium: artificial freshwater (total hardness: 2.70 +- 0.5 mmol/l, acid capacity to pH 4.3: 0.90 +- 0.10 mmol/l; molar ratio Ca:Mg = ca. 4:1; molar ratio of Na:K = 10:1; conductivity: 600-700 µSiemens/cm; pH 8.0 +- 0.5)
- aeration: aerated till saturation with oil-free air and allowed to stabilize for 24 h
- temperature range: 18.9-20.9 °C
- test vessels: glass tubes with flat bottom
- test volume: 10 ml (2 ml/animal)

- 5 animals per vessel
- 20 animals per concentration level (=4 replicates)
- illumination: diffuse light
- observation times: visually after 0, 3, 6, 24 and 48 h
- observation parameters: mobility
- test concentrations: 0 (control), 31.25, 62.5, 125, 250, and 500 mg/l
- EC 50 after 24 h and EC 50 after 48 h were determined according to Spearman-Karber (Sachs, L. (1974): Angewandte Statistik, Springer, Berlin.)

A parallel study using only the highest test concentration (500 mg/L) was performed using the neutralized test substance.

Reference substance (positive control)

no data

Any other information on materials and methods incl. tables

Results and discussions

Effect concentrations

Duration	48 h		
Endpoint	EC50		
Effect conc.	> 500 mg/L		
Nominal/Measured	nominal		
Conc. based on	test mat.	**Basis for effect**	mobility
Remarks (e.g. 95% CL)	neutralized sample		
Duration	48 h		
Endpoint	EC50		
Effect conc.	189 mg/L		
Nominal/Measured	nominal		
Conc. based on	test mat.	**Basis for effect**	mobility
Remarks (e.g. 95% CL)	non-neutralized sample		
Duration	48 h		
Endpoint	EC0		
Effect conc.	125 mg/L		
Nominal/Measured	nominal		
Conc. based on	test mat.	**Basis for effect**	mobility
Remarks (e.g. 95% CL)	non-neutralized sample		
Duration	48 h		
Endpoint	EC100		
Effect conc.	500 mg/L		
Nominal/Measured	nominal		
Conc. based on	test mat.	**Basis for effect**	mobility
Remarks (e.g. 95% CL)	non-neutralized sample		

Remarks on results including tables and figures

Main Study (non-neutralized test substance):

The 48 hr EC50 = 189.46 mg/L (95 % confidence interval (CI): 172.55-208.03 mg/l)

The highest tested concentration without an effect after 48 h was EC0 = 125 mg/l.

The lowest tested concentration with 100 % effect after 48 h was EC 100 = 500 mg/l.

Immobility:

Nominal concentration (mg/l)	Cumulative immobility (n)				
	0 h	3 h	6 h	24 h	48 h
0 (Control)	0	0	0	0	0
31.25	0	0	0	0	0
62.5	0	0	0	0	0
125	0	0	0	0	0
250	0	0	0	9	18
500	0	0	0	20	20

pH values

Nominal conc.(mg/l)	pH values after	
	0 h	48 h
0	8.09	8.09
31.25	8.88	8.14
62.5	9.24	8.29
125	9.51	8.51
250	9.77	8.49
500	10.3	8.78

In the parallel study using only the highest concentration tested (500 mg/L) of neutralized test substance the 48 hr EC50 = > 500 mg/L in which only 5% mortality occurred.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Validity criteria fulfilled

yes

Conclusions

After 24 h test duration, 100% mortality was observed in the non-neutralized concentration of 500 mg/l (pH 10.03), whereas in the neutralized concentration of 500 mg/l only 5% mortality occurred. Thus, it is likely that the alkalinity of this test item concentration contributed to the mortality.

Short-term toxicity to aquatic invertebrates.002

UUID IUC5-a10d67c6-9e1b-4204-a6be-29cecd1dd1de
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 20:01:48 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Data are derived from acceptable estimation software

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Data access

not applicable

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

Estimation software - default input parameters

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Results and discussions

Effect concentrations

Duration 48 h
Endpoint EC50
Effect conc. 181 mg/L
Nominal/Measured
Conc. based on **Basis for effect** mortality
Remarks (e.g. 95% CL)

Applicant's summary and conclusion

Conclusions

The test substance is estimated to have a low acute toxicity in aquatic invertebrate.

6.1.5 Toxicity to aquatic algae and cyanobacteria

Toxicity to aquatic algae and cyanobacteria

UUID	IUC5-c5085174-540e-437f-857a-861c5c25c209
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 09:50:06 EST
Remarks	

Administrative Data

Short description of key information

The acute toxicity of the test substance to aquatic algae is low.

Key parameter (optional)

EC50/LC50 for freshwater in mg/L	202
EC50/LC50 for marine water in mg/L	
EC10/LC10 or NOEC for freshwater in mg/L	
EC10/LC10 or NOEC for marine water in mg/L	

Discussion

In a 72-hour static test with the green alga *Scenedesmus subspicatus* (new name: *Desmodesmus subspicatus*) according to German Industrial Standard DIN 38412 part 9 (non-GLP), the estimated NOEC is 62.5 mg/L. The 72 hr EC50 (nominal) for growth rate (ECr50) and biomass (ECb50) for the non-neutralized test substance are 202 and 135 mg/L, respectively. When the test substance is neutralized, the 72 hr EC50 is 261 mg/L (nominal)

Key BASF 2/w506/89t72 1990.Toxicity to aquatic algae and cyanobacteria

UUID IUC5-7d0900e9-ed75-43f0-bac4-1623ab156a60
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 09:48:24 EST
Remarks

Administrative Data

[]

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability Guideline study with acceptable restrictions (e.g. no analytical verification of test concentrations)

Data source

Reference

Reference type study report
Author BASF SE **Year** 1990
Title Algentest
Bibliographic source unpublished report
Testing laboratory Laboratory for Ecology **Report no.**
Owner company BASF SE
Company study no. 2/w506/89t72 **Report date** 1990-06-24

Reference type other: recalculation report
Author ECT Oekotoxikologie GmbH **Year** 2007
Title Statistical evaluation with|ToxRatPro (v2.09) of BASF algae study
Bibliographic source unpublished data, original study, report No. 2/0506/89 (start of test: 29 May 1990)
Testing laboratory ECT Oekotoxikologie GmbH **Report no.**
Owner company BASF SE
Company study no. **Report date** 2007-02-14

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier according to
Guideline other guideline: German Industrial Standard DIN 38412 part 9
Deviations

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6

Details on test material

TS-Freetext:
2.2-Aminoethoxyethanol

Analytical monitoring

no

Test organisms

Test organisms (species)

other: other algae: Desmodesmus subspicatus (formerly: Scenedesmus subspicatus)

Details on test organisms

- species: Scenedesmus subspicatus (renamed to Desmodesmus subspicatus)
- strain: SAG 86.81
- source: algae collection of the University of Goettingen, Germany

Study design

Test type

static

Water media type

freshwater

Limit test

no

Total exposure duration

72 h

Remarks

Test conditions

Details on test conditions

- medium: according to DIN 38412, part 9
- temperature: 20 °C
- test flasks: 250 ml-Erlenmeyer flasks
- test volume: 100 ml

Test culture:
- No. of algae in test flasks at test start: 10000 cells/ml
- coloration of test substance: colorless

- test volume: 10 ml
- tubes were incubated for 72 h at 20 °C
- samples were taken at regular intervals (0, 24, 48, 72 h)
- measurements: fluorescence

Non-neutralized test conditions:
- test concentrations: 0 (control), 3.9, 7.8, 15.625, 31.25, 62.5, 125, 250, 500 mg/l

- replicates: 4 per concentration and control; 2 blank per concentration (w/o cells)

Neutralized test conditions:
- test concentrations: 0 (control), 7.8, 62.5, 500 mg/l
- replicates: 2 per concentration and control; 2 blank per concentration (w/o cells)

Reference substance (positive control)

no data

Any other information on materials and methods incl. tables

The test was performed under non-neutralized test conditions (4 replicates per concentration). However, for comparison some concentrations were neutralized (2 replicates).

Non-neutralized test concentrations (mg/l): 0 (control), 3.9, 7.8, 15.6, 31.3, 62.5, 125, 250, 500

Neutralized test concentrations (mg/l): 0 (control), 7.8, 62.5, 500

Results and discussions

Effect concentrations

Duration	72 h
Endpoint	EC50
Effect conc.	202 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	growth rate
Remarks (e.g. 95% CL)	non-neutralized
Duration	72 h
Endpoint	NOEC
Effect conc.	62.5 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	growth rate
Remarks (e.g. 95% CL)	non-neutralized
Duration	72 h
Endpoint	LOEC
Effect conc.	125 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	growth rate
Remarks (e.g. 95% CL)	non-neutralized
Duration	72 h
Endpoint	EC10
Effect conc.	105 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	growth rate
Remarks (e.g. 95% CL)	non-neutralized
Duration	72 h
Endpoint	EC20
Effect conc.	131 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	growth rate
Remarks (e.g. 95% CL)	non-neutralized
Duration	72 h

Endpoint	EC50
Effect conc.	261 mg/L
Nominal/Measured	nominal
Conc. based on	test mat.
Basis for effect	
Remarks (e.g. 95% CL)	neutralized

Remarks on results including tables and figures

Non-neutralized test conditions:

The following nominal effect concentrations related to yield (EyC), growth rate (ErC), and biomass integral (EbC) were recalculated according to OECD TG 201 (adopted 23 Mar 2006) using the fluorescence values for inhibition of biomass from the original report. Since no calibration curve data were available, fluorescence data were equated with cell numbers (95 % confidence intervals in brackets):

Yield (mg/l; 72 h)
EyC10:57.6 (34.2-77.8)

EyC20:77.5 (51.8-99.7)

EyC50:134.5 (107.3-170.3)

NOEyC: 3.9

LOEyC: 7.8

Growth rate (mg/l; 72 h)
ErC10: 104.5 (86.7-120.0)

ErC20: 131.2 (113.5-147.3)

ErC50: 202.4 (182.7-224.7)

NOErC: 62.5

LOErC: 125.0

Biomass integral (mg/l; 72 h)
EbC10: 57.8 (20.6-82.7)

EbC20: 77.3 (37.4-102.9)

EbC50: 134.5 (100.3-180.4)

NOEbC: 7.8

LOEbC: 15.6

Original effect values as given in the report (nominal concentrations in mg/l):

EC20 (72 h): 89.4

EC50 (72 h): 162.4

EC90 (72 h): 248.4

Neutralized test conditions:

Due to the limited study design with 2 replicates per concentration test (0. 7.8, 62.5 and 500 mg/L) only, a statistical re-evaluation according to new OECD TG 201 was not possible.

Original effect values as given in the report (nominal concentrations in mg/l):

EC20 (72 h): -

EC50 (72 h): 261

EC90 (72 h): -

No data were given on pH, oxygen and temperature development during the test.
In the 500 mg/l test concentration, algae growth was less inhibited under neutralized conditions compared to non-neutralized test conditions.

Overall remarks, attachments

Overall remarks

Applicant's summary and conclusion

Validity criteria fulfilled

yes

Conclusions

In the 500 mg/l test concentration, algae growth was less inhibited under neutralized conditions compared to non-neutralized test conditions. The non-neutralized 72 hr EC50 is 202 mg/L while the neutralized test substance 72 hr EC50 is 261 mg/L.

Toxicity to aquatic algae and cyanobacteria.002

UUID IUC5-45f9af76-17ef-45d5-8467-2922e89e2780
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 20:19:56 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type estimated by calculation
Reliablility 2 (reliable with restrictions)
Rationale for reliability Data are from acceptable estimation softward

Data source

Reference

Reference type other: estimation software
Author United States Environmental Protection Agency **Year** 2009
Title Estimation Programs Interface Suite™ for Microsoft® Windows, Version 4.0 (EPIWEB 4.0)
Bibliographic source
Testing laboratory **Report no.**
Owner company
Company study no. **Report date** 2009-12-12

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

estimation software - default input parameters
ECOSAR v 1.0

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Results and discussions

Effect concentrations

Duration 96 h
Endpoint EC50
Effect conc. 22 mg/L
Nominal/Measured
Conc. based on
Basis for effect growth rate
Remarks (e.g. 95% CL)

Details on results

Data are predicted for the non-neutralized test substance

Applicant's summary and conclusion

Conclusions

Estimated data of the non-neutralized test substance indicates an ECr50 of 22 mg/L. This value is considered to be a conservative estimate.

6.6 Additional ecotoxicological information

Additional ecotoxicological information, IUC4#2/Ch.4.9

UUID	IUC5-9a3aa16c-c112-46aa-ac80-1312bb2ddb70
Dossier UUID	0
Author	hubere / BASF SE / Ludwigshafen am Rhein / Germany
Date	2008-12-13 10:25:13 EST
Remarks	

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS

Reliablility 4 (not assignable)

Rationale for reliability Manufacturer / producer data without proof

Data source

Reference

Reference type

Author BASF AG (2006). 2-(2-Aminoethoxy)ethanol, Material Safety|Data Sheet according 91/155/EEC, update 04 Oct 2006. **Year**

Title

Bibliographic source

Testing laboratory **Report no.**

Owner company

Company study no. **Report date**

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

TS-Freetext:
2-(2-aminoethoxy)-ethanol

Results and discussions

Remarks on results including tables and figures

```
Memo: Other ecotoxicity information: Based on the pH of the product, a  neutralization is generally required before discharging effluent into a  sewage plant.
```

7 Toxicological information
7.2 Acute Toxicity
Acute Toxicity

UUID	IUC5-a515b4d6-1069-4a54-8a12-b988542d91a4
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 17:26:39 EST
Remarks	

Administrative Data

Short description of key information

Acute Toxicity:
- oral: LD50: 2558 - 5660 mg/kg bw (rat);
- inhalation: no mortality after 8 h saturated vapor.
- dermal:LD50: > 3000 mg/kg bw (OECD 402);

Key parameter (optional)

Acute toxicity: oral

Effect level		in	
	LD50	mg/kg bw	2558

Acute toxicity: dermal

Effect level	in	
	mg/kg bw	3000

Discussion

Oral:

In a study conducted in accordance with OECD TG 401 under GLP conditions the acute oral toxicity (LD50) of AEE was determined to be 2558 mg/kg bw (Huntsman, 1991 (RL=1). Doses of 1600, 2500 and 5000 mg/kg bw were applied to 10 male/female rats/dose via gavage. The following clinical effects were observed: decreased activity, piloerection, tremors, prostration, discolored urine,diarrhea, abnormal gait, abnormal stance,poor grooming, chromodacryorrhea, dyspnea and body drop. In a similar study, BASF AG, 1969, which was in large parts equivalent to methods described in OECD guideline 401, the LD50 for oral acute toxicity in rats was calculated as ca. 3400 mg/kg body weight (reliability score: 2). Doses of 212, 1696, 2120, 2650, 3392, 4240, 5300, and 6784 mg/kg bw of an aqueous solution were applied by gavage followed by a post dose observation period of 7 days. Main clinical signs observed were staggering, apathy, irregular respiration, shallow flanks, abdomial position, closed eyes, ruffled fur. At necropsy, gastrorrhagia, sagged gastrointestinal tract and serous smeared snouts were observed. In an additional study, the LD50 was determined to be 5660 mg/kg bw (Smyth et al. 1951; RL=2).
Dermal:
In an OECD guideline 402 study conducted in accordance with GLP, the acute dermal toxicity of 2-(2-aminoethoxy)ethanol was evaluated in New Zealand White rabbits. No mortalities were observed at the highest test dose level of 3000 mg/kg bw. Observations noted on live animals included decreased activity, poor grooming, diarrhoea, abnormal gait and stance and dyspnoea. A clear mucous anal discharge and a yellow discolouration of fur, with necrosis and skin sloughing surrounding the application site were observed. Terminal necropsy of animals revealed severe irritation and/or yellow discolouration of the underlying muscle tissue at the application site and also necrotic or discoloured fascia. Mottled lungs and pale kidneys were also observed ((LD50 > 3000 mg/kg bw; Huntsman 1991; relibility score 1). A dermal LD50 value of 1190 µl/kg bw, equivalent to 1260 mg/kg bw was published in a study with White New Zealand rabbits, with no further details provided (Smyth et al.1951; reliability score: 2).

Justification for classification or non-classification

No EU classification according to Annex I of Directive 67/548/EEC for acute toxicity.

According to GHS classification:
acute oral: Cat. 5; maybe harmful if swallowed.
acute dermal: Cat. 5; maybe harmful in contact with skin.

7.2.1 Acute toxicity: oral

Huntsman: oral.001

UUID	IUC5-73d0fe20-4048-4a14-bd67-3f4b28e47faa
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 16:08:10 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	1 (reliable without restriction)
Rationale for reliability	Study was performed according to EPA Federal Register , Vol. 50, No. 188 (Friday, September 27,1985) guideline and in compliance with the GLP Regulations.

Data source

Reference

Reference type	study report		
Author	Mallory VT, PharmakonResearch International, Inc.	**Year**	1991
Title	Acute Exposure Oral Toxicity		
Bibliographic source			
Testing laboratory	PharmakonResearch International, Inc. Waverly, PA 18471	**Report no.**	
Owner company	Huntsman		
Company study no.	PH 402-TX-012-90	**Report date**	1991-01-18

Data access

data submitter is data owner

Materials and methods

Test type

fixed dose procedure

Limit test

no

Test guideline

Qualifier	equivalent or similar to
Guideline	OECD Guideline 401 (Acute Oral Toxicity)
Deviations	no
Qualifier	according to
Guideline	other guideline: EPA Federal Register ,Vol.50, No.188, 1985
Deviations	

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4

Details on test material

- Name of test material (as cited in study report): 6398-21-1 (laboratory/sponsor ID)
- Physical state: clear, colorless liquid
- Analytical purity: responsibility of the Sponsor (>99% as identified by sponsor)
- Lot/batch No.:90-013
- Stability under test conditions: no apparent change in the physical state of the test article during administration
- Storage condition of test material: no data
- Other: specific gravity=1.06 gm/ml

Test animals

Species

rat

Strain

Sprague-Dawley

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Charles River Laboratories, Inc., Wilmington, Massachusetts
- Age at study initiation: young adults
- Weight at study initiation: 258-293 g
- Fasting period before study: yes
- Housing: individually in stainless steel 1/2" wire mesh cages, sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Animal Resources, National Research Council
- Diet (e.g. ad libitum): Wayne Teklad Lab Blox, ad libitum,
- Water (e.g. ad libitum): fresh tap water, ad libitum
- Acclimation period:min.5 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 22°C±3°C
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light): 12h dark/12h light

IN-LIFE DATES: From: 1990-11-20 To:1990-12-31

Administration / exposure

Route of administration

oral: gavage

Vehicle

unchanged (no vehicle)

Doses

1600, 2500 and 5000mg/kg

No. of animals per sex per dose

10 (5♂ and 5♀)

Control animals

no data

Details on study design

- Duration of observation period following administration: 14 days
- Frequency of observations and weighing: at 1,4 and 24h after dosing and once daily through Day 14; viability: once a day; body weight: d0,d7 and d14 or when dead
- Necropsy of survivors performed: yes
- Other examinations performed: clinical signs, body weight

Statistics

LD50 calculations performed via Litchfield and Wilcoxon on Pharmacological Calculations System, version 4.1.

Any other information on materials and methods incl. tables

Results and discussions

Preliminary study (if fixed dose study)

Not applicable.

Effect levels

Sex	male/female
Endpoint	LD50
Effect level	2557.9 mg/kg bw
95% CL	1896.9 — 3449.4
Remarks	

Sex	male
Endpoint	LD50
Effect level	3222.2 mg/kg bw
95% CL	2241.9 — 4631.1
Remarks	

Sex	female
Endpoint	LD50
Effect level	2270.5 mg/kg bw
95% CL	1216.5 — 4237.8
Remarks	

Mortality

-2/10 animals died at the 1600mg/kg dose level
-4/10 animals died at the 2500 mg/kg dose level
-10/10 animals died at the 5000 mg/kg dose level

Clinical signs

-decreased activity, piloerection, tremors, prostration, discolored urine,diarrhea, abnormal gait, abnormal stance,poor grooming, chromodacryorrhea, dyspnea and body drop

Body weight

d0-d7-d14:both ♂ and ♀: body weights increase (survivors)

Gross pathology

Necropsy of the animals dying on study revealed distended and fluid-filled stomachs and intestines, discolored stomach mucosa with and without multiple lesions throughout, discolored glandular portion of the stomach with and· without scattered necrotic areas, ascites and discolored spleens. Terminal necropsy of the remaining animals revealed mottled kidneys, and adhesions of the liver to the stomach and small intestines with a greenish-yellow puslike filled mass at the site of adhesion (-2 cm x 2 cm).

Remarks on results including tables and figures

Applicant's summary and conclusion

Interpretation of results

Toxicity Category V

Criteria used for interpretation of results

OECD GHS

Conclusions

Based on the results from the Acute Exposure Oral Toxicity in Rats, the definitive acute oral LD50 in males and females for the test substance 6398-21-1 (AEE; >99%) was determined to be 2557.9 mg/kg (95% of 1896.9 to 3449.4 mg/kg). The LD50 in males was determined to be 3222.2 mg/kg (95%CL of 2241.9 to 4631.1 mg/kg). The LD50 in females was determined to be 2270.5 (95% CL of 1216.5 to 4237.8 mg/kg).

