CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

Substance Name: 1,2-epoxybutane

EC Number: **203-438-2**

CAS Number: **106-88-7**

Index Number: **603-102-00-9**

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PART A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	*1,2-epoxybutane*
EC number:	*203-438-2*
CAS number:	*106-88-7*
Annex VI Index number:	*603-102-00-9*
Degree of purity:	*> 99.5%*

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	Regulation (EC) No 1272/2008 (2nd ATP)	**Directive 67/548/EEC (Dangerous Substances Directive; DSD)**
Current entry in Annex VI, CLP Regulation	Flam. Liq. 2; H225 Carc. 2; H351 Acute Tox. 4*; H332 Acute Tox. 4*; H312 Acute Tox. 4*; H302 Eye Irrit. 2; H319 STOT SE 3; H335 Skin Irrit. 2; H315 Aquatic Chronic 3; H412	F; R11 Carc. Cat. 3; R40 Xn; R20/21/22 Xi; R36/37/38 R52-53
Current proposal for consideration by RAC	Removal of Aquatic Chronic 3; H412	Removal of R52-53
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Flam. Liq. 2; H225 Carc. 2; H351 Acute Tox. 4*; H332 Acute Tox. 4*; H312 Acute Tox. 4*; H302 Eye Irrit. 2; H319 STOT SE 3; H335 Skin Irrit. 2; H315	F; R11 Carc. Cat. 3; R40 Xn; R20/21/22 Xi; R36/37/38

1.3 Proposed harmonised classification based on CLP Regulation and/or DSD criteria

According 67/548/EEC Annex I, the substance meets the criteria for classification as harmful to aquatic organisms, which may cause long-term adverse effects in the aquatic environment (R52-53). According to Regulation (EC) No 1272/2008 Annex VI, the substance has to be classified as harmful to aquatic life with long lasting effects (Aquatic Chronic 3). The main argument for the classification according to CLP and DSD was the lack of data on biodegradation.

Since new experimental results show that 1,2-epoxybutane is readily biodegradable, the data gap on biodegradability of 1,2-epoxybutane is closed. Hence the database for the classification of 1,2-epoxybutane is conclusive. The hazard assessment of 1,2-epoxybutane reveals no need to classify the substance for the environment.

Table 3: Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives				Conclusive but not sufficient for classification
2.2.	Flammable gases				Conclusive but not sufficient for classification
2.3.	Flammable aerosols				Conclusive but not sufficient for classification
2.4.	Oxidising gases				Conclusive but not sufficient for classification
2.5.	Gases under pressure				Conclusive but not sufficient for classification
2.6.	Flammable liquids	Flam. Liquid 2		Flam. Liquid 2	
2.7.	Flammable solids				Conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures				Conclusive but not sufficient for classification
2.9.	Pyrophoric liquids				Conclusive but not sufficient for classification
2.10.	Pyrophoric solids				Conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures				Conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases				Conclusive but not sufficient for classification
2.13.	Oxidising liquids				Conclusive but not sufficient for classification
2.14.	Oxidising solids				Conclusive but not sufficient for classification
2.15.	Organic peroxides				Conclusive but not sufficient for classification
2.16.	Substance and mixtures				Conclusive but not sufficient for

	corrosive to metals				classification
3.1.	Acute toxicity - oral	Acute Tox. 4*		Acute Tox. 4*	
	Acute toxicity - dermal	Acute Tox. 4*		Acute Tox. 4*	
	Acute toxicity - inhalation	Acute Tox. 4*		Acute Tox. 4*	
3.2.	Skin corrosion / irritation	Skin Irrit. 2		Skin Irrit. 2	
3.3.	Serious eye damage / eye irritation	Eye Irrit. 2A		Eye Irrit. 2A	
3.4.	Respiratory sensitisation				Data lacking
3.4.	Skin sensitisation				Conclusive but not sufficient for classification
3.5.	Germ cell mutagenicity				Conclusive but not sufficient for classification
3.6.	Carcinogenicity	Carc. Cat. 2		Carc. Cat. 2	
3.7.	Reproductive toxicity				Conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	STOT SE 3		STOT SE 3	
3.9.	Specific target organ toxicity – repeated exposure				Conclusive but not sufficient for classification
3.10.	Aspiration hazard				Conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	none		Aquatic Chronic 3; H412	Conclusive but not sufficient for classification
5.1.	Hazardous to the ozone layer				Data lacking

