CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification: Ethyl acrylate

EC Number: 205-438-8

CAS Number: 140-88-5

Index Number: 607-032-00-X

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1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other	Ethyl prop-2-enoate
international chemical name(s)	
Other names (usual name, trade name, abbreviation)	Ethyl acrylate
	2-Propenoic acid, ethyl ester
	Acrylic acid ethyl ester
	EA
	Ethoxycarbonylethylene
	Ethyl 2-propenoate
	Ethyl Acrylate Monomer
	Ethyl acrylic ester
	Ethyl propenoate
ISO common name (if available and appropriate)	Not applicable
EC number (if available and appropriate)	205-438-8
EC name (if available and appropriate)	Ethyl acrylate
CAS number (if available)	140-88-5
Other identity code (if available)	RTECS: AT0700000
	ICSC: 0267
	UN Number: 1917
	PubChem CID: 8821
Molecular formula	$C_5H_8O_2$
Structural formula	H ₂ C CH ₃
SMILES notation (if available)	CCOC(=O)C=C
Molecular weight or molecular weight range	100.12 g/mol
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Not applicable
Description of the manufacturing process and identity of the source (for UVCB substances only)	Not applicable
Degree of purity (%) (if relevant for the entry in Annex VI)	≥ 80 wt %

1.2 Composition of the substance

Ethyl acrylate is a mono-constituent substance.

Table 2: Constituents (non-confidential information).

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multiconstituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)
Ethyl acrylate EC 205-438-8	Not applicable	Flam. Liq. 2 (H225)	Flam. Liq. 2 (H225)
CAS 140-88-5		Acute Tox. 4 * (H302)	Acute Tox. 4 (H302)
		Acute Tox. 4 * (H312)	Acute Tox. 4 (H312)
		Acute Tox. 4 * (H332)	Acute Tox. 3 (H331)
		Skin Irrit. 2 (H315), $C \ge 5$	Skin Irrit. 2 (H315)
		%	Eye Irrit. 2 (H319)
		Eye Irrit. 2 (H319), $C \ge 5$ %	Skin Sen. 1 (H317)
		Skin Sen. 1 (H317)	STOT SE 3 (H335)
		STOT SE 3 (H335), $C \ge 5$ %	
		Note D	

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance.

]	Impurity	Concentration	Current	CLH	in	Current	self-	The i	mpur	ity
(Name and	range	Annex VI	Table	3.1	classification	and	contributes	to 1	the
]	numerical	(% w/w minimum	(CLP)			labelling (CLP)		classification	n a	nd
i	dentifier)	and maximum)						labelling		
	No data available									

Table 4: Additives (non-confidential information) if relevant for the classification of the substance.

Additive (Name and numerical identifier)	Function	Concentration range (% w/minimum anmaximum)	 Current self- classification and labelling (CLP)	The additive contributes to the classification and labelling
No data available				

Table 5: Test substances (non-confidential information).

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)		The study(ies) in which the test substance is used
The test substance in all reported studies is ethyl acrylate or formulations containing ethyl acrylate. If available, the purity is given in the study records below.		The test substance frequently contains a polymerization inhibitor.	The classification in Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 accounts for	
			stabilizers (Note D)	

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6: Proposed harmonised classification

			Classification		cation		Labelling																																				
	Index No	Chemical name	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors	Notes																																
					Flam. Liq. 2	H225		H225																																			
					Acute Tox. 4 *	H302		H302																																			
			Acute Tox. 4 * H312 GHS02 H312 H319 Acute Tox. 4 * H332 GHS02 H332 STO		1				Eye Irrit. 2; H319: C ≥ 5 %																																		
Current	607-032-	Fd. 1 1.4		140.00.5	H332		STOT SE 3;	N. D																																			
Annex VI entry	00-X	Ethyl acrylate	205-438-8	140-88-5	Skin Irrit. 2 H315 H315 H335: C≥5 %	H335: C ≥ 5 %	Note D																																				
				Eye Irrit. 2	H319	Dgr	H319		Skin Irrit. 2; H315: C ≥ 5 %																																		
			Skin Sen. 1 H317 H317	H313: C ≥ 3 %																																							
					STOT SE 3	H335		Н335																																			
					Modify	Modify		Modify		Add																																	
								Acute Tox. 4	H302		H302		Oral: ATE =																														
								1					1]		1	1	1		1	1	1	1	1	1																Acute Tox. 4	H312
					Acute Tox. 3	H331	Modify	H331		Dermal: ATE = 1800 mg/kg bw																																	
Dossier	607-032-	Fd 1 1	205 420 0	140.00.5	Retain	Retain	GHS06	Retain		Inhalation:	Retain																																
submitters proposal	00-X	Ethyl acrylate	205-438-8	140-88-5	140-88-5	Flam. Liq. 2	H225	Retain	H225		ATE = 9 mg/L	Note D																															
		Skin Irrit. 2 H315 GHS02 H315		(vapours)																																							
					Eye Irrit. 2	H319	Dgr	H319		Retain																																	
		Skin Sen. 1 H317 H317	Eye Irrit. 2; H319: C ≥ 5 %																																								
					STOT SE 3	H335		H335		STOT SE 3;																																	