Executive summary

BASFAG XIX/51.Acute toxicity: oral.rat

UUID IUC5-70344184-3a4b-4727-a037-fcad01d9ba20
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-08 23:19:36 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability Acceptable, well documented report which meets basic scientific principles.

Data source

Reference

Reference type study report
Author BASF AG **Year** 1969
Title Industrial hygiene orientating investigation
Bibliographic source unpublished data
Testing laboratory BASF AG, Department of Toxicology **Report no.** XIX/51
Owner company BASF SE
Company study no. **Report date** 1969-03-22

Data access

data submitter is data owner

Materials and methods

Test type

standard acute method

Test guideline

Qualifier equivalent or similar to
Guideline OECD Guideline 401 (Acute Oral Toxicity) Internal BASF study guideline
Deviations

Principles of method if other than guideline

BASF-test, see details in remarks on material and methods.

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): Aminodiglykol, 2-(2-Hydroxyaethoxy-)aethylamin
- Physical state: liquid
- Analytical purity: > 99 %

Test animals

Species

rat

Strain

no data

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Weight at study initiation: male: 186 - 280 g (mean); female: 166 - 218 g (mean)

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on oral exposure

VEHICLE
- Concentration in vehicle: 2 %, 20 % and 30 %.

Doses

200, 1600, 2000, 2500, 3200, 4000, 5000, 6400 µl/kg bw = 212, 1696, 2120, 2650, 3392, 4240, 5300, 6784 mg/kg bw (conversation is based on the density of 1.06 g/cm3).

No. of animals per sex per dose

10

Control animals

no data

Details on study design

- Duration of observation period following administration:7 days
- Frequency of observations: several times on the day of application and daily thereafter
- Necropsy of survivors performed: yes
- Other examinations performed: clinical signs

Any other information on materials and methods incl. tables

The study was conducted according to an internal BASF method which in principle is comparable to the OECD Guideline 401. A test group consisting of 10 animals/sex was treated by single gavage application with an aqueous solution of the test substance. The animals were observed for mortality and for clinical symptoms of toxicity. At the end of the observation period of 7 days, the surviving animals were sacrificed for the purpose

of necropsy; animals that died during the observations period also were subjected to necropsy. The LD50 value was estimated on the basis of the observed mortalities.

Results and discussions

Effect levels

Sex	male/female
Endpoint	LD50
Effect level	ca. 3400 mg/kg bw
95% CL	
Remarks	

Sex	male
Endpoint	LD50
Effect level	ca. 3700 mg/kg bw
95% CL	
Remarks	

Sex	female
Endpoint	LD50
Effect level	ca. 3000 mg/kg bw
95% CL	
Remarks	

Mortality

See details in remarks on results.

Clinical signs

Staggering, abdomial position, apathy, irregular respiration, shallow flanks, closed eyes, ruffled fur.

Body weight

no data

Gross pathology

2120 - 6784 mg/kg bw: gastrorrhagia, sagged gastrointestinal tract, serous smeared snouts.

Remarks on results including tables and figures

Mortality

Dose (mg/kg bw)	Conc. (%)	Gender	1 h	24 h	48 h	8 days
6784	30	male	0/10	10/10	10/10	10/10
6784	30	female	0/10	10/10	10/10	10/10
5300	30	male	0/10	0/10	8/10	8/10
4240	30	male	0/10	0/10	8/10	8/10
3392	30	male	0/10	3/10	3/10	3/10
3392	30	female	0/10	8/10	8/10	8/10
2650	20	female	0/10	0/10	3/10	3/10
2120	20	female	0/10	0/10	1/10	1/10
1696	20	male	0/10	0/10	0/10	0/10
1696	20	female	0/10	0/10	0/10	0/10
212	2	male	0/10	0/10	0/10	0/10
212	2	female	0/10	0/10	0/10	0/10

The test substance caused systemic toxicity (including mortality) in a dose dependent manner.

Applicant's summary and conclusion

Interpretation of results

Toxicity Category V

Criteria used for interpretation of results

OECD GHS

Smyth 1951.Acute toxicity: oral.rat

UUID IUC5-32cf2939-c4b5-4497-b2bc-cb1335602f94
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 20:27:46 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability basic data provided; reliable reference

Data source

Reference

Reference type publication
Author Smyth H.F. et al **Year** 1951
Title RANGE-FINDING TOXICITY DATA: LIST IV
Bibliographic source Arch. Ind. Hyg. Occup. Med. 4, 119-122
Testing laboratory Mellon Institute of Industrial Reseach **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Test type

standard acute method

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

see details in remarks on material and methods

GLP compliance

no

Test materials

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-aminoethoxyethanol

Test animals

Species

rat

Sex

no data

Administration / exposure

Route of administration

oral: gavage

Vehicle

no data

Doses

no data

No. of animals per sex per dose

5

Control animals

no data

Details on study design

- Duration of observation period following administration: 14 days

Any other information on materials and methods incl. tables

Single oral dose toxicity is estimated by the gastric intubation of groups of five non-fasted, rats four to five weeks of age and 90 to 120 grams. The dosages are arranged in a logarithmic series differing by a factor of two. Whenever possible, the chemical was administered undiluted. Based upon mortalities during a 14-day observation period, the most probable LD50 value and its fiducial range are estimated by the method of Thompson.

Results and discussions

Effect levels

Sex no data
Endpoint LD50
Effect level 5660 mg/kg bw
95% CL
Remarks

Mortality

no data

Clinical signs

no data

Body weight

no data

Gross pathology

no data

Applicant's summary and conclusion

Interpretation of results

not classified

Conclusions

Results are similar to other reliable acute oral toxicity values

7.2.2 Acute toxicity: inhalation

BASFAG XIX/51.Acute toxicity: inhalation.IRT.rat

UUID IUC5-c9371832-547b-4dfa-8b71-9f547856af76
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 17:18:32 EST
Remarks

Administrative Data

Purpose flag (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 11 Mar 1969 - 19 Mar 1969
Reliablility 4 (not assignable)
Rationale for reliability Due to the lack of a detailed study protocol, lack of any analytical determinations as to whether or not the atmosphere was saturated, or essentially saturated, or compromised, we discount the utility of the data.

Data source

Reference

Reference type study report
Author BASF AG **Year** 1969
Title Industrial hygiene orientating investigation
Bibliographic source unpublished data
Testing laboratory BASF AG, Department of Toxicology **Report no.** XIX/51
Owner company BASF SE
Company study no. **Report date** 1969-04-23

Data access

data submitter is data owner

Materials and methods

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

BASF-test, see details in remarks on material and methods

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): Aminodiglykol, 2-(2-Hydroxyaethoxy-)aethylamin
- Physical state: liquid
- Analytical purity: > 99 %

Test animals

Species

rat

Strain

no data

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Weight at study initiation: 157 g (mean)

Administration / exposure

Route of administration

inhalation

Type of inhalation exposure

no data

Vehicle

unchanged (no vehicle)

Analytical verification of test atmosphere concentrations

no

Duration of exposure

8 h **Remarks**

Concentrations

In the raw data no substance loss but an increase in substance weight was recorded.

No. of animals per sex per dose

6

Control animals

no data

Details on study design

- Duration of observation period following administration: 7 days
- Frequency of observations: several times on the day of exposure and daily thereafter
- Frequency of weighing: day 0 and day 7
- Necropsy of survivors performed: yes
- Other examinations performed: clinical signs, body weight

Any other information on materials and methods incl. tables

The test demonstrates the toxicity of an atmosphere saturated with vapours of the volatile components of a test substance at the temperature chosen for vapour generation (20 °C). 6 rats per sex were exposed sequentially to the vapours, generated by bubbling 200 l/h air through a substance column of about 5 cm above a fritted glassdisc in a glass cylinder for 8 h. The documentation of clinical signs was performed over a period of 8 days.

Results and discussions

Effect levels

Sex	male/female
Endpoint	other: Inhalation Risk Test
Effect level	Inhalation Risk Test
95% CL	
Exp. duration	8 h
Remarks	

Mortality

No mortality occured.

Clinical signs

No symptoms observed.

Body weight

The animals gained weight.

Gross pathology

2x bronchitis

Remarks on results including tables and figures

The inhalation of a highly saturated vapour-air mixture for 8 h caused no mortality.

Overall remarks, attachments

Overall remarks

Smyth 1951.Acute toxicity: inhalation, IRT.rat

UUID IUC5-6c52e83f-ce07-4903-9818-cfab4c0cad4e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 17:13:55 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 4 (not assignable)
Rationale for reliability Publication with only limited data. Due to the lack of a detailed study protocol, lack of any analytical determinations as to whether or not the atmosphere was saturated, or essentially saturated, or compromised, we discount the utility of the data.

Data source

Reference

Reference type publication
Author Smyth H.F. et al. **Year** 1951
Title Range-Finding Toxicity Data List IV
Bibliographic source Arch. Ind. Hyg. Occup. Med., 4, 119
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Principles of method if other than guideline

see details in remarks on materials methods

GLP compliance

no

Test materials

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-aminoethoxyethanol

Test animals

Species

rat

Strain

no data

Sex

no data

Administration / exposure

Route of administration

inhalation

Type of inhalation exposure

no data

Vehicle

no data

Analytical verification of test atmosphere concentrations

no

Duration of exposure

8 h **Remarks**

Concentrations

saturated vapour

No. of animals per sex per dose

6

Control animals

no data

Results and discussions

Effect levels

Sex no data
Endpoint other: Inhalation Risk Test
Effect level Inhalation Risk Test
95% CL
Exp. duration 8 h
Remarks

Mortality

no mortalty occured within 8 h.

Clinical signs

no data

Body weight

no data

Gross pathology

no data

Remarks on results including tables and figures

The exposition of rats in a saturated vapor caused no deaths.

Overall remarks, attachments

Overall remarks

7.2.3 Acute toxicity: dermal

Huntsman: dermal.001

UUID	IUC5-259a2a63-445d-4068-bf28-d4af598db096
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 17:50:31 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	1 (reliable without restriction)
Rationale for reliability	OECD/GLP

Data source

Reference

Reference type	study report		
Author	Mallory VT, Pharmakon Research International, Inc.	**Year**	1991
Title	Acute Exposure Dermal Toxicity		
Bibliographic source			
Testing laboratory	Pharmakon Research International, Inc. Waverly, Pennsylvania 18471	**Report no.**	
Owner company	Huntsman		
Company study no.	PH, 422-TX-012-90	**Report date**	1991-01-15

Data access

data submitter is data owner

Materials and methods

Test type

fixed dose procedure

Limit test

yes

Test guideline

Qualifier	according to
Guideline	OECD Guideline 402 (Acute Dermal Toxicity)
Deviations	

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4

Details on test material

- Name of test material (as cited in study report): 6398-21-1 (Laboratory sample ID)
- Physical state: clear, colorless liquid
- Analytical purity: responsibility of the Sponsor (>99% AEE, as stated by Sponsor)
- Lot/batch No.: 90-013
- Stability under test conditions: no apparent change in the physical characteristics of the test article during administration
- Storage condition of test material: no data
- Other: gravity: 1.06g/ml; pH=12 (litmus paper)

Test animals

Species

rabbit

Strain

New Zealand White

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Hare-Marland, Hewitt, New Jersey
- Age at study initiation: young adult
- Weight at study initiation: 2.119-2.764 kg
- Housing:Rabbits were housed individually in cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Animal Resources, National Research Council
- Diet (e.g. ad libitum): Purina Rabbit Ration H.F., ad libitum,
- Water (e.g. ad libitum):fresh tap water, ad libitum
- Acclimation period: min. 5d

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 20°C±3°C
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light): 12h dark/12h light

IN-LIFE DATES: From: To:

Administration / exposure

Type of coverage

occlusive

Vehicle

unchanged (no vehicle)

Details on dermal exposure

TEST SITE
- Area of exposure: dorsal area of trunk (clipped free of fur)
- Type of wrap if used: rubber dam and an elastic bandage

REMOVAL OF TEST SUBSTANCE: no data

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 3000 mg/kg
- Constant volume or concentration used: YES

Duration of exposure

24h

Doses

3000 mg/kg

No. of animals per sex per dose

10 (5 ♀ and 5♂)

Control animals

not required

Details on study design

- Duration of observation period following administration: 14 days
- Frequency of observations and weighing:observation:daily through 14d/Body weight: d0, d7 and d14
- Necropsy of survivors performed: YES
- Other examinations performed: clinical signs, body weight

Statistics

Not applicable.

Any other information on materials and methods incl. tables

Results and discussions

Effect levels

Sex	male/female
Endpoint	LD0
Effect level	3000 mg/kg bw
95% CL	
Remarks	

Mortality

No mortality observed during study.

Clinical signs

Days 1 and 2: 10/10 animals:decreased activity, abnormal stance and gait. Days 3 up to 14, no signs noted in any observed animals.
Day 2: 10/10 animals poor grooming. Days 3 up to 14 no signs noted in any observed animals.
Days 1 &2 10/10 animals and Day 4 3/10 animals: dyspnea. Days 5 up to 14 no signs noted in any observed animals.
-necrosis and sloughing of the skin at application site/a clear, mucous and discharge and yellow discoloration of fur surrounding application site

Body weight

Observation
d0-d7: both ♂ and ♀: body weight decreases (mean male bw: 2417 - 2384g; mean female bw: 2493 - 2457g)
d7-d14: both ♂ and ♀ : body weight increase (mean male bw: 2384 - 2555g; mean female bw: 2457 - 2615g)

Gross pathology

At terminal necropsy, animals revealed severe irritation and/or yellow discoloration of the underlying muscle tissue at the application site, necrotic or discolored yellow fascia at the application site, mottled lungs and pale kidneys.

Other findings

no other data

Remarks on results including tables and figures

Applicant's summary and conclusion

Conclusions

Based upon the observations made in the Acute Exposure Dermal Toxicity study in rabbits, the estimated dermal LD50 for AEE (laboratory sample ID 6398-21-1) is > 3000 mg/kg bw.

Smyth 1951.Acute toxicity: dermal.rabbit

UUID	IUC5-57347da7-c5b9-4feb-be1d-dd24ba6a5fc0
Dossier UUID	0
Author	beigelj / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-08-12 08:55:27 EDT
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Acceptable publication but only limited data is given.

Data source

Reference

Reference type	publication		
Author	Smyth H.F. et al.	**Year**	1951
Title	Range-Finding Toxicity Data, List IV		
Bibliographic source	Arch. Ind. Hyg. Occup. Med., 4, 119		
Testing laboratory		**Report no.**	
Owner company			
Company study no.		**Report date**	

Data access

data published

Materials and methods

Principles of method if other than guideline

see details in remarks on material and methods

GLP compliance

no

Test materials

Test material identity

Identifier	Common name
Identity	2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-aminoethoxyethanol

Test animals

Species

rabbit

Strain

New Zealand White

Sex

male

Administration / exposure

Type of coverage

occlusive

Vehicle

no data

Duration of exposure

24 h

Doses

no data

No. of animals per sex per dose

4

Control animals

no data

Details on study design

- Duration of observation period following administration: 14 days

Any other information on materials and methods incl. tables

Penetration of rabbit skin is estimated by a technique closely to the one-day cuff method of Draize and associates, using groups of four male albino rabbits weighing 2.5 to 3.5 kg. The fur is removed from the entire trunk by clipping, and the dose is retained beneath an impervious plastic film. The animals are immobilized during the 24 hour contact period, after which the film is removed and the rabbits are caged for the subsequent 14 day observation period.

Results and discussions

Effect levels

Sex	male
Endpoint	LD50
Effect level	ca. 1260 mg/kg bw
95% CL	
Remarks	conversion into mg/kg is based on the density d= 1.06 g/cm3 (according to BASF internal data).

Mortality

no data

Clinical signs

no data

Body weight

no ata

Gross pathology

no data

7.2.4 Acute toxicity: other routes

BASF AG XIX/51.Acute toxicity: other routes,I.P. mouse

UUID	IUC5-f6499404-0794-4777-afa1-e23c4c64ba0c
Dossier UUID	0
Author	beigelj / BASF SE / Ludwigshafen am Rhein / Germany
Date	2009-08-12 09:16:16 EDT
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	3 (not reliable)
Rationale for reliability	unsuitalbe route of exposure

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1969
Title	Industrial Hygiene orientating Investigation		
Bibliographic source	npublished data		
Testing laboratory	BASF AG, Department of Toxicology	**Report no.**	XIX/51
Owner company			
Company study no.		**Report date**	1969-04-23

Data access

data submitter is data owner

Materials and methods

Principles of method if other than guideline

other: BASF-Test

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Details on test material

IUCLID4 Test substance: as prescribed by 1.1 - 1.4

Test animals

Species

mouse

Strain

no data

Sex

male/female

Administration / exposure

Route of administration

intraperitoneal

Vehicle

water

Results and discussions

Effect levels

Sex	
Endpoint	LD50
Effect level	ca. 320 mg/kg bw
95% CL	
Remarks	

7.3 Irritation / corrosion

Irritation / corrosion

UUID	IUC5-47dd9991-8cad-41fd-82fc-1f828526991d
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-15 17:43:54 EST
Remarks	

Administrative Data

Short description of key information

Irritation:
- skin: corrosive
- eye: corrosive

Key parameter (optional)

Skin irritation / corrosion

corrosive

Eye irritation

corrosive

Discussion

Skin irritation:

In a study conducted in accordance with EPA and OECD test guideline study (404) conducted under GLP conditions, AEE was considered to be severe irritant after 1 hr of exposure (Calvert, 2001)(RL=1). In an additional OECD 404 test guideline study, application of AEE to intact and abraded doral trunks of New Zealand white rabbits resulted in irreversible sever erythema (including necrosis, sloughing, fissuring) with severe oedema being observed at 30 minutes and 4 hours post-exposure. The presence of skin damage remained throughout the post study observation period (Mallory, 1992)(RL=2). In an additonal OECD 404 test guideline study, the study author concluded that there were no signs or necrosis on any of the animals at application site in the 1 -3 minute observation period nor signs of necrosis throughout the study. Slight to severe erythema was observed at the 60 minute and 4 hour observation periods with moderate oedema noted at 4 hours. the author of the study concluded that the substance was determined to be non-hazardous, however, based on the description of the results, it can be concluded that the test substance is a severe irritant (Mallory, 1984)(RL=2).
The application of the test substance caused slight erythema after a 1 and 5 min exposure and moderate to severe erythema after a 15 min or 20 h exposure. After 15 min of exposure one animal developed necrosis 72 post exposure. 20 h of exposure led to anaemic necrosis which developed in 1 animal to hart necrosis at the end of the observation period (BASF AG 1969; reliability score 2). The test substance (0.01 ml) was administered to rabbits resulted in a severity grade 8 out of 10 reaction score, indicating necrosis (Smyth, 1951)(RL=2).

Eye irritation:
In a study conducted in accordance with OECD TG 405, a primary eye irritation study in Vienna White rabbits, 50 µL of the test substance caused moderate to severe irreversible corneal opacity, irritis, moderate erythema and slight to moderate chemosis. At the end of the observation period after 8 days staphyloma and severe corneal opacity were noted (BASF AG 1969; reliability score 2). A further publication confirmed these severe corrosive effects (Smyth et al. 1951; reliability score: 2). In an OECD TG 405, an aqueous solution of ADD was administed (0.1 ml) for 1 second and then observed for 72 hours. Findings from the study indicated a maximum group mean score of 3.7. According to the Modified Kay and Calandra Interpretation of Eye Irritation Test the aqueous solution of AEE is considered a minimal irritant (Class 3).

Justification for classification or non-classification

EU classification according to Annex I of Directive 67/548/EEC: C; R34

7.3.1 Skin irritation / corrosion

Calvert - Huntsman 2001/ corrosion.001

UUID IUC5-f29af94a-60dd-4fb2-ba86-8020c4893716
Dossier UUID 0
Author Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 17:39:12 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 1 (reliable without restriction)
Rationale for reliability OECD - EPA guideline study conducted in accordance with GLP

Data source

Reference

Reference type study report
Author Calvert Preclinical Services, Inc. (Calvert) **Year** 2001
Title Primary Dermal Irritation (D.O.T.)
Bibliographic source
Testing laboratory Calvert Preclinical Services, Inc. (Calvert) Scott Technology Park 100 Discovery Drive 0lyphant, PA 18447 **Report no.**
Owner company Huntsman
Company study no. 0420XH11.018 **Report date**

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Test guideline

Qualifier
Guideline OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Deviations

Qualifier
Guideline EPA OTS 798.4470 (Acute Dermal Irritation)
Deviations

GLP compliance

yes

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): AMP-95
- Molecular formula (if other than submission substance):
- Molecular weight (if other than submission substance):
- Smiles notation (if other than submission substance):
- InChI (if other than submission substance):
- Structural formula attached as image file (if other than submission substance): see Fig.
- Substance type:
- Physical state:
- Analytical purity:
- Impurities (identity and concentrations):
- Composition of test material, percentage of components:
- Isomers composition:
- Purity test date:
- Lot/batch No.:
- Expiration date of the lot/batch:
- Radiochemical purity (if radiolabelling):
- Specific activity (if radiolabelling):
- Locations of the label (if radiolabelling):
- Expiration date of radiochemical substance (if radiolabelling):
- Stability under test conditions:
- Storage condition of test material: The test article will be stored at room temperature unless -otherwise specified by the Sponsor.
- Other:

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Hare-Marlapd, Hewitt, NJ or any other· V.S.D.A. registered acceptable source.
- Age at study initiation: Healthy young adults (8-26 weeks)
- Weight at study initiation: Generally 2-3.5 kilograms
- Housing:All animals will be housed individually incompliance with USDA guidelines. Calvert is USDA Registered and a fully accredited AAALAC Facility.
- Diet (e.g. ad libitum): Teklad Certified Rabbit Diet or equivalent, unless otherwise specified
- Water (e.g. ad libitum): ad libitum
- Acclimation period:A minimum of five (5) days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 16 to 21°C
- Humidity (%): 30-70%

- Air changes (per hr):
- Photoperiod (hrs dark / hrs light):12h artificial light, 12h dark

IN-LIFE DATES: From: To:

Test system

Type of coverage

semiocclusive

Preparation of test site

shaved

Vehicle

unchanged (no vehicle)

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.5 ml (liquid) or 500mg (solid/semi-solid)
- Concentration (if solution):

VEHICLE
- Amount(s) applied (volume or weight with unit):
- Concentration (if solution):
- Lot/batch no. (if required):
- Purity:

Duration of treatment / exposure

The test article is administered once per designated site and remains in contact with the site for 3 minutes, 60 minutes and 4 hours.