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Table 4: Proposed classification according to DSD

Hazardous property	Proposed classification	Proposed SCLs	Current classification [1)]	Reason for no classification [2)]
Explosiveness				Conclusive but not sufficient for classification
Oxidising properties				Conclusive but not sufficient for classification
Flammability	F; R11		F; R11	
Thermal stability				Conclusive but not sufficient for classification
Acute toxicity	Xn; R20/21/22		Xn; R20/21/22	
Acute toxicity – irreversible damage after single exposure				Conclusive but not sufficient for classification
Repeated dose toxicity				Conclusive but not sufficient for classification
Irritation / Corrosion	Xi; R36/37/38		Xi; R36/37/38	
Sensitisation				Conclusive but not sufficient for classification
Carcinogenicity	Carc. Cat. 3; R40		Carc. Cat. 3; R40	
Mutagenicity – Genetic toxicity				Conclusive but not sufficient for classification
Toxicity to reproduction – fertility				Conclusive but not sufficient for classification
Toxicity to reproduction – development				Conclusive but not sufficient for classification
Toxicity to reproduction – breastfed babies. Effects on or via lactation				Data lacking
Environment	none		R52-53	Conclusive but not sufficient for classification

[1)] Including SCLs
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

2 BACKGROUND TO THE CLH PROPOSAL

This proposal has been prepared by BASF SE in accordance with Article 37(6) of CLP Regulation and submitted by the DE-MSCA.

REACH registrations available on 12/03/2012 have been considered by the MSCA.

2.1 History of the previous classification and labelling

The existing classification R 52/53 has been added to Annex I of Directive 67/548/EEC in 1998 by the 25th ATP. The classification was discussed at the TC C&L meeting held from 10th-12th September 1997 (ECBI/48/97- Rev.1). The main argument for the classification was the lack of data on biodegradation.

2.2 Short summary of the scientific justification for the CLH proposal

Since new experimental results show that 1,2-epoxybutane is readily biodegradable, the data gap on biodegradability of 1,2-epoxybutane is closed. Hence the database for the classification of 1,2-epoxybutane is conclusive. The hazard assessment of 1,2-epoxybutane reveals no need to classify the substance as dangerous for the environment.

2.3 Current harmonised classification and labelling

Table 5: Current classification in Annex VI, Table 3.1 in the CLP Regulation

Index number	Classification		Labelling		
	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)
603-102-00-9	Flam. Liq. 2 Carc. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Chronic 3	H225 H351 H332 H312 H302 H319 H335 H315 H412	GHS02 GHS08 GHS07 **Dgr**	H225 H351 H332 H312 H302 H319 H335 H315 H412	

Table 6: Current classification in Annex VI, Table 3.2 in the CLP Regulation

Index number	Classification	Labelling
603-102-00-9	F; R11 Carc. Cat. 3; R40 Xn; R20/21/22 Xi; R36/37/38 R52-53	F; Xn R: 11-20/21/22-36/37/38-40-52/53 S: (2-)9-16-29-36/37-61

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

According to 67/548/EEC Annex I, the substance meets the criteria for classification as harmful to aquatic organisms, which may cause long-term adverse effects in the aquatic environment (R52-53). According to Regulation (EC) No1272/2008 Annex VI, the substance has to be classified as harmful to aquatic life with long lasting effects (Aquatic Chronic 3). The main argument for the classification was the lack of data on biodegradation. Since new experimental results show that 1,2-epoxybutane is readily biodegradable, the data gap on biodegradability of 1,2-epoxybutane is closed. Hence the database for the classification of 1,2-epoxybutane is conclusive. The hazard assessment of 1,2-epoxybutane reveals no need to classify the substance for the environment.