Observation period

Fourteen (14) days or less if corrosion occurs in the animal model.

Number of animals

Six (6)

Control animals

no data

Details on study design

TEST SITE
- Area of exposure: dorsal area of trunk (clipped fur)
- % coverage:
- Type of wrap if used: rubber sheeting, wrapped with an elastic bandage and held in place with non-irritating tape.

REMOVAL OF TEST SUBSTANCE
- Washing (if done): washing with mineral oil
- Time after start of exposure: 3 minutes/60minutes/4h

SCORING SYSTEM:
See attached study report Table I, p9

Any other information on materials and methods incl. tables

The test substance was applied to an area of approximately 5 cm x 5 cm of skin and covered with a gauze patch. In the event of severe irritation the guideline allows for the study to be discontinued.

Results and discussions

Irritant/corrosive response data

After the first 3 minute dosing and prior to sacrifice, two female rats were noted to have a score of 1 for erthyema and 1 male rat had a score of 2. The same male rat was observed to have a level 1 oedema. Due to the lack of severity, the study continued forward to1 hr exposure. Immediately after the 1 hr exposure all female rats observed scored a level 4 for erythema and oedma while necrosis was noted, these observations were irreversible prior to sacrifice. In males, the effects were slightly less severe with no necrosis being noted. Based on the observed effects, it was determined by the study sponsor to not proceed forward with a 4 hour exposure. The substance is determined to be a severe irritant.

Remarks on results including tables and figures

Overall remarks, attachments

Attached background material

Attached document ()

Remarks

Applicant's summary and conclusion

Interpretation of results

highly irritating

Criteria used for interpretation of results

other: US DOT

Conclusions

AEE was considered a severe irritant and corrosive (Packing Group II) according to DOT classification. The primary irriation was not calculated since the 4 hr site was not dosed or scored due to severe irritation observed after application of AEE for 1 hr.

Mallory - Huntsman 1992 /corrosion.002

UUID IUC5-904abf6e-5309-4f2c-91a4-56b2b9a30a92
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 17:58:44 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 1990-10-31
Reliability 1 (reliable without restriction)
Rationale for reliability Study was performed according to OECD 404 guideline and in compliance with the GLP Regulations.

Data source

Reference

Reference type study report
Author Mallory VT, PHARMAKON RESEARCH INTERNATIONAL INC. **Year** 1992
Title Primary Dermal Irritation Study
Bibliographic source
Testing laboratory Pharmakon Research International, Inc. Waverly, PA 18471 **Report no.**
Owner company Huntsman
Company study no. PH 420-TX-011-90 **Report date** 1992-02-18

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Test guideline

Qualifier according to
Guideline OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Deviations

GLP compliance

yes

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): 6398-21-1 (laboratory sample ID)
- Physical state: clear, colorless liquid
- Analytical purity: responsibility of the Sponsor (> 99% as stated by sponsor)
- Stability under test conditions: no apparent change in the physical state of the test article during administration
- Other: total amount submitted :1408.3g (materials and containers)/pH=10 (litmus paper)

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Hare-Marland, Hewitt, NJ
- Age at study initiation: adult
- Weight at study initiation: 2.504-2.865 kg
- Housing:Rabbits were housed individually in cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Animal Resources, National Research Council.
- Diet (e.g. ad libitum): Purina Rabbit Ration HF, ad libitum
- Water (e.g. ad libitum): fresh tap water, ad libitum.
- Acclimation period: min.5d

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 20°C±3°C (63-73°F)
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light):12h light, 12h dark

IN-LIFE DATES: From: To:

Test system

Type of coverage

occlusive

Preparation of test site

other: shaved and abraded

Vehicle

unchanged (no vehicle)

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.5mL/site

Duration of treatment / exposure

4h (upper: intact dorsal trunk)
24h (lower: intact and abraded dorsal trunk)

Observation period

14d

Number of animals

6 (3M and 3F)

Control animals

other: OECD 404: untreated area of the test animal serves as control

Details on study design

TEST SITE
- Area of exposure: dorsal trunk (clipped free of fur)
- Type of wrap if used: rubber dam and an elastic bandage

REMOVAL OF TEST SUBSTANCE
- Washing (if done):
- Time after start of exposure: 4 and 24h

SCORING SYSTEM: observation
Draize Evaluation of Dermal Irritation (Primary Irritation Index) and Modified Primary Irritation Index

Any other information on materials and methods incl. tables

The abraded site was prepared using a burred needle; the abrasion penetrated the stratum corneum but not the derma. Following the application of the test material, gauze patches were applied to each of the sites then wrapped.

Results and discussions

Irritation / corrosion results

Irritation parameter	primary dermal irritation index (PDII)
Basis	mean
Time point	
Score	8
Max. score	
Reversibility	
Remarks	8=severe dermal irritation
Irritation parameter	erythema score
Basis	animal: 6/6
Time point	30min (4h exposure)
Score	4
Max. score	4
Reversibility	not reversible 14d observation
Remarks	severe erythema, sloughing, fissuring and necrosis
Irritation parameter	edema score
Basis	animal: 6/6
Time point	30min (4h exposure)
Score	4
Max. score	4
Reversibility	not reversible 14d observation
Remarks	severe edema, sloughing, fissuring and necrosis
Irritation parameter	erythema score
Basis	animal: 6/6
Time point	24h (24h exposure)
Score	4
Max. score	4
Reversibility	not reversible 14d observation
Remarks	severe erythema, necrosis, sloughing and fissuring
Irritation parameter	edema score
Basis	animal: 6/6
Time point	24h (24h exposure)
Score	4
Max. score	4
Reversibility	not reversible 14d observation
Remarks	severe edema, sloughing and fissuring

Irritant/corrosive response data

irreversible severe erythema (including necrosis, sloughing, fissuring) and severe edema is observed 30 min after 4h exposure. The skin damage remained throughout the study (14d)

Remarks on results including tables and figures

Applicant's summary and conclusion

Interpretation of results

corrosive

Criteria used for interpretation of results

OECD GHS

Conclusions

The test article was considered to be a severe dermal irritant at both 4 and 24 hour exposures with irreversible necrosis. Interpretation not identified by study author but determined by data submitter (corrosive).

Mallory - Huntsman 1984 / corrosion.003

UUID IUC5-1d096b4e-63e5-44a4-a140-f74b65b17091
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 18:42:47 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 1984
Reliability 2 (reliable with restrictions)
Rationale for reliability Study was comparable to the OECD 404 guideline with acceptable restrictions which do not impair the overall conclusion from the data.

Data source

Reference

Reference type study report
Author Mallory VT, Pharmakon Research International, Inc. **Year** 1984
Title Primary Dermal Irritation Study in Rabbits (ICAO)
Bibliographic source
Testing laboratory Pharmakon Research International, Inc. Waverly, Pennsylvania 18471 **Report no.**
Owner company Huntsman
Company study no. PH 420-TX-011-84 **Report date** 1984-12-20

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Test guideline

Qualifier according to
Guideline OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Deviations

GLP compliance

no

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): 5601-47-20 (laboratory/sponsor ID)
- Physical state: clear liquid
- Analytical purity: responsibility of the Sponsor (>99%)
- Lot/batch No.: #J-221

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Sgarlat's Rabbitry, Harvey's Lake, Pennsylvania
- Age at study initiation: adult
- Weight at study initiation: 2.480-2.570 kg
- Housing:Rabbits individually in cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Resources, National Research Council.
- Diet (e.g. ad libitum): Wayne Rabbit Ration, ad libitum
- Water (e.g. ad libitum):fresh .tap water, ad libitum
- Acclimation period: Five (5) days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 20°C±3°C
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light):12h light, 12h dark

IN-LIFE DATES: From: 12/11/1984 To: 12/11/1984

Test system

Type of coverage

no data

Preparation of test site

shaved

Vehicle

unchanged (no vehicle)

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.5 mL/site, 1 site per animal

Duration of treatment / exposure

4h

Observation period

4h

Number of animals

3 (2M and 1 F)

Control animals

other: OECD 404: untreated area of the test animal serves as control

Details on study design

TEST SITE
- Area of exposure: intact site (clipped free of fur)
- Type of wrap if used:

REMOVAL OF TEST SUBSTANCE
- Washing (if done): no data
- Time after start of exposure:

SCORING SYSTEM: Draize Scoring System

CLASSIFICATION (classified by the lenght of contact necessary to produce visible necrosis of the skin site):
Group I (very dangerous):substances that caused visible necrosis of the skin tissue in 3 minor less
Group II (substances producing medium danger) -substances that caused visible necrosis of the skin tissue in a time period of 3 to 60 minutes
Group III (substances presented minor danger) - substances that caused visible necrosis of the skin tissue in 60 to 240 minutes

Results and discussions

Irritation / corrosion results

Irritation parameter	erythema score
Basis	animal: 1/3
Time point	60min
Score	3
Max. score	4
Reversibility	
Remarks	severe erythema
Irritation parameter	erythema score
Basis	animal: 2/3
Time point	60min
Score	1
Max. score	4
Reversibility	
Remarks	slight erythema
Irritation parameter	erythema score
Basis	animal #1
Time point	4h
Score	3 — 4
Max. score	4
Reversibility	
Remarks	severe erythema: 15-20% of the application site
Irritation parameter	erythema score
Basis	animal #2
Time point	4h
Score	3 — 4
Max. score	4
Reversibility	
Remarks	severe erythema: 30% of the application site
Irritation parameter	erythema score
Basis	animal #3
Time point	4h
Score	4
Max. score	4
Reversibility	
Remarks	severe erythema at application site
Irritation parameter	edema score
Basis	animal #3
Time point	4h
Score	3
Max. score	4
Reversibility	no data
Remarks	moderate edema at application site

Irritant/corrosive response data

No signs or necrosis on any of the animals at application site in the 1-3 min observation period.
No signs of necrosis in any animal throughout the study.

Remarks on results including tables and figures

In the study report, no scores were assigned, only a description of the effects was reported.

Applicant's summary and conclusion

Interpretation of results

highly irritating

Criteria used for interpretation of results

OECD GHS

Conclusions

Slight to severe erythema was observed at the 60 minute and 4 hour observation periods.
Moderate edema was observed at 4 hours. No signs of necrosis were visible in any of the animals throughout the study.

The author of the study report concluded that the substance was determined to be a non-hazardous chemical.
However, based on the description of the results it can be concluded that the substance is a severe (highly) irritant.

BASFAG XIX/51.Skin irritation / corrosion.rabbit

UUID IUC5-5345d729-52c0-4cac-b622-0b3664d11acb
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-09 10:35:45 EST
Remarks

Administrative Data

Purpose flag (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability Acceptable, well documented report which meets basic scientific principles.

Data source

Reference

Reference type study report
Author BASF AG **Year** 1969
Title Industrial hygiene orientating investigation
Bibliographic source unpublished data
Testing laboratory BASF AG, Department of Toxicology **Report no.** XIX/51
Owner company BASF SE
Company study no. **Report date** 1969-04-20

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Principles of method if other than guideline

BASF-Test, see details in remarks on results.

GLP compliance

no

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): Aminodiglykol, 2-(2-Hydroxyaethoxy-)aethylamin
- Physical state: liquid
- Analytical purity: > 99 %

Test animals

Species

rabbit

Strain

Vienna White

Details on test animals and environmental conditions

TEST ANIMALS
- Weight at study initiation: 2.46 and 2.88 kg

Test system

Type of coverage

occlusive

Preparation of test site

other: clipped

Vehicle

unchanged (no vehicle)

Duration of treatment / exposure

1 min, 5 min, 15 min or 20 h.

Observation period

8 days

Number of animals

8 days

Control animals

other: untreated skin of the same animals served as control.

Details on study design

TEST SITE
- Area of exposure: 2.5x2.5 cm

REMOVAL OF TEST SUBSTANCE
- Washing (if done): concentrated Lutrol and 50% Lutrol
- Time after start of exposure: 1 min, 5 min and 15 min

Any other information on materials and methods incl. tables

Two animals were treated for 1, 5, 15 min or 20 hours using occlusive conditions. An application site of 2.5x2.5 cm was covered with the liquid test substance. The animals were observed for 8 days and skin changes were recorded daily. The report describes findings after 24 hours and at the end of the observation period of 8 days. For a final evaluation, the findings after 48 and 72 hours from the raw data were taken into account.

Results and discussions

Irritation / corrosion results

Irritation parameter erythema score , 1 min exposure

Basis mean
Time point 24 h - 48 h - 72 h
Score 0.3
Max. score 4
Reversibility fully reversible within: 48 h
Remarks

Irritation parameter erythema score , 5 min
Basis mean
Time point 24 h - 48 h - 72 h
Score 0.6
Max. score 4
Reversibility not fully reversible within: 8 days
Remarks scale formation

Irritation parameter erythema score , 15 min exposure
Basis mean
Time point 24 h - 48 h - 72 h
Score 1.5
Max. score 4
Reversibility not fully reversible within: 8 days
Remarks necrosis

Irritation parameter erythema score 20 h exposure
Basis mean
Time point 24 h - 48 h - 72 h
Score 2.5
Max. score 4
Reversibility not reversible
Remarks full thickness necrosis

Irritation parameter edema score
Basis mean
Time point 24 h - 48 h - 72 h
Score 0
Max. score 4
Reversibility other: no symptoms
Remarks

Remarks on results including tables and figures

Mean erythema score after 24, 48 and 72 h (animal1/2)

Exposure time	24 h	48 h	72 h	mean
1 min	1/1	0/0	0/0	0.3/0.3
5 min	1/1	0/1	0/1	0.3/1
15 min	1/3	0/3	0/2	0.3/2.7
20 h	2/3	2/3	3/3	2/3

Mean edema score after 24, 48 and 72 h (animal1/2)

Exposure time	24 h	48 h	72 h	mean
1 min	0/0	0/0	0/0	0/0
5 min	0/0	0/0	0/0	0/0
15 min	0/0	0/0	0/0	0/0
20 h	0/0	0/0	0/0	0/0

The application of the test substance caused slight erythema after a 1 and 5 min exposure and moderate to severe erythema after a 15 min or 20 h exposure. After 15 min of exposure one animal developed necrosis 72 post exposure. 20 h of exposure led to anaemic necrosis which developed in 1 animal to hart necrosis at the end of the observation period. The appearing necrosis is considered as a full thickness necrosis.
The original BASF grading was converted into the numerical grading according the OECD Draize system.

Applicant's summary and conclusion

Interpretation of results

corrosive

Conclusions

Classification: corrosive (causes burns)

Smyth 1951.Skin irritation / corrosion,rabbit

UUID IUC5-072d7cf7-6f8f-48ae-b6d7-9d89dffec20a
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-09 10:39:53 EST
Remarks

Administrative Data

Purpose flag (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 2 (reliable with restrictions)
Rationale for reliability Acceptable publication but only limited data is given.

Data source

Reference

Reference type publication
Author Smyth H.F. et al. **Year** 1951
Title Range-Finding Toxicity Data, List IV
Bibliographic source Arch. Ind. Hyg. Occup. Med., 4, 119
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

in vivo

Principles of method if other than guideline

see details in remarks on material and methods

GLP compliance

no

Test materials

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-aminoethoxyethanol

Test animals

Species

rabbit

Strain

no data

Test system

Type of coverage

open

Preparation of test site

other: clipped

Vehicle

no data

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.01 ml

Duration of treatment / exposure

24 h

Observation period

24 h

Number of animals

5

Control animals

no data

Any other information on materials and methods incl. tables

Primary skin irritation on rabbits is recorded in a 10 grade ordinal series and is based upon the severest reaction that develops on the clipped skin of each of five albino rabbits within 24 hours of the uncovered application of 0.01 ml of undiluted sample or of solutions in water, propylene glycol, or acetone. Grade 1 in the Table indicates no irritation and Grade 2 the least visible capillary injection from the undiluted chemical. Grade 6 indicates necrosis when undiluted and Grade 10 indicates necrosis from a 0.01% solution.

Results and discussions

Irritation / corrosion results

Irritation parameter overall irritation score
Basis mean
Time point 24 h
Score 6
Max. score 10
Reversibility no data
Remarks

Remarks on results including tables and figures

The severity of the reaction was graded 6 by the authors, indicating necrosis when test substance was applied undiluted.

Overall remarks, attachments

Overall remarks

7.3.2 Eye irritation

BASFAG XIX/51.Eye irritation.rabbit

UUID	IUC5-dede84d1-b6ec-452a-8dad-c3d553597ec9
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 19:56:42 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Basic scientific data.

Data source

Reference

Reference type	study report		
Author	BASF AG: department of toxicology,	**Year**	1966
Title	Industrial hygiene orientating investigation		
Bibliographic source	unpublished data		
Testing laboratory	BASF AG, Department of Toxicology	**Report no.**	XIX/51
Owner company	BASF SE		
Company study no.		**Report date**	1966-04-23

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Test guideline

Qualifier	equivalent or similar to
Guideline	OECD Guideline 405 (Acute Eye Irritation / Corrosion)
Deviations	

Principles of method if other than guideline

BASF-Test, see details in remarks on results.

GLP compliance

no

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier	Common name
Identity	2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): Aminodiglykol, 2-(2-Hydroxyaethoxy-)aethylamin
- Physical state: liquid
- Analytical purity: > 99 %

Test animals

Species

rabbit

Strain

Vienna White

Details on test animals and environmental conditions

TEST ANIMALS
- Weight at study initiation: 2.87 and 2.92 kg

Test system

Vehicle

unchanged (no vehicle)

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 50 µl

Duration of treatment / exposure

8 days (single application)

Observation period

8 days

Number of animals

2

Control animals

other: The adjacent eye served as saline control.

Any other information on materials and methods incl. tables

50 µL of the test substance were applied to the conjunctival sac of one eye in 2 animals. The animals were observed after 10 min, 1 and 3h on the day of treatment and up to 8 days afterwards. The eyes were not washed out after 24 hours as specified in OECD Guideline 405.

Results and discussions

Overall irritation / corrosion results

Irritation parameter	cornea score
Basis	mean
Time point	24 h - 48 h - 72 h

2

Max. score 4

Reversibility not reversible

Remarks

Irritation parameter iris score

Basis mean

Time point 24 h - 48 h - 72 h

1

Max. score 2

Reversibility not fully reversible within: 8 days

Remarks

Irritation parameter conjunctivae score

Basis mean

Time point 24 h - 48 h -72 h

2

Max. score 3

Reversibility not fully reversible within: 8 days

Remarks

Irritation parameter chemosis score

Basis mean

Time point 24 h - 48 h - 72 h

1.5

Max. score 4

Reversibility not fully reversible within: 8 days

Remarks

Remarks on results including tables and figures

Findings animal1/2:

Time	Opacity	Iritis	Erythema	Chemosis
1h	1/3	0/0	2/2	2/2
24h	1/3	0/0	2/2	2/2
48h	1/1	1/2	2/2	1/1
72h	3/3	1/2	2/2	1/2
8d	3/3	0/2	0/2	0/2

Mean values over 24h, 48h and 72h:

Animal1: Opacity: 1.7; Iritis: 0.7; Erythema: 2; Chemosis: 1.3;

Animal2: Opacity: 2.3; Iritis: 1.3; Erythema: 2; Chemosis: 1.7;

The application of the test substance caused moderate to severe corneal opacity, irritis, moderate erythema and slight to moderate chemosis.

At the end of the observation period after 8 days staphyloma and severe corneal opacity were noted. Severe corneal opacity, is considered to be an irreversible effect to ophthalmic tissue.

The original BASF grading was converted into the numerical grading according to the OECD Draize system.

Smyth 1951.Eye irritation,rabbit

UUID IUC5-a080b809-ab71-4bee-9b6b-1205ba6093fc
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-10 16:05:02 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 2 (reliable with restrictions)
Rationale for reliability Acceptable publication but only limited data given.