PART B.

SCIENTIFIC EVALUATION OF THE DATA

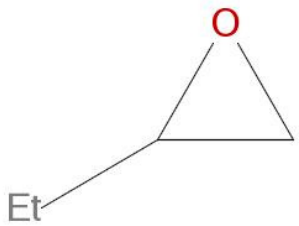
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 7: Substance identity

EC number:	203-438-2
EC name:	1,2-epoxybutane
CAS number:	106-88-7
CAS name:	Oxirane, 2-ethyl-
IUPAC name:	2-ethyloxirane
CLP Annex VI Index number:	603-102-00-9
Molecular formula:	C4H8O
Molecular weight range:	72.1057 g/mol

Structural formula:



1.2 Composition of the substance

Table 8: Constituents

Constituent	Typical concentration	Concentration range	Remarks
1,2-epoxybutane EC No: 203-438-2 CAS No.: 106-88-7	>= 99.8 % (w/w)	>= 99.5 <= 100 % (w/w)	

Table 9: Impurities

Impurity	Typical concentration	Concentration range	Remarks
See conf. Annex			

Table 10: Additives

Additive	Function	Typical concentration	Concentration range	Remarks
See conf. Annex				

1.3 Physico-chemical properties

Table 11: Summary of physico - chemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance at 20°C and 101,3 kPa	liquid	[16] GESTIS (2008)	literature
Melting/freezing point	- 129.5 °C	[1] BASF AG (1976)	measured
Boiling point	63.4 °C	[2] BASF AG (1986)	measured
Relative density	0.83 g/cm3	[3] BASF AG (1986)	measured
Vapour pressure	227 hPa	[4] BASF AG (1986)	measured
Surface tension	not surface active		expert judgement
Water solubility	86.8 g/L at 25 °C	[5] BASF AG (1981)	measured
Partition coefficient n-octanol/water	0.68 at 25 °C	[6] BASF AG (1988)	measured
Flash point	-25.5 °C	[7] BASF AG (1974)	measured
Flammability	highly flammable		expert judgement
Explosive properties	non explosive		expert judgement
Self-ignition temperature	370°C	[7] BASF AG (1974)	
Oxidising properties	no oxidising properties		expert judgement
Granulometry	Substance is marketed or used in a non solid or granular form.		expert judgement
Stability in organic solvents and identity of relevant degradation products	The stability of the substance is not considered as critical.		expert judgement
Dissociation constant	The substance does not contain any ionic structure.		expert judgement
Viscosity	0.42 mPa_s at 20°C		estimated

2 MANUFACTURE AND USES

2.1 Manufacture

Confidential Information

2.2 Identified uses

Production of 1,2-epoxybutane

Mixing into a formulation

Industrial use as intermediate for the synthesis of other substances

Industrial use as monomer in a polymerization process

Industrial use as monomer in a polymerization process of down stream users

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Not relevant for this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for this dossier.

5 ENVIRONMENTAL HAZARD ASSESSMENT

5.1 Degradation

Table 12: Summary of relevant information on degradation

Method	Results	Remarks	Reference
Photodegradation (EPIWin, AOP v1.92)	degraded slowly by photochemical processes (DT50 = 8.8 days)		[8] BASF AG (2007)
Hydrolyses (measured)	hydrolyse slowly (DT50 = 156 hours, pH =7)		[9] Gervasi et al. (1985)
Biodegradation (ISO 14593)	readily biodegradable (80-90 % CO2 evolution after 28 days)		[10] BASF AG (2000)
Biodegradation (OECD 301 C)	Readily biodegradable (>= 100 % O2 consumption after 28 days)		[15] MITI (1997)
Biodegradation (OECD 301A)	readily biodegradable, but missing the 10 day window (90 % DOC removal after 28 days)		[11] Dow Chemical Company (1999)

5.1.1 Stability

After evaporation or exposure to the atmosphere, the substance is expected to photodegrade by reaction with OH-radicals with a half-life of about 8.8 days (EPIWin, AOP v1.92) [8]. No further information on the photodegradation products is available. In contact with water the substance will hydrolyse slowly [9].

5.1.2 Biodegradation

5.1.2.1 Biodegradation estimation

5.1.2.2 Screening tests

The ready biodegradability of 1,2-epoxybutane was investigated in three different screening tests, a headspace test according to ISO 14593 guideline (further on OECD 310) , which base on the detection of CO2 evolution [10], a test from the Ministry of International Trade and Industry (MITI I, OECD 301C), which base on the measurement of oxygen consumption [15] and additional a DOC-Die-Away test according to OECD guideline 301 A [11]. As it is required for ready tests the used inoculum was not adapted in all three cases. Since 1,2-epoxybutane is moderately volatile (Henry's law = 21.48 Pa.m3/mol) [18], closed systems were indicated for testing the biodegradability. The headspace test (ISO 14593) and the MITI I test (OECD 301C) are commonly prepared in closed systems, whereas the DOC-Die-Away test (OECD 301A) is usually prepared in an open test system. In case of testing 1,2-epoxybutane, the DOC-Die-Away test (OECD 301A) was exceptionally prepared in a closed test system. Therefore specially designed 1 liter shake flasks were used, which were filled with 500 mL mineral medium and a sufficient amount of test substance. After

closing the test flasks the remaining space results into a headspace volume of air. In both studies with closed flasks (ISO 14593 and OECD 301A) abiotic controls where performed to assess volatilization processes. There was no indication of volatilization during the 28 days incubation period.

In all three reported guideline studies the pass level for ready biodegradability of 1,2-epoxybutane was reached within the required 28 days' time period. Besides reaching the pass level within 28 days, the ready criteria include the requirement on achievement of the pass level within ten days from the onset of biodegradation. This so-called 10-day-time window requirement applies not to all test systems. MITI I (OECD 301C) is excluded from the ten-day-time window requirement. Hence from the result of the reported MITI I test [15] 1,2-epoxybutane can be stated as ready biodegradable according to OECD criteria. In the headspace test according to ISO 14593 guideline the detection of the 10-day-time window turned out to be difficult, since the kinetic was recorded in 7 days measuring intervals. From the resulting curves it can be assessed, that the lag phase lasted for about 8 to 10 days and the pass level was reached after approximately 19 to 20 days. Since it was not possible to determine more precise time points, it is not definitely been proved that the 10-day-time window was hold. To take this lack of definition into account, the OECD guidelines permit in case of the Closed Bottle test (OECD 301D), which usually base also on a 7-days measuring interval, to use a 14-days window instead of a 10-day-time window [17]. In the described headspace test [10] the time window is very close to 10 days and a 14-days window was definitely hold. Therefore in the study report of the headspace test (ISO 14593) 1,2-epoxybutane is stated as readily biodegradable. The ready results from the MITI I and from the headspace test are complimented by the results of the DOC-Die-Away test [11]. At the end of the DOC-Die-away test the degradation exceed 90%, but missing the 10-day-time window.

5.1.2.3 Simulation tests

No data available.

5.1.3 Summary and discussion of degradation

Concluding all available data on biodegradation of 1,2-epoxybutane, the substance can be assessed as ready biodegradable according to OECD criteria. Hence, 1,2-epoxybutane is rapidly degradable according to the classification and labelling criteria.

5.2 Environmental distribution

Based upon a calculated log Koc = 0.652, adsorption to solid soil phase is not expected. From the water surface, the substance will slowly evaporate into the atmosphere (Henry´s law constant = 21.48 Pa·m³/mol; SRC HENRYWIN v3.10). Hence it can be expected that 1,2-epoxybutane will preferentially distribute into the compartments air and water.