Data source

Reference

Reference type publication
Author Smyth H.F. et al. **Year** 1951
Title Range-Finding Toxicity Data List IV
Bibliographic source Arch. Ind. Hyg. Occup. Med., 4, 119
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data published

Materials and methods

Type of method

in vivo

Test guideline

Qualifier
Guideline other guideline:
Deviations

Principles of method if other than guideline

see details in remarks on material and methods

GLP compliance

no

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier Common name
Identity 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-aminoethoxyethanol

Test animals

Species

rabbit

Strain

no data

Test system

Vehicle

no data

Duration of treatment / exposure

24 h

Observation period

24 h

Number of animals

5

Control animals

no data

Any other information on materials and methods incl. tables

Eye injury in rabbits is recorded in a 10-grade ordinal series and is based upon the degree of corneal necrosis that results from instillation of various volumes and concentrations of chemical, as detailed by Carpenter and Smyth. Grade 1 in the table indicates at most a very small area of necrosis resulting from 0.5 ml of undiluted chemical in the eye. Grade 5 indicates a so-called severe burn from 0.005 ml, and grade 10 indicates a severe burn from 0.5 ml of a 1% solution in water or propylene glycol.

Results and discussions

Overall irritation / corrosion results

Irritation parameter overall irritation score
Basis mean
Time point 24 h
9
Max. score 10
Reversibility no data
Remarks

Overall remarks, attachments

Overall remarks

Calvert/Huntsman.001

UUID IUC5-2a496e72-9a34-4f04-993d-25589732b9aa
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 19:48:04 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** May 1-6, 2002
Reliability 1 (reliable without restriction)
Rationale for reliability Study was performed according to OECD 405 guideline and GLP of the EPA (4 CFR Part 792) and OECD.

Data source

Reference

Reference type study report
Author Calvert Preclinical Services, Inc. **Year** 2002
Title Primary Eye Irritation
Bibliographic source
Testing laboratory Calvert Preclinical Services, Inc.,Scott Technology Park 100 Discovery Drive Olyphant, PA 18447 **Report no.**
Owner company Huntsman
Company study no. 0421XH11.013 **Report date** 2002-06-25

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Test guideline

Qualifier according to
Guideline OECD Guideline 405 (Acute Eye Irritation / Corrosion)
Deviations no

Test material equivalent to submission substance identity

yes

Test materials

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): aqueous Solution of DGA Agent
- Physical state: clear, slightly viscous liquid
- Analytical purity: responsibility of the Sponsor - not reported
- Stability under test conditions: responsibility of the Sponsor-not reported (Sponsor reports >99%)
- Storage condition of test material: room temp.

Test animals

Species

rabbit

Strain

New Zealand White

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Harlan Sprague Dawley, Oxford, MI
- Age at study initiation: 12 weeks (adult)
- Weight at study initiation: 2.4-2.6 kg
- Housing:individually in compliance with USDA guidelines. Calvert is USDA registered and a fully A4ALAC accredited-facility.
- Diet (e.g. ad libitum): Teklad Certified Rabbit Diet, ad libitum
- Water (e.g. ad libitum):ad libitum
- Acclimation period: min. 5d

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 16-21°C
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light): 12h light,12h dark

Test system

Vehicle

unchanged (no vehicle)

Amount/concentration applied

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.1 ml
- Concentration (if solution):

Duration of treatment / exposure

1 second

Observation period

72h

Number of animals

6 (3M and 3F)

Control animals

yes, concurrent no treatment

Details on study design

REMOVAL OF TEST SUBSTANCE
- Washing (if done): no washing
- Time after start of exposure:

SCORING SYSTEM:observation
Draize scoring and Kay & Calendra modified scoring system

TOOL USED TO ASSESS SCORE: no data

Results and discussions

Overall irritation / corrosion results

Irritation parameter Maximum mean total score (MMTS)
Basis mean
Time point 1h
3.7
Max. score 110
Reversibility fully reversible within: 48h
Remarks

Irritation parameter cornea score
Basis mean
Time point 1h, 24h, 48h, 72h
0
Max. score 80
Reversibility
Remarks

Irritation parameter iris score
Basis mean
Time point 1h, 24h, 48h, 72h
0
Max. score 10
Reversibility
Remarks

Irritation parameter conjunctivae score
Basis animal: 6
Time point 1h
2 — 6
Max. score 20
Reversibility
Remarks

Irritation parameter conjunctivae score
Basis animal:
Time point 24h
0 — 2
Max. score 20
Reversibility fully reversible within: 48h
Remarks

Irritant/corrosive response data

According to the Modified Kay and Calandra Interpretation of Eye Irritation Test, Aqueous Solution of DGA Agent is considered a minimal irritant (Class 3).

Applicant's summary and conclusion

Interpretation of results

other: minimal irritant

Criteria used for interpretation of results

other: Kay and Calandra

Conclusions

Based on the results obtained from the Primary Eye Irritation with Aqueous Solution of DGA Agent, the Maximum Group Mean Score is 3.7.
According to the Modified Kay and Calandra Interpretation of Eye Irritation Test, Aqueous Solution of DGA Agent is considered a minimal irritant (Class 3).

7.4 Sensitisation

Sensitisation

UUID	IUC5-be82fe8e-599e-4b23-811d-e9c5cfdec560
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-14 20:17:43 EST
Remarks	

Administrative Data

Skin sensitisation

Short description of key information

Skin sensitisation: not sensitizing.
Respiratory sensitisation: no data available.

Key parameter (optional)

Skin sensitisation

not sensitising

Discussion

In an OECD 406 test guideline study conducted in accordance with GLP, AEE was evaluated at 10% concentration for dermal sensitization in 20 guinea pigs (10 f, 10 m) for a 3 x 6 hour induction period. Animals were challenged after 14 days and one positive response was observed after 24 and 48 hours relative to 100% response (5/5) in the positive control group. In a rechallenge after 7 days 2/20 positive responses were observed after 24 and 48 hours (Huntsman 1991; reliability score: 1).

Respiratory sensitisation

Short description of key information

No data available for the determination of the respiratory sensitisation potential.

Discussion

Altough 10 % of the animals showed a positive result, a minimum figure of 15% under any study would be necessary for classification as a sensitizer under EU standards.

No EU classification according to Annex I of Directive 67/548/EEC.

7.4.1 Skin sensitisation

Skin sensitisation.001

UUID IUC5-03051b1e-6c49-4700-b8f4-c721245584bd
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-14 20:14:33 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** Jan-March 1991
Reliablility 1 (reliable without restriction)
Rationale for reliability Study was performed according to OECD 406 guideline and in compliance with the GLP Regulations.

Data source

Reference

Reference type study report
Author Armondi SE **Year** 1991
Title Delayed contact hypersensitivity in guinea pigs
Bibliographic source
Testing laboratory Pharmakon Research International, Inc. **Report no.** PH 424-TX-006-90
Owner company Huntsman
Company study no. **Report date** 1991-03-18

Data access

data submitter is data owner

Materials and methods

Type of method

in vivo

Type of study

Buehler test

Test guideline

Qualifier equivalent or similar to
Guideline OECD Guideline 406 (Skin Sensitisation)
Deviations no

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): 6398-21-1 (laboratory ID)
- Physical state: liquid
- Analytical purity: responsibility of the sponsor
- Stability under test conditions: no apparent change in the physical appearance of the test article during administration
- Storage condition of test material: responsibility of the sponsor

Test animals

Species

guinea pig

Strain

Hartley

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Buckberg Lab Animals, Tomkins Cove, New York
- Weight at study initiation: 300-700g
- Housing: individually in stainless steel wire mesh cages
- Diet (e.g. ad libitum): purina guinea pig diet, ad libitum
- Water (e.g. ad libitum): fresh tap water, ad libitum
- Acclimation period: minimum 5 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 20 ± 3°C
- Humidity (%): 30-70 %
- Photoperiod (hrs dark / hrs light): 12 hrs dark / 12 hrs light

IN-LIFE DATES: From: Jan 1991 To: March 1991

Test system

Traditional sensitisation test

Route of induction exposure

epicutaneous, occlusive

Route of challenge exposure

epicutaneous, occlusive

Vehicle

other: 80% ethanol (induction) and acetone (challenge)

Concentration

0.3 ml/site (10%)

No. of animals per dose

dose range: 8 or 10 (unclear)
test article: 20 (10 male, 10 female)
positive control: 5
negative control: 10

Details on study design (Traditional tests)

RANGE FINDING TESTS:
10 unexposed animals (5male/5female) are exposed to 4 different concentrations of the test material: 80% ethanol as the vehicle.
primary challenge responses were graded
Highest non-irritatting concentration = concentration that induced responses not exceeding 2 + and 2 0 grades in the group of 4 animals.
the dose chosen for induction, challenge and rechallenge : 10%

MAIN STUDY
A. INDUCTION EXPOSURE
- No. of exposures: 5 (3 inductions, 1challenge, 1 rechallenge)
- Exposure period: -
- Test groups: test substance in vehicle (80% ethanol)
- Control group: vehicle only (80% ethanol)
- Site: L shoulder
- Frequency of applications: once a week
- Duration: 6 h
- Concentrations: 10%

B. CHALLENGE EXPOSURE
- No. of exposures: 2
- Day(s) of challenge: day 28 (or 29) and 35 (or 36) (unclear)
- Exposure period: -
- Test groups: test substance in vehicle
- Control group: vehicle only (left flank), test article (right flank)
- Site: naive site on left side
- Concentrations: 10%
- Evaluation (hr after challenge): 24 and 48h

OTHER: 24h after challenge, all animals were depilated with Neet Cream Hair Remover (Whitehall Laboratories, Inc., New York). A minimum of 2h after depilation test sites were graded. The grading was repeated 24h later (48h grade).

Challenge controls

The negative control group was challenged with vehicle on the left flank and test article on the right flank.
7 days after the primary challenge, all test article treated animals, along with an additional group of naive guina pigs were rechallenged.

Positive control substance(s)

yes 1-chloro-2,4-dinitrobenzene

LLNA

Any other information on materials and methods incl. tables

Results and discussion

Positive control results

Sensitising effects are observed in all 5 animals of the positive control group.

Traditional sensitisation test

Results of test (except LLNA)

Reading	1st reading
Hours after challenge	24
Group	test group
Dose level	10%
No. with + reactions	1
Total no. in group	20
Clinical observations	severity= 0.3
Reading	2nd reading
Hours after challenge	48
Group	test group
Dose level	10%
No. with + reactions	1
Total no. in group	20
Clinical observations	severity= 0.2
Reading	rechallenge
Hours after challenge	24
Group	test group
Dose level	10%
No. with + reactions	2
Total no. in group	20
Clinical observations	severity= 0.3
Reading	rechallenge
Hours after challenge	48
Group	test group
Dose level	10%

No. with + reactions	2
Total no. in group	20
Clinical observations	severity= 0.3
Reading	1st reading
Hours after challenge	24
Group	negative control
Dose level	vehicle
No. with + reactions	0
Total no. in group	10
Clinical observations	severity= 0.0
Reading	2nd reading
Hours after challenge	48
Group	negative control
Dose level	vehicle
No. with + reactions	0
Total no. in group	10
Clinical observations	severity= 0.0
Reading	other: naive control
Hours after challenge	24
Group	negative control
Dose level	10%
No. with + reactions	0
Total no. in group	10
Clinical observations	severity= 0.2
Reading	other: naive control
Hours after challenge	48
Group	negative control
Dose level	10%
No. with + reactions	0
Total no. in group	10
Clinical observations	severity= 0.2
Reading	1st reading
Hours after challenge	24
Group	positive control
Dose level	0.3%
No. with + reactions	5
Total no. in group	5
Clinical observations	severity= 3.0
Reading	2nd reading
Hours after challenge	48
Group	positive control
Dose level	0.3%
No. with + reactions	5
Total no. in group	5
Clinical observations	severity= 2.6

LLNA

Remarks on results including tables and figures

Applicant's summary and conclusion

Interpretation of results

not sensitising

Conclusions

Based upon the observations made in the assay, the test article induced, challenged and rechallenged at a 10% concentration, did not cause delayed contact hypersensitivity in guinea pigs. The test substance is not considered a sensitizer.

Executive summary

7.5 Repeated dose toxicity

Repeated dose toxicity

UUID	IUC5-592f72fa-c5f6-460d-bfbd-f28b55494fde
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2010-01-20 16:10:15 EST
Remarks	

Administrative Data

Short description of key information

AEE was administered intact cutaneous site for approximately 6 hours daily to 10 male and female Sprague-Dawley rats for 90 consecutive days at a concentration of 0, 50, 250 and 500 mg/kg bw/day (nominal) which is equivalent to an actual concentration of 0, 17, 87 and 175 mg/kg bw/day, respectively.

An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints. The range finding study has been completed with concentrations of 0, 10, 50 and 250 mg/m3 of the test substance. The findings from the study are in the process of being reviewed by the pathologist. Initial, draft findings, include irritation effects at the mid and high dose groups.
Results from this study are as follows: ulceration, epidermal hyperplasia, fibrosis and/or inflammation at doses of 87 and 175 mg/kg bw/d. These changes represent local irritation following topical administration. The NOAEL for dermal effects is 17 mg/kg/day bw (actual dose). In females there was a statistically significant increase in absolute and relative neutrophil counts at 87 mg/kg bw/day this effect was considered to be incidental and not dose related. In females exposed at 87 and males and females at 175 mg/kg bw/day, a statistically significant increase in globulin and decrease in albumin/globulin ratios were observed. The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance. The systemic NOAEL is 175 mg/kg bw/day (actual dose)(highest dose tested).

Key parameter (optional)

Repeated dose toxicity: dermal

Effect level			
NOAEL	in mg/kg bw/day	175	

Discussion

In a range finding study, AEE was administered via topical administration to the intact skin sites of Sprague-Dawley rats, once daily for 14 consecutive days, the dermal no-observed adverse effect level (NOAEL) was 250 mg/kg/day based on dermal irritation (Chrysalis, 2000). Results from this study were used to select the doses for the 90 -day repeat dose dermal toxicity study conducted in accordance with OECD test guideline 411 under GLP conditions (Zeiders, 2002). In this study AEE was administered intact cutaneous site for approximately 6 hours daily to 10 male and female Sprague-Dawley rats for 90 consecutive days at a concentration of 0, 50, 250 and 500 mg/kg bw/day (nominal) which is equivalent to an actual concentration of 0, 17, 87 and 175 mg/kg bw/day, respectively.

Results from this study are as follows: ulceration, epidermal hyperplasia, fibrosis and/or inflammation at doses of 87 and 175 mg/kg bw/d. These changes represent local irritation following topical administration. The NOAEL for dermal effects is 17 mg/kg/day bw (actual dose). In females there was a statistically significant increase in absolute and relative neutrophil counts at 87 mg/kg bw/day this effect was considered to be incidental and not dose related. In females exposed at 87 and males and females at 175 mg/kg bw/day, a statistically significant increase in globulin and decrease in albumin/globulin ratios were observed. The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance. The systemic NOAEL is 175 mg/kg bw/day (actual dose)(highest dose tested).

An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.

7.5.2 Repeated dose toxicity: dermal

Repeated dose toxicity: dermal.001

UUID	IUC5-f4e73a1d-fb15-40ed-9603-b0895a2822f7
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-15 15:58:25 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliability	1 (reliable without restriction)
Rationale for reliability	Guideline study conducted under GLP conditions

Data source

Reference

Reference type	study report		
Author	Zeiders, JL	**Year**	2002
Title	A 90-day dermal toxicity study in rats		
Bibliographic source			
Testing laboratory	Calvert Preclinical Services Inc., PA 18447 USA	**Report no.**	0470RH11.001
Owner company	Huntsman		
Company study no.		**Report date**	2002-11-13

Data access

data submitter is data owner

Data protection claimed

yes

Materials and methods

Test type

subchronic

Limit test

no

Test guideline

Qualifier	according to
Guideline	OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study)
Deviations	

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4

Details on test material

- Name of test material (as cited in study report): DGA(AEE)
- Substance type: clear, colorless
- Physical state: liquid
- Lot/batch No.: 9F10
- Expiration date of the lot/batch: 15 July 2001
- Stability under test conditions: stability information was not provided
- Storage condition of test material: room temp

Test animals

Species

rat

Strain

Sprague-Dawley

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Harlan Sprague Dawley, strain Hsd:SD
- Age at study initiation: 6 weeks
- Weight at study initiation: 143-247 grams
- Fasting period before study:
- Housing:
* before the study: rats were groups-housed by sex
* during the study: animals were housed individually in stainless steel cages
- Diet (e.g. ad libitum): Teklad Certified LM-485 rodent diet, ad libitum, except overnight prior to scheduled blood collectiong
- Water (e.g. ad libitum): ad libitum
- Acclimation period: min 7 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 19-25°C
- Humidity (%): 30-70% (during 2 days of the study, relative humidity was outside this range. However, this is not considered to have had any adverse

effect on the outcome of this study)
- Photoperiod (hrs dark / hrs light): 12h light, 12h dark

Administration / exposure

Type of coverage

occlusive

Vehicle

water

Details on exposure

TEST SITE
- Area of exposure: between 10 and 20% of the body surface
- Type of wrap if used: gauze pad, rubber dam and an elastic bandage
- Time intervals for shavings or clipplings: minimum of twice weekly

REMOVAL OF TEST SUBSTANCE
- Washing (if done): gently cleansed with gauze soaked in warm water and gently dried
- Time after start of exposure: 6h

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.5 ml/kg bw /d
- Concentration (if solution): 0 - 17- 87- 175 mg/kg bw/d
- Constant volume or concentration used: yes

VEHICLE = deionized water
- Amount(s) applied (volume or weight with unit): 0.5 ml/kg bw/d
- Lot/batch no. (if required): 071099, 201099, 011199, 091199, 171199, 221199, 031299, 081299, 151299, 171299, 281299

USE OF RESTRAINERS FOR PREVENTING INGESTION: no data

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

nominal concentration (mg/kg bw/d): 0 - 50 - 250 - 500 respectively
actual concentration (mg/kg bw/d): 0 - 17 - 87 - 175 respectively

Duration of treatment / exposure

approximately 6h

Frequency of treatment

once daily, 90 consecutive days

Doses/concentrations

17

Basis analytical per unit body weight

87

Basis analytical per unit body weight

175

Basis analytical per unit body weight

No. of animals per sex per dose

10 male and 10 female rats per dose

Control animals

yes, concurrent vehicle

Details on study design

- Dose selection rationale: dose level selected by the sponsor based upon results from range finding study
- Rationale for animal assignment (if not random): random
- Rationale for selecting satellite groups: no satellite group

Positive control

no data

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: No data

DETAILED CLINICAL OBSERVATIONS: Yes
- Time schedule: twice daily

DERMAL IRRITATION (if dermal study): Yes
- Time schedule for examinations: once daily

BODY WEIGHT: Yes
- Time schedule for examinations:
at the time of randomisation
prior to dose administration on day 1
weekly (after that)
on day 91 (fasted)

FOOD CONSUMPTION:
- Food consumption for each animal determined and mean daily diet consumption calculated as g food/kg body weight/day: Yes (weekly)

FOOD EFFICIENCY:
- Body weight gain in kg/food consumption in kg per unit time X 100 calculated as time-weighted averages from the consumption and body weight gain data: No data

WATER CONSUMPTION: No data

OPHTHALMOSCOPIC EXAMINATION: Yes
- Time schedule for examinations: before treatment + prior to terminal sacrifice
- Dose groups that were examined: all animals

HAEMATOLOGY: Yes
- Time schedule for collection of blood: on day 91, prior to terminale sacrifice
- Anaesthetic used for blood collection: Yes, CO2
- Animals fasted: Yes , overnight
- How many animals: all surviving animals (= all animals, 80)
- Following parameters were examined.
* Hematology: differential white blood cell count, hematocrit, hemoglobin, mean corpuscular hemoglobin,
mean corpuscular hemoglobin concntration, mean corpuscular volume, platelet count, red blood cell count and morphology,
white blood cell count
* Coagulation: prothrombin time, acctivated partial thromboplastin time

CLINICAL CHEMISTRY: Yes
- Time schedule for collection of blood:on day 91, prior to terminale sacrifice
- Animals fasted: Yes , overnight
- How many animals: all animals (80)
- Following parameters were examined:
* serum clinical chemistry: alanine aminotransferase, albumin, albumin/globulin ratio (calculated), aspartate aminotransferase, calcium, chloride, cholesterol, creatinine, creatine phosphokinase, globulin (calculated), glucose, phosphorus, potassium, sodium, total bilirubin, total protein, triglycerides, urea nitrogen

URINALYSIS: Yes
- Time schedule for collection of urine: on day 90, urine was collected overnight
- Metabolism cages used for collection of urine: Yes
- Animals fasted: Yes
- Following parameters were examined:
* volume, specific gravity, appearance/color, semi-quantitative estimation: pH, protein, glucose, ketone, urobilinoen, bilirubin, blood, leukocytes, nitrites, microscopic examination of spun deposit

NEUROBEHAVIOURAL EXAMINATION: Yes
- Time schedule for examinations: on day 28 and day 90 during treatment
- Dose groups that were examined: all
- Battery of functions tested: observation of animals / sensory activity / grip strength / motor activity / other: loss of righting reflex, spontaneous locomotor activity, right pupil examination, various reflex responses

OTHER:

Sacrifice and pathology

GROSS PATHOLOGY: Yes
external surface of the body, all orifices, cranial, thoracic and abdominal cavities together with their content

HISTOPATHOLOGY: Yes
gross abnormalities, adrenals, aorta, whole brain, cecum, colon, duodenum, epididymides, esophagus, exorbital lachrymal gland, eyes w/optic nerve, femur, fat (mesentery), heart, ileum, jejunum, kidneys, liver, lungs with mainstem bronchus, mammary gland(s), mesenteric lymph nodes, ovaries, pancreas, pituitary, prostate, rectum, salivary glands (mandibular lymph nodes), sciatic nerve, seminal vesicle(s), skin (with subcutis from a site other than the treated site), spinal cord at three levels - cervical, midthoracic, lumbar - spleen, sternum with bone marrow, stomach, testes, thigh musculature (skeletal muscle), thymus, thyroids/parathyroids, tongue, trachea, treated site (dorsal thoracic region with subcutis), urinary bladder, uterus, vagina

Statistics

evaluation of equality of means: one-way analysis of variance usiing the F distribution to assess statistical significance is differences between the means are statistically significant, Dunnett's test was used to determine the degree of significance.

Results and discussions

Effect levels

Endpoint	NOAEL dermal effects
Effect level	17 mg/kg bw/day (actual dose received)
Sex	male/female
Basis for effect level / Remarks	dermal irritation (erythema and oedema starting on day 6 of administration at 87 mg/kg bw)
Endpoint	NOAEL systemic effets
Effect level	175 mg/kg bw/day (actual dose received)
Sex	male/female
Basis for effect level / Remarks	In females there was a statistically significant increase in absolute and relative neutrophil counts at 87 mg/kg bw/day this effect was considered to be incidental and not dose related. In females exposed at 87 and males and females at 175 mg/kg bw/day, a statistically significant increase in globulin and decrease in albumin/globulin ratios were observed. The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance.

Observations

Clinical signs and mortality

no effects

Dermal irritation

yes

Body weight and weight gain

no effects

Food consumption

no effects

Food efficiency

not examined

Water consumption

not examined

Ophthalmoscopic examination

no effects

Haematology

yes

Clinical chemistry

yes

Urinalysis

no effects

Neurobehaviour

no effects

Organ weights

no effects

Gross pathology

yes

Histopathology: non-neoplastic

yes

Histopathology: neoplastic

no data

Details on results

CLINICAL SIGNS AND MORTALITY
* no animals died during the study

* no clinical signs of toxicity observed during the study
* clinical signs of dermal irritation were noted.
-Erythema and edema of varying degrees was observed in both males and females in the 87 and 175 mg/kg bw/d groups.
-Very slight erythema first appeared on day 6, 7 or 8 of 87 - 175 mg/kg bw/d groups.
-Very slight edema first appeared on day 7 in females recieving 175 mg/kg bw/d and progressed to severe edema by the end of the study.
-Very slight edema was seen on days 28, 38 or 33 respectively in females (87mg/kg bw/d) and males (87 or 175 mg/kg bw/d). This progresses to moderate to severe during the following 90 days of treatment. There was slightly more eythema and edema in females (87 mg/kg bw/d) compared to males recieving the same dose.
- additional signs noted in the male/female 87 and 175 mg/kg bw/d dose groups were all related to irritation at the application site and included scab formation, sloughing, and black areas on the dosing site.

BODY WEIGHT AND WEIGHT GAIN
* no test article-related differences in group mean bw or body weight gains throughout the study

FOOD CONSUMPTION
* no test article-related differences in group mean food consumption throughout the study

FOOD EFFICIENCY
* no data

WATER CONSUMPTION
* no data

OPHTHALMOSCOPIC EXAMINATION
* no test article-related differences in ophthalmology examination, conducted during the final week of treatment

HAEMATOLOGY
* Females, 87 mg/kg bw/d: statistically significant increase in absolute and relative neutrophil counts
* no test article-related differences in erythrocyte morphology for males or females
* no test article-related differences in hematology for males
This effect was considered by the study author to be incidental and not dose related.

CLINICAL CHEMISTRY
* males, 175 mg/kg bw/d + females, 87 and 175 mg/kg bw/d: statistically significant increases in globulin + decreases in albumin/globulin ratios
* all other stat. significant differences were withing normal historical ranges.
The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance.

URINALYSIS
* no test article-related changes in any of the urinalyses parameters observed in M or F rates at the end of the treatment period

NEUROBEHAVIOUR
* no test article-related neurotoxicity observed on day 28 or day 90.

ORGAN WEIGHTS
* no test article-related differences in absolute organ weights, relative organ to body weight ratios, or relative organ to brain weight-ratios
following 90 d of treatment.

GROSS PATHOLOGY
* scab formation of varying degrees was observed at the treatment site of males and females receiving 87 or 175 mg/kg bw/d (see table 9, p. 148)
* varous gross lesions on the skin at the treatment site were test article-related in male and females receiving 87 or 175 mg/kg bw/d
(namely respecitvely in 8/10 males and 10/10 females in 87 mg/kg bw/d dosing group; and 9/10 males and 9/10 females in 175 mg/kg bw/d).

HISTOPATHOLOGY: NON-NEOPLASTIC
test article-related microscopic changes were limited to the site of exposure and included ulceration, epidermal hyperplasia, fibrosis and
inflammation. there was some variation in the severity of these changes, however: most of the males and females in 87 - 175 mg/kg bw/d groups were affected with one or more of these changes. No evidence of a similar effect was seen in the control group and the lowest dose group.

Overall remarks, attachments

Attached full study report

()

Applicant's summary and conclusion

Conclusions

Application of AEE to an intact cutaneous site for approximately six hours, once daily for 90 consecutive days to male and female Sprague-Dawley rats, results in ulceration, epidermal hyperplasia, fibrosis and/or inflammation at doses of 87 and 175 mg/kg bw/d. These changes represent local irritation following topical administration.

The NOAEL for dermal effects is 17 mg/kg/day bw (actual dose).

In females there was a statistically significant increase in absolute and relative neutrophil counts at 87 mg/kg bw/day this effect was considered to be incidental and not dose related. In females exposed at 87 and males and females at 175 mg/kg bw/day, a statistically significant increase in globulin and decrease in albumin/globulin ratios were observed. The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance.

The systemic NOAEL is 175 mg/kg bw/day (actual dose)(highest dose tested).

Executive summary

Repeated dose toxicity: dermal.range finder.002.QCMCS

UUID IUC5-d25d6a9b-2759-4222-a47e-ec6e76845362
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-10 16:46:57 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 1999-08-01 to 2000-09-20
Reliability 2 (reliable with restrictions)
Rationale for reliability Range finding study for OECD guideline 410 "28 Day Dermal Toxicity Study". Duration of dosing 14 days. Not GLP.

Data source

Reference

Reference type study report
Author Chrysalis Preclinical Services Corporation **Year** 2000
Title A 14-Day Dermal Toxicity Study in Rats (Dose-Range-Finding)
Bibliographic source
Testing laboratory Chrysalis Preclinical Services Corporation **Report no.** 0437RH11.001
Owner company Huntsman
Company study no. **Report date** 2000-09-20

Data access

data submitter is data owner

Materials and methods

Test type

other: range finder

Test guideline

Qualifier equivalent or similar to
Guideline OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study)
Deviations yes dosing period was only 14 days due to this study being a ranger finder.

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): DGA (AEE)
- Physical state: clear, colorless liquid

Confidential details on test material

- Lot/batch No.: 9F10
- Expiration date of the lot/batch: 2001-07-15

Test animals

Species

rat

Strain

Sprague-Dawley

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Harlan Sprague Dawley
- Age at study initiation: 6 weeks
- Weight at study initiation: 187-216 grams (males); 138-158 grams (female)
- Housing: All animals were individually housed in compliance with USDA guidelines.
- Diet: Teklad Certified LM-485 Rodent Diet (Harlan Teklad) ad libitum, except overnight prior to scheduled blood collection.

- Water: provided ad libitum
- Acclimation period: minimum of 7 days prior to treatment initiation.

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 18-26 degree C
- Humidity (%): 30-70%
- Photoperiod (hrs dark / hrs light): 12 hours artificial light/ 12 hours dark

Administration / exposure

Type of coverage

occlusive

Vehicle

other: Deionized water

Details on exposure

TEST SITE
- Area of exposure: The pelage covering the interscapular and dorsal thoracic regions of the body.
- % coverage: an area larger than 10%, but no greater than 20%.
- Time intervals for shavings or clipplings: each animal was clipped a minimum of twice weekly.

REMOVAL OF TEST SUBSTANCE
- Washing (if done): each animal was gently cleansed with gauze soaked in warm water and gently dried at the end of each days treatment period.

- Time after start of exposure: removal of the test substance was done at the end of each days treatment period.

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): dose volume: 0.5 ml/kg/day
- Concentration (if solution): low-dose: 500 mg/ml; low-mid dose 1000 mg/ml; high-mid dose 2000 mg/ml; and high dose 3000 mg/ml.
- Constant volume or concentration used: No data

VEHICLE
- Amount(s) applied (volume or weight with unit): 0.5 ml/kg/day
- Concentration (if solution): 0 mg/ml
- Lot/batch no. (if required): 19 Aug 99 (expiration date 2000-02-19

USE OF RESTRAINERS FOR PREVENTING INGESTION: yes: animals were collared during the in-life portion of the study.

Duration of treatment / exposure

14 days

Frequency of treatment

daily for approximately six hours

Doses/concentrations

0, 500, 1000, 2000, 3000 mg/ml

Basis nominal per unit body weight

No. of animals per sex per dose

5 male/5 female

Control animals

yes, concurrent vehicle

Details on study design

- Dose selection rationale: The dermal route was selected, as this is a potential route of exposure in humans.

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: No data
- Time schedule:
- Cage side observations checked in table were included.

DETAILED CLINICAL OBSERVATIONS: Yes
- Time schedule: animals were observed at least twice daily (prior to dose administration and following unwrapping). Animals were also observed prior to sacrifice on Day 15.

DERMAL IRRITATION (if dermal study): Yes
- Time schedule for examinations: The treated area was scored according to Draize, twice daily (prior to dose administration and approximately one hour following unwrapping).

BODY WEIGHT: Yes
- Time schedule for examinations: Animals were weighted at the time of randomization/selection, prior to dose administration on Days 1 and 8 and after dose administration on Day 14. Fasted body weights were recorded on Day 15.

FOOD CONSUMPTION:
- Food consumption for each animal determined and mean daily diet consumption calculated as g food/kg body weight/day: Yes, food consumption was recorded on Days, 1, 8 and 14 during the dosing period.

HAEMATOLOGY: Yes, blood was collected by cardiocentesis.
- Time schedule for collection of blood: All animals had whole blood samples collected for hematology prior to terminal sacrifice on Day 15.
- Anesthetic used for blood collection: Yes, animals were anesthetized with CO2
- Animals fasted: Yes, animals were fasted overnight prior to scheduled blood collection at sacrifice.
- How many animals: all animals (50).

CLINICAL CHEMISTRY: Yes, blood was collected by cardiocentesis for serum clinical chemistry.
- Time schedule for collection of blood: All animals had whole blood samples collected for hematology prior to terminal sacrifice on Day 15.
- Anesthetic used for blood collection: Yes, animals were anesthetized with CO2
- Animals fasted: Yes, animals were fasted overnight prior to scheduled blood collection at sacrifice.
- How many animals: all animals (50).

Sacrifice and pathology

GROSS PATHOLOGY: Yes, gross necropsy which included an examination of the external surface of the body, all orifices and the cranial, thoracic and abdominal cavities together with their contents.

Statistics

Evaluation of equality of means were made by a one-way analysis of variance using the F distribution to assess statistical significance. If statistically significant differences between the means were found Dunnett's test was used to determine the degree of significance from control means. Analysis of discrete data, where appropriate, was conducted using non-parametric procedures chosen by the study director.

Any other information on materials and methods incl. tables

Results and discussions

Effect levels

Endpoint	NOAEL for dermal effects
Effect level	250 mg/kg/day
Sex	male/female
Basis for effect level / Remarks	
Endpoint	LOEL for dermal effects
Effect level	500 mg/kg bw/day (nominal)
Sex	male/female
Basis for effect level / Remarks	Erythema of various degrees occurred in males and females in all dose groups at or above 500 mg/kg-bw/day.

Observations

Clinical signs and mortality

no effects

Dermal irritation

yes

Body weight and weight gain

no effects

Food consumption

no effects

Haematology

no effects

Clinical chemistry

no effects

Gross pathology

no effects

Details on results

CLINICAL SIGNS AND MORTALITY: No animals died during the course of the study. There were no clinical signs of toxicity observed during the study. Clinical signs of dermal irritation were noted. Erythema of varying degrees was observed in both the male and female 500, 1000, and 1500 mg/kg groups. Edema of varying degrees was observed in the male 1000 and 1500 mg/kg groups and female 500, 1000, and 1500 mg/kg groups. Erythema and edema first appeared on Day 2 or 3 and increased over the course of the study in males and females receiving 1000 or 1500 mg/kg/day. Females receiving 500 mg/kg/day did not have any dermal irritation until Day 8 and only 1 male at the same dose level had very slight erythema on Day 15. Additional signs noted in the male and female 1000 and 1500 mg/kg dose groups were all related to irritation at the application site and included scab formation, sloughing, fissuring, and black areas on the dosing site.

HAEMATOLOGY: There were a few statistically significant changes in hematology values but these were considered not to be test article-related.

CLINICAL CHEMISTRY: There was a statistically significant decrease in the A/G ratio for males and females treated with 1500 mg/kg/day. However, these values were within normal historical limits for this laboratory and are not considered to be test article related.

GROSS PATHOLOGY: Scab formation on the test-article treated sites following 14 days of treatment was observed in males treated with 1000 and 1500 mg/kg/day and females treated with 500, 1000, and 1500 mg/kg/day.

Applicant's summary and conclusion

Conclusions

Based on the results of this study when DGA was administered via topical administration to the intact skin sites of Sprague-Dawley rats, once daily for 14 consecutive days, the dermal no-observed adverse effect level (NOAEL) was 250 mg/kg/day based on dermal irritation.

7.5.3 Repeated dose toxicity: inhalation

Repeated dose toxicity: inhalation.001

UUID	IUC5-7c4e2adf-b50c-4195-9bbd-61a74d6167cc
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-21 21:18:35 EST
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Data waiving	other justification
Justification for data waiving	An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.
Study result type	experimental study planned

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

7.6 Genetic toxicity

Genetic toxicity

UUID	IUC5-db5726c4-e4e4-41c5-8188-efd068400a04
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-17 09:47:27 EST
Remarks	

Administrative Data

Short description of key information

In vitro studies:
Ames-Test: negative (NTP standard protocol)

In vivo:
MNA negative

Key parameter (optional)

Genetic toxicity

negative

Discussion

In vitro studies:

2 -(2 -aminoethoxy)ethanol was evaluated for mutagenicity in the Salmonella/microsome preincubation assay using a standard protocol approved by the National Toxicology Program. Doses of 0, 12.5, 25, 50, 100, 500, 2500, 5000 µg/plate were tested in four Salmonella typhimurium strains (TA98, TAI00, TAI535 and TAI537) in the presence and absence of Aroclor-induced rat or hamster liver S9. These tests were negative and the highest ineffective dose level tested in all four Salmonella tester strains under all treatment conditions was 2500 µg/plate (Zeiger et al. 1988; reliability score: 2).

A further AMES-test with 5 strains (TA98, TA100, TA 1535, TA1537 and TA1538) confirmed the negative results (Huntsman, 1982; reliability score: 2). Several other AMES-tests could not be taken into consideration because the test substance was a unknown mixture containing 2-(2-aminoethoxy)ethanol and several other substances (composition confidential, concentration of test substance unclear): In these assays the test substance showed ambiguous results (Chemfirst 1992-1997; reliability:3)

In an In-vitro mammalian cell transformation assay using Mouse BALB/3T3 Cells, both in the absence and presence of metabolic activation (S9 mix) no dose response relationship was observed and transformed foci were not considered to be significant over control dose ranges (Huntsman, 1982; reliability score: 2).

In an unscheduled DNA damage and repair assay with male F344 rat hepatocytes, according to the OECD Guideline 482, no genotoxic potential could be observed (Huntsman, 1982; reliability score: 2).

Justification for classification or non-classification

Two Ames-test (with and without metabolic activation), an in-vitro mammalian cell transformation assay and an in-vitro unscheduled DNA damage and repair assay failed to provide any evidence for a mutagenic effect of 2-(2-aminoethoxy)ethanol.

7.6.1 Genetic toxicity in vitro

Hunstman 1982. Ames Assay. Key

UUID	IUC5-b8006d64-3bab-4e45-a20d-59d71413722f
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-15 18:38:16 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	1 (reliable without restriction)
Rationale for reliability	Guideline/GLP study.

Data source

Reference

Reference type	study report		
Author	Pharmakon Research International, Inc.	**Year**	1982
Title	Ames Salmonella/Microsome Plate Test		
Bibliographic source	Ames, Bruce N., Joyce McCann, and Edith Yamasaki Methods for Detecting Carcinogens and Mutagens with the Salmonella/Mammalian-Microsome Mutagenicity Test. Mutation Research 31: (1975) 347-364		
Testing laboratory	Pharmakon Research International, Inc.	**Report no.**	
Owner company	Huntsman		
Company study no.	PH 301-TX-010-81	**Report date**	1982-02-22

Data access

data submitter is data owner

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Test guideline

Qualifier	equivalent or similar to
Guideline	OECD Guideline 471 (Bacterial Reverse Mutation Assay)
Deviations	

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	EC number
Identity	213-195-4

Details on test material

- Name of test material (as cited in study report): 4236-45-25 (laboratory ID)
- Physical state: clear, colorless liquid
- Analytical purity: responsibility of the Sponsor,(identified as >99% by Sponsor)
- Lot/batch No.:# J-91
- Stability under test conditions: no apparent change in the physical state of the test or control articles during assay
- Storage condition of test material: no data
- Other:

Method

Target gene

not applicable

Species/strain

Species/strain	S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
Details on mammalian cell lines (if applicable)	not applicable
Additional strain characteristics	
Metabolic activation	with and without
Metabolic activation system	S9 Arochlor-induced rat liver
Species/strain	S. typhimurium TA 1538
Details on mammalian cell lines (if applicable)	not applicable
Additional strain characteristics	
Metabolic activation	with and without
Metabolic activation system	S9 Arochlor-induced rat liver

Test concentrations

10.000, 3333, 1000, 333 and 100 µg/plate

Vehicle

- solvent(s) used: distilled water

Controls

Negative controls	
Solvent / vehicle controls	yes with and without metabolic activation
True negative controls	
Positive controls	yes with and without metabolic activation
Positive control substance	sodium azide without metabolic activation
Remarks	
Negative controls	
Solvent / vehicle controls	
True negative controls	
Positive controls	
Positive control substance	9-aminoacridine without metabolic activation
Remarks	
Negative controls	
Solvent / vehicle controls	
True negative controls	
Positive controls	
Positive control substance	2-nitrofluorene without metabolic activation
Remarks	
Negative controls	
Solvent / vehicle controls	
True negative controls	
Positive controls	
Positive control substance	other: 2-anthramine (2-aminoanthracene) with metabolic activation
Remarks	

Details on test system and conditions

METHOD OF APPLICATION: in agar (plate incorporation)

DURATION
- Preincubation period: 48h
- Exposure duration: 48-72h
- Expression time (cells in growth medium):
- Selection time (if incubation with a selection agent):
- Fixation time (start of exposure up to fixation or harvest of cells):

SELECTION AGENT (mutation assays): histidine and biotin

NUMBER OF REPLICATIONS:
negativen controls : in triplicate
positive controls: 5 levels of the test compound in triplicate,
compound-treated plates: in duplicate

DETERMINATION OF CYTOTOXICITY
- Method: growth inhibition is tested at following concentrations: 100, 333, 1000, 3333, 10000 µg/plate with strains TA1538 and TA100 (in duplicate).

After 48h incubation, spontaneous revertants were observed and scored: normal growth, inhibited growth or no growth

Evaluation criteria

revertant colonies are counted (Artek Counter Model 800)
- positive result is defined as a reproducible, dose-related increase in the number of histidine-independent colonies.
- negative result is defined as the absence of a reproducible increase in the number of histidine-independent colonies.

Statistics

not applicable

Any other information on materials and methods incl. tables

Results and discussions

Test results

Species/strain	S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no, but tested up to limit concentrations
Vehicle controls valid	yes
Negative controls valid	not examined
Positive controls valid	yes
Species/strain	S. typhimurium TA 1538
Metabolic activation	with and without

Test system	
Genotoxicity	negative
Cytotoxicity	no, but tested up to limit concentrations
Vehicle controls valid	yes
Negative controls valid	not examined
Positive controls valid	yes

Additional information on results

RANGE-FINDING/SCREENING STUDIES: screening study showed no cytotoxicity at any of the doses

COMPARISON WITH HISTORICAL CONTROL DATA: all solvent and positive controls are within the acceptable range of mean historical data

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

The results of the test substance were negative in strains TA1535, TA1537, TA1538, TA98 and TA100 of Salmonella typhimurium both with and without metabolic activation preparation at 10000, 3333, 1000, 333, and 100 µg/plate (Ames test). All controls were considered valid.