5.3 Aquatic Bioaccumulation

5.3.1 Aquatic bioaccumulation

Regarding the 1-octanol/water partition coefficient (log Kow = 0.68), accumulation of the substance in organisms is not to be expected.

5.3.2 Summary and discussion of aquatic bioaccumulation

Regarding the 1-octanol/water partition coefficient, accumulation of the substance in organisms is not to be expected.

5.4 Aquatic toxicity

Acute tests on all three trophic levels were performed to examine the aquatic toxicity of 1,2-epoxybutane. Daphnia turned out to be the most sensitive species revealing an EC50 (48h) of 70 mg/L. Thus, 1,2-epoxybutane is considered to be acutely harmful to aquatic organisms. Effects of

1,2-epoxybutane towards fish and algae were found in concentrations above 100 mg/L. The results of the acute aquatic toxicity tests base on nominal values, since the test concentration was not analytically verified during the tests. Based on the good water solubility of 86.8 g/L at 25 °C [5] in combination with a moderate volatility (Henry's law = 21.48 Pa.m3/mol) [18], it can be expected that the test substance concentration was constant during the short test duration between 48 and 96 hours. This expectation is confirmed by the sterile controls of the biodegradation studies (headspace and DOC-Die-Away test). Evaporation processes could be determined by decreasing of the DOC concentration in the sterile controls. No DOC removal was observed during the 28 days test duration and therefore volatilization is negligible.

Table 13: Summary of relevant information on aquatic toxicity

Method	Results	Remarks	Reference
Short-term toxicity to fish (DIN 38412)	LC50 (96h) > 100 mg/L		[12] BASF AG (1988)
Short-term toxicity to aquatic invertebrates (EU Directive 84/449/EEC, C2)	EC50 (48h) = 70 mg/L		[13] BASF AG (1988)
Toxicity to aquatic algae (DIN 38412)	EC50 (72h) > 500 mg/L		[14] BASF AG (1989)

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

In an acute fish test according to German national standards (DIN 38412), the LC50 (96h) for *Leuciscus idus* was determined to be > 100 mg/L 1,2-epoxybutane [12].

5.4.1.2 Long-term toxicity to fish

No data available.

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

The toxicity of 1,2-epoxybutane on *Daphnia magna* was tested in an acute toxicity test [13]. The EC50 (48h) determined to be 70 mg/L.

5.4.2.2 Long-term toxicity to aquatic invertebrates

No data available.

5.4.3 Algae and aquatic plants

The toxicity of 1,2-epoxybutane on the green algae *Selenastrum capricornutum* was measured in a test according to German national standards (DIN38412) [14]. The EC50 (72h) for the growth rate determined to be > 500 mg/L.

5.4.4 Other aquatic organisms (including sediment)

No data available.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

	Criteria for environmental hazards		1,2-epoxybutan	Conclusion
	CLP	DSD		
Rapid Degradation	Ready biodegradable in a 28-day test for ready biodegradability		DOC removal ≥ 70 %, ThOD/ThCO2 ≥ 60%	**rapidly degradable**
Bioaccumulation	BCF ≥ 500 Log Kow ≥ 4	BCF ≥ 100 Log Kow ≥ 3	Log Kow = 0.68	**not bioaccumulative**
Aquatic Toxicity	NOEC ≤ 1	LC50/EC50 ≤ 100 mg/L	Fish: LC50 96h > 100 mg/L Invertebrates: EC50 (48h) = 70 mg/L Algae: ErC50 (72h) > 500 mg/L No chronic data available	**EC50 > 10 ≤ 100 mg/L**

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

1,2-Epoxybutane is not acute toxic to aquatic organisms (LC50/EC50 > 1mg/L). The substance is rapidly degradable and not bioaccumulative. No chronic toxicity data are available. Hence, 1,2-epoxybutane does not fulfil the criteria for environmental hazards (according to DSD and CLP Regulation). The existing classification, Aquatic Chronic 3 (R52/53), should be removed.

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