BASFAG 89/230.Genetic toxicity in vitro.AMES-Test

UUID	IUC5-48335d32-6e75-4b08-8f40-8b210134473d
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-16 20:45:13 EST
Remarks	

Administrative Data

Purpose flag	supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	2 (reliable with restrictions)
Rationale for reliability	Guideline study

Data source

Reference

Reference type	study report		
Author	BASF AG	**Year**	1990
Title	REPORT on the Study of 2,2-Aminoethoxyethanol (ZST Test Substance No.: 89/230) in the AMES TEST (Standard Plate Test and Preincubation Test with Salmonella typhimurium)		
Bibliographic source	unpublished data		
Testing laboratory	BASF AG, Department of Toxicology	**Report no.**	40M0230/894476
Owner company	BASF SE		
Company study no.		**Report date**	1990-11-26

Data access

data submitter is data owner

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Test guideline

Qualifier	according to
Guideline	OECD Guideline 471 (Bacterial Reverse Mutation Assay)
Deviations	

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	Common name
Identity	2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2,2-Aminoethoxyethanol
- Analytical purity: 99.6 %
- Other: room temperature

Method

Target gene

Histidin operon

Species/strain

Species/strain	S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
Details on mammalian cell lines (if applicable)	
Additional strain characteristics	
Metabolic activation	with and without
Metabolic activation system	S9-mix from Aroclor 1254 treated male Sprague-Dawley rats.

Test concentrations

All tester strains: 0, 20, 100, 500, 2500 and 5000 ug/plate (standard plate test and preincubation test);
TA 98: 12.5, 25, 50 and 100 ug/plate (preincubation test)

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls	yes water control
Solvent / vehicle controls	yes sterility control
True negative controls	no
Positive controls	yes
Positive control substance	other: with S-9 mix: all strains 2-aminoanthracene; without S-9 mix: strains TA100, TA1535: N-methyl-N'-nitro-N-nitrosoguanidine; TA98: 4-nitro-o-phenylendiamine; TA1537: 9-aminoacridine
Remarks	

Details on test system and conditions

METHOD OF APPLICATION: preincubation

DURATION
- Preincubation period: 20 min
- Exposure duration: 48 h

NUMBER OF REPLICATIONS: 3

METHOD OF APPLICATION: standard plate test

DURATION
- Exposure duration: 48 h

NUMBER OF REPLICATIONS: 3

Evaluation criteria

The test chemical is considered positive in this assay if the following criteria are met: A dose-related and reproducible increase in the number of revertant colonies, i.e. about doubling of the spontaneous mutation rate in at least one tester strain either without S-9 mix or after adding a metabolizing system.

Results and discussions

Test results

Species/strain	S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
Metabolic activation	with and without
Test system	other: Salmonella typhimurium TA1535, TA100, TA1537, TA98
Genotoxicity	negative
Cytotoxicity	yes in the preincubation test without S-9 mix depending on the strain at doses > 2500 µg/plate.
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Additional information on results

TEST-SPECIFIC CONFOUNDING FACTORS
- Water solubility: Complete solubility of test substance in aqua dest.

Remarks on results including tables and figures

Standart plate test:

Dose (µg/plate)	TA1535		TA100		TA1537		TA98	
	-S9	+S9	-S9	+S9	-S9	+S9	-S9	+S9
0	19±4	16±2	95±10	104±11	9±1	12±3	24±5	30±2
20	15±6	11±6	103±13	107±7	10±3	14±4	23±4	33±2
100	18±6	17±2	103±12	105±3	7±2	13±1	22±2	33±3
500	14±5	17±5	93±21	99±9	13±2	18±2	17±2	36±6
2500	16±6	20±1	102±4	92±10	9±3	14±2	20±4	37±4
5000	14±4	21±2	90±11	107±7	14±6	18±3	21±1	30±2
2AA	-	215±10	-	1029±22	-	180±17	-	1003±61
MNNG	1332±112	-	1373±90	-	-	-	-	-
AAC	-	-	-	-	354±56	-	-	-
NOPD	-	-	-	-	-	-	861±14	-

Mean ± SD

Preincubation-test:

Dose (µg/plate)	TA1535		TA100		TA1537		TA98	
	-S9	+S9	-S9	+S9	-S9	+S9	-S9	+S9
0	12±2	12±1	82±4	100±9	7±2	11±2	20±2	37±4
20	12±4	14±2	76±3	93±16	8±3	13±3	18±6	60±2
100	11±4	13±1	79±3	107±9	6±4	15±1	24±5	46±5
500	13±6	11±4	87±2	88±10	5±2	13±2	27±1	53±8
2500	16±3	14±2	61±2	86±5	7±3	10±3	21±9	49±8
5000	10±8	16±3	42±12	81±6	x	15±5	14±2	34±3
2AA	-	271±15	-	1415±74	-	113±26	-	1330±95
MNNG	1310±216	-	1335±88	-	-	-	-	-
AAC	-	-	-	-	426±96	-	-	-
NOPD	-	-	-	-	-	-	804±62	-

Mean ± SD

Preincubation-test:

Dose (µg/plate)	TA98	
	-S9	+S9
0	26±4	34±2
12.5	22±2	35±4
25	20±6	36±3
50	28±2	33±2
100	26±3	33±2
2AA	-	753±8
NOPD	844±33	-

Mean ± SD

X: reduced background growth

2-AA: 2-aminoanthracene;

MNNG; N-methyl-N-nitro-N-nitrosoguanidine
NOPD: 4-nitro-o-phenylendiamine
AAC: 9-aminoacridine chloride monohydrate
Under the conditions tested 2-(2-aminoethoxy)ethanol in non mutagenic in the bacterial AMES-test.

The positive controls gave the expected values.

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

Negative with and without activation

Chemfirst 1996.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-312f56eb-7cc2-4f0b-b5a6-9f821c6826bd
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:08:21 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1994
Title MUTAGENICITY TEST ON EKC 287 (A MIXTURE CONTAINING 2-(2-AMINOETHOXY)ETHANOL) IN THE REVERSE MUTATION ASSAY
Bibliographic source TSCATS/OTS0559023
Testing laboratory **Report no.**
Owner company First Chemical Corporation
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity mixture not defined stated to contain AEE sponsored substance

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).

Test concentrations

In the presence of S9 mix: 4000, 2000, 1000, 500, 250, and 125 µg per plate

in the absence of S9 mix: 2000, 1000, 500, 250, 125, and 62.5 µg per plate

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes
True negative controls no data
Positive controls yes
Positive control substance other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene,
Remarks

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98, TA100) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The doses tested in the mutagenicity assay were selected based on the results of a dose rangefinding study using tester strain TA100 and ten doses of test article ranging from 5000 to 6.67 µg per plate, one plate per dose, both in the presence and absence of S9 mix.
The mutagenicity assay was performed using tester strains TA98, TA100, TA1535,
TA1537 and TA1538, both in the presence and absence of S9 mix. Six doses of test article per activation condition were tested along with concurrent vehicle and positive controls.

Results and discussions

Test results

Species/strain	S. typhimurium, other: TA 1535, TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested TA 1535, TA 100
Genotoxicity	negative
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes
Species/strain	S. typhimurium, other: TA 1537, TA1538, TA 98
Metabolic activation	with and without
Test system	strain/cell type: TA 1537, TA1538, TA 98
Genotoxicity	positive
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) indicate that under the conditions of this study, the test article, EKC 287, did cause positive increases in the numbers of histidine revertants per plate with tester strains TA98

(2.7-fold) and TA1538 (4.2-fold) in the presence of S9 mix and with tester strains TA98 (18.0 and 9.3-fold), TA1537 (6-fold), and TA1538 (24.6-fold) in the absence of S9-mix. No positive increases were observed with any of the remaining tester strain/activation condition combinations.
Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

The positive increases obtained with this test article were observed only when the sample of test article to be used in the assay was removed from the main test article sample 5 - 6 days prior to testing. When the sample to be tested was removed within 1 day prior to testing, no positive increases were observed.

Applicant's summary and conclusion

Interpretation of results

other:

Conclusions

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Chemfirst 1997.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-edd7c9ad-4721-4f94-a6be-4ecc04cb053e
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:07:14 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1997
Title MUTAGENICITY TEST WITH EKC 265 (Mixture containing 2-(2-aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SALMONELLA - ESCHERICHIA COLI/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY
Bibliographic source TSCATS/OTS0559030
Testing laboratory **Report no.**
Owner company ChemFirst Inc .
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain E. coli WP2 uvr A
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).

Test concentrations

Test1: 5000, 3330, 1000, 667, 333, 100, 66.7, and 33.3 µg per plate in both the presence and absence of S9 mix.
Test2: 2500, 2000, 1500, 1250, 1000, 800, and 600 µg per plate in both the presence and absence of S9 mix.

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes
True negative controls no data
Positive controls yes
Positive control substance other: +S9 mix: 2-aminoanthracene; -S9 mix: 4-nitroquinoline-N-oxide
Remarks

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The tester strain used in this study was the Escherichia coli tester strain WP2uvrA. The assay was conducted using three plates per dose both in the presence and absence of S9 mix along with concurrent vehicle and positive controls. The doses of test article tested in the initial experiment were 5000, 3330, 1000, 667, 333, 100, 66.7, and 33.3 ¼g per plate in both the presence and absence of S9 mix. In order to clarify the responses observed, an additional experiment was performed at doses of 2500, 2000, 1500, 1250, 1000, 800, and 600 ¼g per plate in both the presence and absence of S9 mix.

Results and discussions

Test results

Species/strain	E. coli WP2 uvr A
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Escherichia coli WP2uvrA/Mammalian-Microsome Reverse Mutation Assay indicate that under the conditions of this study, the test article, EKC 265, did not cause a positive increase in the number of revertants per plate either in the presence or absence of Aroclor-induced rat liver S9-mix.

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Applicant's summary and conclusion

Interpretation of results

other:

Conclusions

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Chemfirst 1992.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-9fe14e43-f614-44ac-804f-7faf7694ad11
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:03:43 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1994
Title MUTACENICITY TEST ON EKC-241 (Mixture containing 2-(2 aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SAIMONELLA/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY (AMES TEST)
Bibliographic source TSCATS/OTS0559024
Testing laboratory **Report no.**
Owner company First Chemical Corporation
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
- Physical state: clear liquid

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system S9-mix

Test concentrations

In the presence of S9 mix: 3330, 1000, 667, 333, 100 and 66.7 µg per plate.
In the absence of S9 mix:1000, 667, 333, 100, 66.7 and 33.3 µg per plate.

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes water
True negative controls no data
Positive controls yes
Positive control substance other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene
Remarks

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98 and TA100) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The doses tested in the mutagenicity assay were selected based on the results of a dose rangefinding study using tester strain TA100 and ten doses of test article ranging from 5000 to 6.67 ¼g per plate, one plate per dose, both in the presence and absence of S9-mix .

The tester strains used in this study were TA98, TA100, TA1535, TA1537 and TA1538 . The assay was conducted using three plates per dose level both in the presence and absence of S9 mix. Six doses of the test article were tested from 3330 to 66.7 µg per plate in the presence of S9 mix and from 1000 to 33.3 µg per plate in the absence of S9 mix.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no data
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) indicate that kinder the conditions of this study, the test article, EKC-241did not cause a positive increase in the number of histidine revertants per plate of any of the tester strains, either in the presence or absence of Aroclor induced rat liver S9-mix.

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Applicant's summary and conclusion

Interpretation of results

other:

Conclusions

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Executive summary

Chemfirst 1993.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-87ec0de0-4a55-4900-8b78-316af39b9421
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:00:00 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 3 (not reliable)
Rationale for reliability Test substance not defined stated to be a mixture containing AEE.

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1994
Title MUTACENICITY TEST ON POSISTRIP 837 (Mixture containing 2-(2 aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SAIMONELLA/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY (AMES TEST)
Bibliographic source TSCATS/OTS0559025
Testing laboratory **Report no.**
Owner company First Chemical Corporation
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier IUPAC name
Identity 2-(2-aminoethoxy)ethanol
Identifier other:
Identity Test Substance not defined stated to be a mixture containing AEE

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
- Physical state: clear liquid

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system S9-mix

Test concentrations

5000, 3330, 1000, 667, 333, and 100 µg per plate

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes water
True negative controls no data
Positive controls yes
Positive control substance other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene
Remarks

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98 and TA100) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The tester strains used in this study were TA98, TA100, TA1535, TA1537 and TA1538. The assay was conducted using three plates per dose level both in the presence and absence of S9. Six doses of the test article were tested, from 5,000 to 100 µg per plate in both the presence and absence of S9.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no data
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) indicate that kinder the conditions of this study, the test article, Posistrip 830, did not cause a positive increase in the number of histidine revertants per plate of any of the tester strains, either in the presence or absence of Aroclor induced rat liver S9-mix.

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Applicant's summary and conclusion

Interpretation of results

other:

Conclusions

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Executive summary

Chemfirst 1997.Genetic toxicity in vitro.AMES-Test. invalid

UUID IUC5-3927845e-2e67-4ca9-8c40-ee38681ce552
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 19:55:51 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 3 (not reliable)
Rationale for reliability Does not meet standards of current guideline requirements. In addition, lack of detail regarding concentration of test substance used in the assay which is stated to be a mixture..

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1994
Title MUTAGENICITY TEST WITH SPENT 310 (MIXTURE CONTAINING 2-(2-AMINOETHOXY)ETHANOL) IN THE SALMONELLA REVERSE MUTATION ASSAY
Bibliographic source TSCATS OTS0559026
Testing laboratory Chemfirst Inc. **Report no.**
Owner company First Mississippi Corporation
Company study no. **Report date**

Data access

other: clarification required

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity Test substance not defined stated to be a mixture containing AEE

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol; however reference to the substance is stated to be a mixture which is undefined.

Method

Species/strain

Species/strain S. typhimurium TA 98
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation without
Metabolic activation system

Test concentrations

5000, 3330, 1000, 667, 333, 100, 66.7, 33.3, 10, 6.67, 3.33, and 1.0 µg per plate.

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes
True negative controls no data
Positive controls yes 2-nitrofluoren
Positive control substance
Remarks

Results and discussions

Test results

Species/strain S. typhimurium TA 98
Metabolic activation without
Test system strain/cell type:
Genotoxicity positive
Cytotoxicity no data
Vehicle controls valid yes
Negative yes

controls valid

Positive controls valid yes

Remarks on results including tables and figures

Overall remarks, attachments

Overall remarks

The results of the Ames Test indicate that, under the conditions of this study, Spent 310 did cause a 2.5-fold increase in the number of revertants in TA98 in the absence of an exogenous metabolic activation system. The test substance is not further defined.

Applicant's summary and conclusion

Conclusions

The test substance reported to be AEE appears to be an undefined mixture in which the relevance of the results is undefined. In addition, the study does not meet current guidelines, insufficient number of strains, lack of replicates etc..

Chemfirst 1994.Genetic toxicity in vitro.AMES-Test. Invalid

UUID	IUC5-be6d739b-44de-4a49-8c12-bcb8785af827
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-15 19:54:24 EST
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	3 (not reliable)
Rationale for reliability	Test substance not defined, stated to be a mixture containing AEE.

Data source

Reference

Reference type	study report		
Author	Chemfirst Inc.	**Year**	1992
Title	MUTACENICITY TEST ON POSISTRIP 830 (Mixture containing 2-(2 aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SALMONELLA/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY (AMES TEST)		
Bibliographic source	TSCATS/OTS0559025		
Testing laboratory		**Report no.**	
Owner company	First Chemical Corporation		
Company study no.		**Report date**	

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier	CAS number
Identity	929-06-6
Identifier	IUPAC name
Identity	2-(2-aminoethoxy)ethanol
Identifier	other:
Identity	Test substance not defined stated to be mixture containing AEE

Details on test material

- Name of test material (as cited in study report): POSISTRIP 837
- Physical state: clear pale-yellow liquid

Test substance stated to be a mixture which is undefined.

Method

Species/strain

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)	
Additional strain characteristics	
Metabolic activation	with and without
Metabolic activation system	S9-mix

Test concentrations

5000, 3330, 1000, 667, 333, and 100 µg per plate

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls	yes sterility control
Solvent / vehicle controls	yes water
True negative controls	no data
Positive controls	yes
Positive control substance	other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene
Remarks	

Details on test system and conditions

NUMBER OF REPLICATIONS: 2

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98 and TA100) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The mutagenicity assay was performed using tester strains TA98, TA100, TA1535, TA1537 and TA1538, both in the presence and absence of S9 mix. Six doses of test article per activation condition were tested along with concurrent vehicle and positive controls. The dose levels tested were 5000, 3330, 1000, 667, 333, and 100 ¼g per plate in both the presence and absence of S9 mix.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no data
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) indicate that under the conditions of this study, the test substance did not cause a positive increase in the number of histidine revertants per plate of any of the tester strains either in the presence or absence of Aroclor-induced rat liver S9-mix.

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

The test substance in this assay is negative, hwoever the test substance is an undefined mixture stated to contain AEE.

Executive summary

Chemfirst 1997.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-bb91e5ed-265a-4e58-8644-400b4f442119
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 19:52:59 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1994
Title MUTAGENICITY TEST W/EKC 310 (MIXT CONTN'G 2-(2-AMINOETHOXY) ETHANOL) IN THE SALMONELLA-ESCHERICHIA COLI/MAMMALIAN-MICRO SOME REVERSE MUTATION ASSAY,
Bibliographic source TSCATS/OTS0559025
Testing laboratory **Report no.**
Owner company First Mississippi Corporation
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity Test substance not defined stated to be a mixture containing AEE

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
- Physical state: amber liquid
Test substance defined as a mixture containing AEE.

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system S9-mix
Species/strain E. coli WP2 uvr A
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system

Test concentrations

5000, 3330, 1000, 500, 250 and 100 µg per plate in the present of S9-mix and 3300, 1000, 500, 250, 100 and 50 µg per plate in the absence of S9-mix.

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes water
True negative controls no data
Positive controls yes

Positive control substance	other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene, WP2uvrA: 4-nitroquinoline-N-oxide
Remarks	

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98, TA100 and WP2uvrA) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The mutagenicity assay was performed using tester strains TA98, TA100, TA1535, TA1537, TA1538 and WP2uvrA, both in the presence and absence of S9 mix. Six doses of test article per activation condition were tested along with concurrent vehicle and positive controls. The doses tested for all strains in the initial mutagenicity were 5000, 3330, 1000, 500, 250 and 100 ¼g per plate in the present of S9-mix and 3300, 1000, 500, 250, 100 and 50 µg per plate in the absence of S9-mix.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	strain/cell type: TA98
Genotoxicity	positive 2.6 fold increase in the absence of S9-mix
Cytotoxicity	no data
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes
Species/strain	E. coli WP2 uvr A
Metabolic activation	with and without
Test system	strain/cell type:
Genotoxicity	positive 2.6 fold increase
Cytotoxicity	no data
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella - Escherichia coli/Mamalian-Microsome Reverse Mutation Assay indicate that under the conditions of this study, test article EKC 310, did cause positive increases in the mean number of revertants per plate with tester strain TA98 in the absence of S9 mix and with tester strain WP2uvrA in both the presence and absence of S9 mix. While these increases were reproducible, they did not reproducibly meet the dose-responsive, 2-fold criteria necessary for a positive evaluation. Positive increases were observed with tester strain TA98 in the absence of S9 mix in one of two trials (2.6-fold [dose responsive] and 2.6-fold [non-dose responsive]) and with tester strain WP2uvrA in both the presence (in two of three trials, 2.2-fold, 1.9-fold, and 2.0-fold) and absence (in one of three trials 1.9-fold, 2 .6-fold, and 1.7-fold) of S9 mix. No positive increases in the mean number of revertants per plate was observed with any of the remaining tester strain/activation condition combinations.

Test substance not clearly defined and stated to contain AEE.

Applicant's summary and conclusion

Interpretation of results

negative TA1535, TA1537, TA1538 and TA100

positive without metabolic activation in TA98

positive WP2uvrA

Executive summary

Chemfirst 1996.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-75911216-7675-4370-bf98-9ac251be17e0
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 19:51:49 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliability 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1996
Title MUTAGENICITY TEST WITH EKC310 (Mixture containing 2-(2-aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SALMONELLA - ESCHERICHIA COLI/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY
Bibliographic source TSCATS/OTS0559028
Testing laboratory **Report no.**
Owner company First Mississippi Corporation
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity test substance not defined stated to be a mixture containing AEE

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol
Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).
Species/strain E. coli WP2 uvr A
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).

Test concentrations

TA100 and TA1535 in the presence of S9 mix and with WP2uvrA in both the presence and absence of S9 mix were 5000, 3330, 1000, 500, 250, 100, 50.0, and 25.0 µg per plate.

TA100 and TA1535 in the absence of S9 mix were 3330, 1000, 500, 250, 100, 50.0, 25.0, and 10.0 µg per plate.
TA98 and TA 1537 in both the presence and absence of S9 mix were 1,000, 500, 250, 100, 50.0, 25.0, 10.0, and 5.00 µg per plate.

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes
True negative controls no data
Positive controls yes

Positive control substance other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene, WP2uvrA: 4-nitroquinoline-N-oxide

Remarks

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98, TA100 and WP2uvrA) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The tester strains used in the mutagenicity assay were Salmonella typhimurium tester strains TA98, TA100, TA1535, TA1537, and Escherichia coli tester strain WP2uvrA. The assay was conducted with eight dose levels of test article in both the presence and absence of S9 mix along with concurrent vehicle and positive controls using three plates per dose. The doses tested with TA100 and TA1535 in the presence of S9 mix and with WP2uvrA in both the presence and absence of S9 mix were 5000, 3330, 1000, 500, 250, 100, 50.0, and 25.0 µg per plate. The doses tested with TA100 and TA1535 in the absence of S9 mix were 3330, 1000, 500, 250, 100, 50, 25, and 10 ¼g per plate. The doses tested with TA98 and TA 1537 in both the presence and absence of S9 mix were 1000, 500, 250, 100, 50, 25, 10,and 5 ¼g per plate.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes
Species/strain	E. coli WP2 uvr A
Metabolic activation	with and without
Test system	strain/cell type:
Genotoxicity	negative
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella - Escherichia coli/Mammalian-Microsome Reverse Mutation Assay indicate that, under the conditions of this study, the test article, EKC310, did not cause a positive increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor-induced rat liver (S9).

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Chemfirst 1996.Genetic toxicity in vitro.AMES-Test. Invalid

UUID IUC5-a18a4be2-4a8b-4527-b9a8-89e1f4a28c21
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 19:50:44 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 3 (not reliable)
Rationale for reliability Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Data source

Reference

Reference type study report
Author Chemfirst Inc. **Year** 1997
Title MUTAGENICITY TEST WITH W/EKC325 (Mixture containing 2-(2-aminoethoxy)ethanol, CAS No. 929-06-6) IN THE SALMONELLA - ESCHERICHIA COLI/MAMMALIAN-MICROSOME REVERSE MUTATION ASSAY
Bibliographic source TSCATS/OTS0559030
Testing laboratory **Report no.**
Owner company ChemFirst Inc .
Company study no. **Report date**

Data access

data published

Materials and methods

Type of genotoxicity

gene mutation

Type of study

bacterial reverse mutation assay (e.g. Ames test)

Principles of method if other than guideline

The experimental materials, methods and procedures are based on those described by Ames et al (1975).

GLP compliance

no data

Test materials

Test material equivalent to submission substance identity

no

Test material identity

Identifier other:
Identity mixture not defined but stated to contain AEE

Details on test material

- Name of test material (as cited in study report): 2-(2-aminoethoxy)ethanol

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Method

Species/strain

Species/strain S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).
Species/strain E. coli WP2 uvr A
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation with and without
Metabolic activation system Aroclor-induced rat liver (S9).

Test concentrations

The doses tested with the Salmonella tester strains in the presence of S9 mix were 5000, 2500, 1000, 500, 250, 100, and 50 µg per plate. The doses tested with the Salmonella tester strains in the absence of S9 mix were 2500, 1000, 500, 250, 100, 50, and 25 µg per plate. The doses tested with tester strain WP2uvrA in both the presence and absence of S9 mix were 5000, 2500, 1000, 500, 250, and 100 µg per plate. TA98 and TA 1537 in both the presence and absence of S9 mix were 1,000, 500, 250, 100, 50.0, 25.0, 10.0, and 5.00 µg per plate.

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls yes sterility control
Solvent / vehicle controls yes
True negative no data

controls	
Positive controls	yes
Positive control substance	other: +S9 mix all strains: 2-aminoanthracene; -S9 mix: TA98: 2-nitrofluorene, TA100: sodium azide, TA1535: sodium azide, TA1537: ICR-19, TA1538: 2-nitrofluorene, WP2uvrA: 4-nitroquinoline-N-oxide
Remarks	

Details on test system and conditions

NUMBER OF REPLICATIONS: 3

Evaluation criteria

For a test article to be considered positive, it had to produce at least a 2-fold (TA98, TA100 and WP2uvrA) or 3-fold (TA1535, TA1537, TA1538) increase in the mean revertants per plate of at least one of these tester strains over the mean revertants per plate of the appropriate vehicle control.

Any other information on materials and methods incl. tables

The doses tested in the mutagenicity assay were selected based on the results of a dose rangefinding study using tester strains TA 100 and WF2uvrA and ten doses of test article ranging from 5000 to 6.67 µg per plate, one plate per dose, both in the presence and absence of S9 mix. The tester strains used in the mutagenicity assay were Salmonella typhimurium tester strains TA98, TA100, TA1535, TA1537, and Escherichia coli tester strain WP2uvrA. The assay was conducted with a minimum of six dose levels of test article in both the presence and absence of S9 mix along with concurrent vehicle and positive controls using three plates per dose. The doses tested with the Salmonella tester strains ranged from 5000 to 5 µg per plate. The doses tested with tester strain WP2uvrA ranged from 5000 to 100 µg per plate.

Results and discussions

Test results

Species/strain	S. typhimurium, other: S. typhimurium TA 1535, TA 1537, TA1538, TA 98 and TA 100
Metabolic activation	with and without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes
Species/strain	E. coli WP2 uvr A
Metabolic activation	with and without
Test system	strain/cell type:
Genotoxicity	positive 2.8-fold increase in the presence and 2.3-fold increase in the absence of S9 mix
Cytotoxicity	no
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Remarks on results including tables and figures

The results of the Salmonella - Escherichia coli/Mammalian-Microsome Reverse Mutation Assay indicate that under the conditions of this study, the test article, EKC325, did cause positive increases in the number of revertants per plate with tester strain WP2uvrA in both the presence (2.8-fold) and absence (2.3-fold) of S9 mix. No positive increases were observed with any of the remaining tester strains in either the presence or absence of microsomal enzymes prepared from Aroclor induced rat liver (S9).

Test subtstance not defined stated to be a mixture containing 2-(2-aminoethoxy)ethanol

Rundell - Huntsman BALB 3T3 cell.001

UUID IUC5-614bba2a-2c69-4c45-9c34-2f867586a7af
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:16:15 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** 8 jan 1982 - 22 feb 1982
Reliability 1 (reliable without restriction)
Rationale for reliability study performed in accordance with EU guideline B21. Clear description of results. No deviations from protocol or GLP.

Data source

Reference

Reference type study report
Author Rundell JO **Year** 1982
Title Evaluation of 4236-45-25 in the in vitro transformation of BALB/3T3 cells assay
Bibliographic source
Testing laboratory Litton Bionetics, Inc **Report no.** 20992
Owner company Huntsman
Company study no. **Report date** 1982-02-28

Data access

data submitter is data owner

Materials and methods

Type of genotoxicity

genome mutation

Type of study

in vitro mammalian cell transformation assay

Test guideline

Qualifier equivalent or similar to
Guideline EU Method B.21 (In Vitro Mammalian Cell Transformation Test)
Deviations

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): 4236-45-25 (laboratory ID)
- Physical state: liquid

Method

Species/strain

Species/strain mammalian cell line, other: BALB/3T3 mouse cells
Details on mammalian cell lines (if applicable) - Type and identity of media: Eagle's Minimum Essential Medium (EMEM) supplemented with fetal bovine serum, L-glutamine, penicillin and streptomycin
- Periodically checked for Mycoplasma contamination: yes

- Properly maintained: yes/no
- Periodically checked for karyotype stability: yes/no
- Periodically "cleansed" against high spontaneous background: yes/no

Additional strain characteristics other: selected for low spontaneous frequencies of foci formation
Metabolic activation no data
Metabolic activation system

Test concentrations

313, 625, 938, 1250, 1563 nl/ml

Vehicle

- Vehicle(s)/solvent(s) used: none

Controls

Negative controls yes culture medium
Solvent / vehicle controls other: not applicable
True negative controls
Positive controls yes
Positive control substance 3-methylcholanthrene 2.5 µg/ml
Remarks

Details on test system and conditions

METHOD OF APPLICATION: in medium

DURATION
- Preincubation period: 24h
- Exposure duration: 24h
- Expression time (cells in growth medium): 4 weeks (refeeding twice a week)
- Fixing the cell monolayers with methanol and staining with Giemsa

NUMBER OF REPLICATIONS: 20 dishes per dose, 20 for negative control, 20 for positive control

Examined by eye and by microscope to determine the number of foci of transformed cells.

Evaluation criteria

- negative control dishes consist of a contiguous monolayer of cells which may or may not contain transformed foci. The lack of contiguous sheet of cells indicates growth conditions too poor to allow the reliable detection of weak transforming agents.
- the negative control transformation frequency does not exceed an average of 2-3 foci/dish after log10 analysis. Attempts are made to isolate and maintain cell stacks (subclones of Balb/3T3 1-13) with a very low spontaneous frequncy of transformation.
- positive control yields an average number of foci/dish that is signicficantly different from the negative control at the 95% CL.
- a minimum of 10 flasks per test condition are available for analysis. At least 3 dose levels of test substance are assayed.
- the dose range of test substance assayed falls within the 10-100% survival range as determined by the preliminary toxicity test, which measures relative cloning efficiencies.

Statistics

Bailey's modification of student's t-test will be used to determine whether the results for each treatment condition was significantly different from the experimental negative control.

Results and discussions

Test results

Species/strain	mammalian cell line, other: BALB/3T3 cells
Metabolic activation	
Test system	
Genotoxicity	negative
Cytotoxicity	
Vehicle controls valid	not applicable
Negative controls valid	yes
Positive controls valid	yes

Additional information on results

RANGE-FINDING/SCREENING STUDIES:
Fifteen dose levels of the test compound are chosen (max 1000 nl/ml - min 0.061 nl/ml)(decreaing in two-fold dilution steps).
Each dose is applied to 3 culture dishes seeded 24h earlier with 200 cells per dish. After an exposure period of 24h, the cells are washed and incubated in growth medium for an additional 5-7 days.
Surviving colonies are stained and counted and a relative survival for each dose is obtained by comparing the number of colonies surviving treatment to the colony counts in negative control dishes.
The highest dose chosen for subsequent transformation assays should normally cause no more than an 90% reduction in colony forming ability. Four lower doses (usually including 1dose with little apparent toxicity) are also selected for the transformation assay.

COMPARISON WITH HISTORICAL CONTROL DATA:
negative control: in this study 2 transformed foci were observed among 20 dishes. This spontaneous transformation frequency is within the expected range (0 - 0.5 focus/dish). Also negative control dishes with high number of transformed foci (>10/dish) have been observed in other assays forming the historical negative control data base.

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

Compared to the negative control value, none of the frequencies of transformed foci observed for the remaining four test material treatments achieved the 95% confidence level of being significantly altered. In addition, no evidence of a dose-related response was observed, therefore concentrations from 1563 to 313 nl/ml were evaluated as being nontransforming to 3T3 cells.
The test material is considered to be inactive in the Balb/3T3 in vitro transformation assay.

Executive summary

AHF - Huntsman UDS. key

UUID IUC5-607836e1-b026-4d9a-a741-1d44a722f3f4
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-15 20:20:54 EST
Remarks

Administrative Data

Purpose flag key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result **Study period** March 2, 1982 to May 28, 1982
Reliability 2 (reliable with restrictions)
Rationale for reliability Guideline study with minor deviations. Specific number of cells evaluated for each group not provided stated between 5 to 20 cells from each quadrant of each coverslip (3 coverslips) were counted.

Data source

Reference

Reference type company data
Author American Health Foundation **Year** 1982
Title The Hepatocyte Primary Culture/DNA Repair Assay on Compound 4236-45-25 Using Rat Hepatocytes in Culture
Bibliographic source
Testing laboratory American Health Foundation **Report no.** 030882 (Texaco Testing)
Owner company Huntsman
Company study no. **Report date** 1982-06-25

Data access

data submitter is data owner

Data protection claimed

yes, but willing to share

Materials and methods

Type of genotoxicity

DNA damage and/or repair

Type of study

DNA damage and repair assay, unscheduled DNA synthesis in mammalian cells in vitro

Test guideline

Qualifier equivalent or similar to
Guideline OECD Guideline 482 (Genetic Toxicology: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells In Vitro)
Deviations yes Non GLP, no analytical, specific number of cells evaluated for each group not provided. However, study stated between 5 to 20 cells from each quadrant of each coverslip (3 coverslips) were counted.

GLP compliance

no

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): 4236-45-25

Method

Species/strain

Species/strain hepatocytes: Freshly prepared rat hepatocyte cultures from adult male F344 rats
Details on mammalian cell lines (if applicable)
Additional strain characteristics
Metabolic activation without
Metabolic activation system

Test concentrations

0.00001, 0.0001, 0.001, 0.01, 0.1 and 1%

Vehicle

- Vehicle(s)/solvent(s) used: DMSO

Controls

Negative controls yes untreated
Solvent / vehicle controls yes DMSO
True negative controls yes Pyrene-5 E-4 M
Positive controls yes see positive control below
Positive control substance
Remarks

Negative controls yes untreated
Solvent / vehicle yes DMSO

controls

True negative controls	yes Pyrene
Positive controls	yes
Positive control substance	benzo(a)pyrene 5 E-4 M
Remarks	

Details on test system and conditions

METHOD OF APPLICATION: in medium

DURATION
- Exposure duration: 18-20 hours
- Fixation time (start of exposure up to fixation or harvest of cells): After exposure, each coverslip with cells was removed from its well and rinsed in three successive washes of WME. Coverslips were then immersed with the cell surface up in 1% sodium citrate in a clean 6 well dish for 10. Finally, the cells were fixed in three 30 minute changes of ethanol-glacial acetic acid (3:1).

NUMBER OF REPLICATIONS: 3 (coverslips per group)

NUMBER OF CELLS EVALUATED: Only those cells which were viable at the time of fixation, indicated by swollen nuclei, and those evenly coated with emulsion were scored between 5 to 20 cells randomly selected from each quadrant of the coverslips were counted. The number of cells to be scored depended on the nuclear/cyto-plasmic ratio obtained.

DETERMINATION OF CYTOTOXICITY
- Method: Cytotoxicity of the test substance was identified by the absence of S phase cells in the autoradiograph and by general morphology.

OTHER: 10 UCi/ml tritiated thymidine (3H-TdR), 60-80 Ci/mM, was added to the cell cultures along with the test substance.

Evaluation criteria

The scoring method was designed to avoid false positive by choosing the highest cytoplasmic count of each cell as a background. The test substance was reported positive when the minimum net grain count of 5 per nucleus was consistently observed throughout the experiment. Where possible, a dose response profile would be developed for each species in which the test substance was positive. Results of individual experiments were reported as the mean +/- standard deviation of net grain counts for triplicate coverslips.
The test substance was reported negative in the assay if the net nuclear count was less than 5 at the highest non-toxic dose.

Results and discussions

Test results

Species/strain	hepatocytes: rat
Metabolic activation	without
Test system	all strains/cell types tested
Genotoxicity	negative
Cytotoxicity	yes
Vehicle controls valid	yes
Negative controls valid	yes
Positive controls valid	yes

Additional information on results

ADDITIONAL INFORMATION ON CYTOTOXICITY AND DNA REPAIR: When the two sets of slides exposed to the two highest concentrations of the test substance were examined under the microscope, after they had been processed for autoradioagraphy, cytotoxicity was observed in all of the slides in the two sets. Cytotoxicity was identified by a general absence of S-phase cells, an absence of grains in the few remaining hepatocytes and presence of hepatocytes with non-swollen nuclei. Thus counting of slides began with the slides exposed at 0.01 % concentration and lower. The mean net nuclear grain counts of the slides exposed to the different concentrations of the test substance did not exceed 5. It was concluded therefore that the test substance was not genotoxic to the hepatocyte sin the DNA repair assay. Parallel run DMSO and cell culture control gave a mean net nuclear grain count of 0.3 +/- 0.3 and 0.2 +/- 0.4 respectively. The mean net nuclear grain count of the parallel run positive control was 20 +/- 11.3 and the negative control (pyrene) was 1.2 +/- 1.1.

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

The test substance , when assayed at maximum solubility and at the highest nontoxic concentration, was non-genotoxic to primary rat hepatocytes in the HPC/DNA repair assay.

7.6.2 Genetic toxicity in vivo

Genetic toxicity in vivo MNA.002

UUID	IUC5-ba388cb6-af88-4df5-8d8a-862d006f79c4
Dossier UUID	0
Author	Imacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-21 21:16:26 EST
Remarks	

Administrative Data

Purpose flag	key study (X) robust study summary ( ) used for classification ( ) used for MSDS
Study result type	experimental result
Reliablility	1 (reliable without restriction)
Rationale for reliability	OECD Guideline GLP

Data source

Reference

Reference type	study report		
Author	Erexson, GL	**Year**	2001
Title	In vivo mouse micronucleus assay with Diglycolamine (DGA)		
Bibliographic source	study report		
Testing laboratory	Covance Laboratories	**Report no.**	2239-0455OECD
Owner company	Hunstman Corporation		
Company study no.		**Report date**	2001-07-25

Data access

data submitter is data owner

Materials and methods

Type of genotoxicity

chromosome aberration

Type of study

micronucleus assay

Test guideline

Qualifier	according to
Guideline	OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)
Deviations	
Qualifier	according to
Guideline	EPA OPP 84-2
Deviations	

Principles of method if other than guideline

Due to mortality in the high dose group (250 mg/kg) assigned to both the 48-hour harvest and the replacement animal groups, only four animals were available for harvest. This deviation had no impact on the integrity of this study.

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

Details on test material

- Name of test material (as cited in study report): Diglycolamine (DGA)
- Physical state: transparent colorless liquid
- Analytical purity: responsability of the Sponsor
- Lot/batch No.: Lot 8043-70, recieved on 2001-03-28
- Storage condition of test material: ambient

Test animals

Species

mouse

Strain

CD-1

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Strain: CD-1 (ICR) BR strain
- Source: Charles River Laboratories, Kingston, NY (dose range finding study) + Charles River Laboratories, Raleigh, NC (definitive study)
- Age at study initiation: young adult mice, 7 weeks
- Weight at study initiation: 20-40g (weight variation did not exceed 20% of the mean weight of each sex). 28.4 -33.5 g in the final study.
- Assigned to test groups randomly, by a computer program
- Fasting period before study: no
- Housing: sanitary, polycarbonate cages containing Sani-Chips hardwood Chip Laboratory bedding.
- Housed separated by gender, up to 5 animals per cage during acclimation, and full dose group after randomization.
- Diet (e.g. ad libitum): commercial diet, ad libitum
- Water (e.g. ad libitum): ad libitum
- Acclimation period: at least 6 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 64-79 °F
- Humidity (%): 30-70%
- Air changes (per hr): at least 10 per hour
- Photoperiod (hrs dark / hrs light): 12 hrs dark, 12 hrs light

IN-LIFE DATES: From: 17 April 2001 To: 08 May 2001

Administration / exposure

Route of administration

intraperitoneal

Vehicle(s)

- Vehicle(s)/solvent(s) used: 0.5 % CMC (carboxymethyl cellulose)
- Justification for choice of solvent/vehicle: no data

Details on exposure

one single intraperitoneal dose per mouse

Duration of treatment / exposure

The animals were treated once and samples of bone marrow were taken at 24 and 48 h after treatment.

Frequency of treatment

Once

Post exposure period

1st dose ranging study: 24h
2nd dose ranging study: 48h
final study: 24h and 48h

Doses / concentrations

62.5, 125, 250 mg/kg

Basis nominal conc.

No. of animals per sex per dose

6

Control animals

yes, concurrent vehicle

Positive control(s)

- Cyclophosphamide, dissolved in sterile deionized water
- Route of administration: oral, gavage
- Doses / concentrations: 80 mg/kg

Examinations

Tissues and cell types examined

Bone marrow of femur. At least 2000 PCDs per animal were analyzed for the frequency of micronuclei. Cytotoxicity was assessed by scoring the number of PCEs and normochromic erythrocytes (NCEs) in at least 500 erythrocytes for each animals.

Details of tissue and slide preparation

CRITERIA FOR DOSE SELECTION:
Based on first dose range finding study with following doses: 500, 1000, 2000 mg/kg bw: all animals were found dead after 24h.
a second dose range finding study was performed with following doses: 62.5, 125, 250 mg/kg bw (3 animals per dose): animals were observed immediately after dosing, one hour after dosing and daily (for 2 days). 2 animals of the highest dose group died. Based on these results, the maximum tolerated dose was estimated to be 250 mg/kg bw.

TREATMENT AND SAMPLING TIMES (in addition to information in specific fields):
Only males were used because there were no substantial differences in between the sexes in the dose range finding study.
Animals were dosed on April 30, 2001. Per dosing group (62.5, 125, 250 mg/kg, vehicle control and positive control), cells were harvested at 24 h after dosing. For both the 250 mg/kg and the vehicle control group, cells were harvested at 48 h after dosing in an extra group of 6 mice.
Animals were euthanized by CO2 inhalation followed by incision of the diaphragm.

DETAILS OF SLIDE PREPARATION:
Hind limb bones (tibias) were removed for marrow extraction. For each animal, the marrow flushed from the bones was combined in an individual centrifuge tube containing 3 to 5 mL fetal bovine serum (one tube per animal).
Following centrifugation to pellet the tissue, the supernatant was removed by aspiration and portions of the pellet were spread on slides and air dried. The slides were fixed in methanol, stained in May-Grünwald solution followed by Giemsa, and protected by permanently mounted coverslips. For control of bias, all slides were coded prior to analysis. Slides prepared were coded prior to analysis.

METHOD OF ANALYSIS:
Slides were scored for micronuclei and the PCE to NCE cell ratio. The micronucleus frequency (expressed as percent icronucleated cells) was determined by analysing the number of micronucleated PCEs from at least 2000 PCEs per animal. The PCE: NCE ratio was determined by scoring the number of PCEs and NCEs observed scoring at least the first 500 erythrocytes per animal.

Evaluation criteria

The criteria for the identification of micronuclei were those of Schmid (1976). Micronuclei were darkly stained and generally round, although amond- and ring-shaped micronuclei occasionally occurred. Micronuclei were sharp bordered and generally between 1/20th and 1/5th the size of the PCEs. The unit of scoring was the micronucleated cell, not the micronucleus.
The criteria for a positive response was the detection of a statistically significant increase in micronucleated PCEs for at least one dose level, and a statistically significant dose-related response. A test article that did not induce both of these responses as considered negative. Statistical significance was not the only determinant of a positive response. Biological relevance of the results were also considered in the final evaluation.

Statistics

Assay data analysis was performed using an analysis of variance (Winer, 1971) on untransformed proportions of cells with micronuclei per animal and on untransformed PCE:NCE ratios when the variances were homogenous. Ranked proportions were used for heterogeneous variances. If the analysis of variance was statistically significant ($p <= 0.05$), a Dunnet's t-test was used to determine which groups, if any, were statistically significantly different from the vehical control. Analyses were performed separately for each sampling time.

Any other information on materials and methods incl. tables

Dosing Schema for the Micronucleus Assay

Target Treatment (mg/kg)	Stock Concentation (mg/ml)	Route of Administraion	Dosing Volume (ml/kg)	Males/ Harvest Timepoint		Replacement Males[a]
				24-Hour	48 Hour	
62.5	6.25	Intraperitoneal injection	10	6	-	-
125	12.5	Intraperitoneal injection	10	6	-	-
250	25	Intraperitoneal injection	10	6	6	6
Vehicle Control, 0.5% carboxymethylcellulose	0	Intraperitoneal injection	10	6	6	-
Positive Control, Cyclophosphamide, 80	8	Oral gavage	10	6	-	-

[a]The animals in the secondary group were dosed as potential replacements for the original high-dose group. Animals not used as replacements were euthanized at the completion of the trial.

Results and discussions

Test results

Sex male

Genotoxicity negative

Toxicity yes signs of clinical toxicity and mortality

Vehicle controls valid yes

Negative controls not applicable

valid

Positive controls valid yes

Additional information on results

RESULTS OF first RANGE-FINDING STUDY
- Dose range: 500, 1000, 2000 mg/kg
- Clinical signs of toxicity in test animals: animals were found dead within 24h

RESULTS OF second RANGE-FINDING STUDY
- Dose range: 62.5, 125, 250 mg/kg
- Clinical signs of toxicity in test animals: no clinical signs in the lowest dosing groups (62.5 and 125 mg/kg). In the highest dosing group, slightly hypoactive 1h after dosing, rough haircoat 24h after dosing (+ 1/6 animals was found dead), clear discharge from eyes, hunched, labored respiration, hypoactive 48h after dosing.
- the maximum tolerated dose was estimated to be 250 mg/kg.

RESULTS OF DEFINITIVE STUDY
- Induction of micronuclei (for Micronucleus assay): no induction
- % micronucleated PCEs (mean of 2000 per animal +/- S.E.):
62.5 mg/kg (24h harvest): 0.06 +- 0.02
125 mg/kg (24h harvest): 0.06 +- 0.02
250 mg/kg (24h harvest): 0.07 +- 0.03
250 mg/kg (48h harvest): 0.21 +- 0.08
vehicle control (24h harvest): 0.09 +- 0.04
vehicle control (48h harvest): 0.12 +- 0.03
positive control (24h harvest) 1.17 +- 0.12

- Appropriateness of dose levels and route: appropriate

- Statistical evaluation: the test article showed a statistically significant decrease in the PCE:NCE ratio at the 250 mg/kg dose level for the 24h harvest timepoint (cytotoxic to bone marrow). A statistically significant increase in micronucleated PCEs was not observed at any dose level or harvest timepoint. The positive control induced statistically significant increases in micronucleated PCEs as compared to that of the vehicle controls with a mean standard error of 1.17 +- 0.12 %.

Remarks on results including tables and figures

Micronucleus Data Summary Table

Treatment	Dose	Harvest Time	% Micronucleated PCEs mean of 2000[a] Per animals ± S.E. males	Ratio PCE:NCE Mean ± S.E. Males
Controls				
Vehicle	0.5 % CMC	24 hr	0.09 ± 0.04	0.67 ± 0.09
		48 hr	0.12 ± 0.03	0.51 ± 0.02
Positive	CP 80 mg/kg	24 hr	1.17 ± 0.12*	0.55 ± 0.06
Test article	62.5 mg/kg	24 hr	0.06 ± 0.02	0.61 ± 0.05
	125 mg/kg	24 hr	0.06 ± 0.02	0.48 ± 0.05
	250 mg/kg	24 hr	0.07 ± 0.03	0.41 ± 0.04**
		48 hr	0.21 ± 0.08	0.41 ± 0.05

*Significantly greater than the corresponding vehicle control, ps0.01.
** Significantly less than the corresponding vehicle control, ps0.05.
[a]One animal from the 24-hour vehicle control group and two animais from the 62.5 mg/kg dose goup were scored out of >2000 PCE/animal. See individual animal data, Table 2.
CMC = Carboxymethy1 cellulose
CP = Cyclophosphamide
PCE = Polychromatic erythrocyte
NCE = Normochromatic erythrocyt

Overall remarks, attachments

Overall remarks

The test article diglycolamine (DGA) which is also AEE, induced signs of clinical toxicity and mortality in the treated animals and was cytotoxi to the bone marrow (i.e. statistically significant decrease in the PCE:NCE ratio) at the 250 mg/kg dose level for the 24 hr harvest timepoint. A statistically significant increase in micronucleated PCEs was not observed at any dose level or harvest timepoint. The positive control, cyclophosphamide, induced statistically significant increases in micronucleated PCEs as compared to that of the vehicle controls.

Applicant's summary and conclusion

Interpretation of results

negative

Conclusions

Diglycolamine (DGA), also known as AEE, was evaluated as negative in the mouse bone marrow micronucleus assay under the conditions of this assay.

7.8 Toxicity to reproduction

Toxicity to reproduction

UUID	IUC5-bd8afea9-7324-49ad-a675-4c9ca5ff349c
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2010-01-20 16:11:32 EST
Remarks	

Administrative Data

Effects on fertility

Short description of key information

Data are available from an existing 90-day repeated dose study (Zeiders, 2002) via the dermal route (OECD 411). Evaluations from this study show no effects on the male and female reproductive organs. An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.

Developmental toxicity / teratogeniticy

Short description of key information

No data available concerning developmental toxicity. An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.

7.8.1 Toxicity to reproduction

Toxicity to reproduction.001

UUID IUC5-4ecbe777-2249-4698-8c5d-84838aa04ccc
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2010-01-20 16:15:18 EST
Remarks

Administrative Data

Purpose flag supporting study (X) robust study summary ( ) used for classification ( ) used for MSDS
Data waiving other justification
Justification for data waiving Data are from an existing 90-day study which fully evaluated the reproductive organs. Results from this study do not reveal any effects on the male and female reproductive organs upon evaluation.
Study result type experimental result
Reliablility 1 (reliable without restriction)
Rationale for reliability OECD GLP study

Data source

Reference

Reference type study report
Author Zeiders, JL **Year** 2002
Title A 90 day dermal toxicity study in rats
Bibliographic source Calvert Preclinical Services, Inc. PA 18447 USA
Testing laboratory **Report no.** 0470RH11.001
Owner company Huntsman
Company study no. **Report date** 2002-11-13

Data access

data submitter is data owner

Cross-reference to same study

Refer to full summary of Key repeated dose toxicity: dermal study.

Materials and methods

Test type

other:

Test guideline

Qualifier according to
Guideline other guideline: OECD Guideline 411
Deviations

GLP compliance

yes

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier EC number
Identity 213-195-4

Details on test material

substance purity >99% as stated by sponsor

Test animals

Species

rat

Strain

Sprague-Dawley

Sex

male/female

Details on test animals and environmental conditions

TEST ANIMALS
- Source: Harlan Sprague Dawley, strain Hsd:SD
- Age at study initiation: 6 weeks
- Weight at study initiation: 143-247 grams
- Fasting period before study:
- Housing:
* before the study: rats were groups-housed by sex
* during the study: animals were housed individually in stainless steel cages
- Diet (e.g. ad libitum): Teklad Certified LM-485 rodent diet, ad libitum, except overnight prior to scheduled blood collectiong
- Water (e.g. ad libitum): ad libitum
- Acclimation period: min 7 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 19-25°C
- Humidity (%): 30-70% (during 2 days of the study, relative humidity was outside this range. However, this is not considered to have had any adverse

effect on the outcome of this study)
- Photoperiod (hrs dark / hrs light): 12h light, 12h dark

Administration / exposure

Route of administration

dermal

Vehicle

water

Details on exposure

TEST SITE
- Area of exposure: between 10 and 20% of the body surface
- Type of wrap if used: gauze pad, rubber dam and an elastic bandage

- Time intervals for shavings or clipplings: minimum of twice weekly

REMOVAL OF TEST SUBSTANCE
- Washing (if done): gently cleansed with gauze soaked in warm water and gently dried
- Time after start of exposure: 6h

TEST MATERIAL
- Amount(s) applied (volume or weight with unit): 0.5 ml/kg bw /d
- Concentration (if solution): 0 - 17- 87- 175 mg/kg bw/d
- Constant volume or concentration used: yes

VEHICLE = deionized water
- Amount(s) applied (volume or weight with unit): 0.5 ml/kg bw/d
- Lot/batch no. (if required): 071099, 201099, 011199, 091199, 171199, 221199, 031299, 081299, 151299, 171299, 281299

USE OF RESTRAINERS FOR PREVENTING INGESTION: no data

Analytical verification of doses or concentrations

yes

Duration of treatment / exposure

approximately 6 hrs per day

Frequency of treatment

once daily for 90 consecutive days

Doses / concentrations

0, 17, 87, 175 mg/kg/bw/day

Basis other: actual dose received

0, 50, 250, 500 mg/kg/bw/day

Basis other: nominal

No. of animals per sex per dose

10 male and 10 female

Control animals

yes, concurrent vehicle

Further details on study design

Dose levels were selected based on results from the range finding study
Rationale for animal selection is random

Positive control

No data

Examinations

Parental animals: Observations and examinations

GROSS PATHOLOGY: Yes
external surface of the body, all orifices, cranial, thoracic and abdominal cavities together with their content

HISTOPATHOLOGY: Yes
gross abnormalities, adrenals, aorta, whole brain, cecum, colon, duodenum, epididymides, esophagus, exorbital lachrymal gland, eyes w/optic nerve, femur, fat (mesentery), heart, ileum, jejunum, kidneys, liver, lungs with mainstem bronchus, mammary gland(s), mesenteric lymph nodes, ovaries, pancreas, pituitary, prostate, rectum, salivary glands (mandibular lymph nodes), sciatic nerve, seminal vesicle(s), skin (with subcutis from a site other than the treated site), spinal cord at three levels - cervical, midthoracic, lumbar - spleen, sternum with bone marrow, stomach, testes, thigh musculature (skeletal muscle), thymus, thyroids/parathyroids, tongue, trachea, treated site (dorsal thoracic region with subcutis), urinary bladder, uterus, vagina

Postmortem examinations (Parental animals)

GROSS PATHOLOGY: Yes
external surface of the body, all orifices, cranial, thoracic and abdominal cavities together with their content

HISTOPATHOLOGY: Yes
gross abnormalities, adrenals, aorta, whole brain, cecum, colon, duodenum, epididymides, esophagus, exorbital lachrymal gland, eyes w/optic nerve, femur, fat (mesentery), heart, ileum, jejunum, kidneys, liver, lungs with mainstem bronchus, mammary gland(s), mesenteric lymph nodes, ovaries, pancreas, pituitary, prostate, rectum, salivary glands (mandibular lymph nodes), sciatic nerve, seminal vesicle(s), skin (with subcutis from a site other than the treated site), spinal cord at three levels - cervical, midthoracic, lumbar - spleen, sternum with bone marrow, stomach, testes, thigh musculature (skeletal muscle), thymus, thyroids/parathyroids, tongue, trachea, treated site (dorsal thoracic region with subcutis), urinary bladder, uterus, vagina

Results and discussions

Effect levels

Endpoint	NOAEL dermal irritation
Generation	P
Sex	male/female
Effect level	17 mg/kg bw/day (actual dose received)
Basis for effect level / Remarks	
Endpoint	NOAEL systemic
Generation	P
Sex	male/female
Effect level	175 mg/kg bw/day (actual dose received)
Basis for effect level / Remarks	

Observations: parental animals

Clinical signs (parental animals)

no effects

Body weight and food consumption (parental animals)

no effects

Test substance intake (parental animals)

no effects

Organ weights (parental animals)

no effects

Gross pathology (parental animals)

no effects

Histopathology (parental animals)

no effects

Details on results (parental animals)

CLINICAL SIGNS AND MORTALITY
* no animals died during the study
* no clinical signs of toxicity observed during the study
* clinical signs of dermal irritation were noted.
-Erythema and edema of varying degrees was observed in both males and females in the 87 and 175 mg/kg bw/d groups.
-Very slight erythema first appeared on day 6, 7 or 8 of 87 - 175 mg/kg bw/d groups.
-Very slight edema first appeared on day 7 in females recieving 175 mg/kg bw/d and progressed to severe edema by the end of the study.
-Very slight edema was seen on days 28, 38 or 33 respectively in females (87mg/kg bw/d) and males (87 or 175 mg/kg bw/d). This progresses to moderate to severe during the following 90 days of treatment. There was slightly more eythema and edema in females (87 mg/kg bw/d) compared to males recieving the same dose.
- additional signs noted in the male/female 87 and 175 mg/kg bw/d dose groups were all related to irritation at the application site and included scab formation, sloughing, and black areas on the dosing site.

BODY WEIGHT AND WEIGHT GAIN
* no test article-related differences in group mean bw or body weight gains throughout the study

FOOD CONSUMPTION
* no test article-related differences in group mean food consumption throughout the study

FOOD EFFICIENCY
* no data

WATER CONSUMPTION
* no data

OPHTHALMOSCOPIC EXAMINATION
* no test article-related differences in ophthalmology examination, conducted during the final week of treatment

HAEMATOLOGY
* Females, 87 mg/kg bw/d: statistically significant increase in absolute and relative neutrophil counts
* no test article-related differences in erythrocyte morphology for males or females
* no test article-related differences in hematology for males
This effect was considered by the study author to be incidental and not dose related.

CLINICAL CHEMISTRY
* males, 175 mg/kg bw/d + females, 87 and 175 mg/kg bw/d: statistically significant increases in globulin + decreases in albumin/globulin ratios
* all other stat. significant differences were withing normal historical ranges.
The study author concluded these findings to be considered a secondary effect and as a result of severe dermal irritation observed in the mid and high dose groups. These findings are not considered to be a direct effect of the test article but an indirect effect based on dermal irritation caused by the administration of the test substance.

URINALYSIS
* no test article-related changes in any of the urinalyses parameters observed in M or F rates at the end of the treatment period

NEUROBEHAVIOUR
* no test article-related neurotoxicity observed on day 28 or day 90.

ORGAN WEIGHTS
* no test article-related differences in absolute organ weights, relative organ to body weight ratios, or relative organ to brain weight-ratios
following 90 d of treatment.

GROSS PATHOLOGY
* scab formation of varying degrees was observed at the treatment site of males and females receiving 87 or 175 mg/kg bw/d (see table 9, p. 148)
* varous gross lesions on the skin at the treatment site were test article-related in male and females receiving 87 or 175 mg/kg bw/d
(namely respecitvely in 8/10 males and 10/10 females in 87 mg/kg bw/d dosing group; and 9/10 males and 9/10 females in 175 mg/kg bw/d).

HISTOPATHOLOGY: NON-NEOPLASTIC
test article-related microscopic changes were limited to the site of exposure and included ulceration, epidermal hyperplasia, fibrosis and
inflammation. there was some variation in the severity of these changes, however: most of the males and females in 87 - 175 mg/kg bw/d groups were affected with one or more of these changes. No evidence of a similar effect was seen in the control group and the lowest dose group.

Applicant's summary and conclusion

Conclusions

AEE did not have any effects on the reproductive organs upon evaluation in a 90-day dermal repeated dose toxicity study.

Toxicity to reproduction.002

UUID	IUC5-c0a2089e-33e7-49af-a367-46a9ce8ded3f
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-21 21:19:16 EST
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Data waiving	other justification
Justification for data waiving	An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.
Study result type	experimental study planned

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

7.8.2 Developmental toxicity / teratogenicity

Developmental toxicity / teratogenicity.001

UUID	IUC5-b64c2021-7f75-4875-9c20-225c109adee1
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-21 21:20:05 EST
Remarks	

Administrative Data

Purpose flag	( ) robust study summary ( ) used for classification ( ) used for MSDS
Data waiving	other justification
Justification for data waiving	An OECD 422 is proposed via the inhalation route to further address the repeated dose, reproductive and developmental endpoints.
Study result type	experimental study planned

Materials and methods

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier	EC number
Identity	213-195-4

7.10 Exposure related observations in humans
7.10.4 Sensitisation data (humans)
Sensitisation data (humans).001.QCMCS

UUID IUC5-26782b56-630b-46eb-9ce5-1de96f984328
Dossier UUID 0
Author lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date 2009-12-16 06:00:35 EST
Remarks

Administrative Data

Purpose flag ( ) robust study summary ( ) used for classification ( ) used for MSDS
Study result type experimental result
Reliablility 4 (not assignable)
Rationale for reliability Case study of a metal worker with no history of atopy with a work related hand dermatitis.

Data source

Reference

Reference type publication
Author Geier J, Lessmann H, Graefe A, Fuchs T **Year** 2002
Title Contact allergy to diglycolamine in water-based metalworking fluid
Bibliographic source Contact Dermatitis 2002:26:121
Testing laboratory **Report no.**
Owner company
Company study no. **Report date**

Data access

data submitter is data owner

Materials and methods

Type of sensitisation studied

skin

Study type

case report

Test guideline

Qualifier no guideline followed
Guideline
Deviations

Principles of method if other than guideline

Patient with work related dermatitis was patch tested with the German standard series, industrial biocides, metalworker series, and ointment based series as recommended by the German Contact Dermatitis Research Group (DKG). In addition, clinic specific extensions to the standard and preservative series and additional constituents of metalworking fluid were tested. Patch tests were performed and read according to the DKG guidelines.

Test materials

Test material equivalent to submission substance identity

yes

Test material identity

Identifier CAS number
Identity 929-06-6
Identifier EC number
Identity 213-195-4

Details on test material

- Name of test material (as cited in study report): diglycolamine (syn. 2-(2-aminoethoxy)ethanol, CAS-No. 929-06-6)

Method

Type of population

occupational

Ethical approval

no data

Subjects

- Number of subjects exposed: 1
- Sex: Male
- Age: 39

Clinical history

- History of allergy or casuistics for study subject or populations: No history of atopy; subsequent prick tests for atopy screening remained negative except for a weak reaction to cat allergen, which was without clinical relevance.
- Symptoms, onset and progress of the disease: work related hand dermatitis, spreading to arms; symptoms diminished when taking 1-4 weeks of sick leave
- Exposure history: 1-2 years

Controls

Eighty other metal workers (71 males, 9 females) were tested with diglycolamine 1% petrolatum in the course of this study; 79 of which patch tested negative. One resulted in a questionable reaction with a few follicular papules.

Route of administration

dermal

Details on study design

TYPE OF TEST(S) USED: patch test

ADMINISTRATION
- Other: Patch test performed according to the DKG guidelines.

EXAMINATIONS
- Grading/Scoring system: Patch test read according to the DKG guidelines.

Any other information on materials and methods incl. tables

Results and discussions

Results of examinations

The only positive test reaction was to diglycolamine, which elicited erythema, infiltration and vesicles at Day 3. Prick tests for atopy screening remained negative except for a weak reaction to cat allergen, which was

without clinical relevance.

Overall remarks, attachments

Overall remarks

A stock solution of the metal working fluid from the patient's work place contaied 10% diclycolamine. This particular metal working fluid was not however used for patch testing.

Reference substance: 2-(2-aminoethoxy)ethanol

UUID	ECB5-d966af20-7dea-42ad-a7be-87278757dbab
Dossier UUID	0
Author	gerstma
Date	2009-10-23 02:22:52 EDT
Remarks	Added EU: REACH data protection flag

General information

Reference substance name	2-(2-aminoethoxy)ethanol

EC inventory

EC number	213-195-4	CAS number	929-06-6
EC name	2-(2-aminoethoxy)ethanol		
Molecular formula	C4H11NO2		

Molecular and structural information

Legal entity: The Acta Group EU, Ltd

UUID	IUC5-2c6670cc-9ac8-497c-8863-58c8bfa6260b
Dossier UUID	0
Author	lmacdougall / The Acta Group EU, Ltd / Runcorn / United Kingdom
Date	2009-12-05 12:06:35 EST
Remarks	

General information

Legal entity name	The Acta Group EU, Ltd
Legal entity type	consultant

Identifiers

Legal entity identifiers

Identifier type	VAT
ID	897 1702 85

Other IT system identifiers

IT system	LEO
ID	11983

Contact information

Contact address

Address	Heath Road South
Postal code	WA7 4QX
Town	Runcorn
Region / State	Cheshire
Country	United Kingdom
Phone	44 1928 500 056
Fax	44 1928 248905
E-mail	gww@onesourcepsg.com
Web site	http://actagroup.com/indexeu.html

Contact persons

Organisation	The Acta Group EU, LTD
Title	IT Manager
First name	George
Last name	Wilson
Phone	240-864-0431
Mobile	301-928-5512
Fax	240-864-0450
E-mail	gww@onesourcepsg.com
Address	400 Professional Drive
Address	Suite 310
Postal code	20879
Town	Gaithersburg
Region / State	MD
Country	United States of America

Sites

Test site
test site1