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									H335: C ≥ 5 % Skin Irrit. 2; H315: C ≥ 5 %	
Resulting Annex VI entry if agreed by RAC and COM	607-032- 00-X	Ethyl acrylate	205-438-8	140-88-5	Flam. Liq. 2 Acute Tox. 4 Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sen. 1 STOT SE 3	H225 H302 H312 H331 H315 H319 H317	GHS02 GHS06 Dgr	H225 H302 H311 H332 H315 H319 H317	Oral: ATE = 1120 mg/kg bw Dermal: ATE = 1800 mg/kg bw Inhalation: ATE = 9 mg/L (vapours) Eye Irrit. 2; H319: $C \ge 5$ % STOT SE 3; H335: $C \ge 5$ % Skin Irrit. 2; H315: $C \ge 5$ %	Note D

Table 7: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	hazard class not assessed in this dossier	No
Flammable gases (including chemically unstable gases)	hazard class not assessed in this dossier	No
Oxidising gases	hazard class not assessed in this dossier	No
Gases under pressure	hazard class not assessed in this dossier	No
Flammable liquids	hazard class not assessed in this dossier	No
Flammable solids	hazard class not assessed in this dossier	No
Self-reactive substances	hazard class not assessed in this dossier	No
Pyrophoric liquids	hazard class not assessed in this dossier	No
Pyrophoric solids	hazard class not assessed in this dossier	No
Self-heating substances	hazard class not assessed in this dossier	No
Substances which in contact with water emit flammable gases	hazard class not assessed in this dossier	No
Oxidising liquids	hazard class not assessed in this dossier	No
Oxidising solids	hazard class not assessed in this dossier	No
Organic peroxides	hazard class not assessed in this dossier	No
Corrosive to metals	hazard class not assessed in this dossier	No
Acute toxicity via oral route	Acute Tox 4, H302	Yes
Acute toxicity via dermal route	Acute Tox 4, H312	Yes
Acute toxicity via inhalation route	Acute Tox 3, H331	Yes
Skin corrosion/irritation	hazard class not assessed in this dossier	No
Serious eye damage/eye irritation	hazard class not assessed in this dossier	No
Respiratory sensitisation	hazard class not assessed in this dossier	No
Skin sensitisation	hazard class not assessed in this dossier	No
Germ cell mutagenicity	hazard class not assessed in this dossier	No
Carcinogenicity	hazard class not assessed in this dossier	No
Reproductive toxicity	hazard class not assessed in this dossier	No
Specific target organ toxicity- single exposure	hazard class not assessed in this dossier	No
Specific target organ toxicity-	hazard class not assessed in this dossier	No
repeated exposure Aspiration hazard	hazard class not assessed in this dossier	No
Hazardous to the aquatic environment	hazard class not assessed in this dossier	No
Hazardous to the ozone layer	hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Ethyl acrylate had a harmonized classification under the Dangerous Substances Directive (67/548/EEC). This was translated to a harmonized CLP classification in Annex VI, Regulation (EC) No 1272/2008 (CLP Regulation) and the minimum classification (according to Annex VII) was applied to acute toxicity for all routes (marked as Acute Tox. 4 * for all routes).

The harmonised classification for ethyl acrylate is

Flam. Liq. 2, H225

Acute Tox. 4 *, H302

Acute Tox. 4 *, H312

Acute Tox. 4 *, H332

Skin Irrit. 2, H315, C ≥ 5 %

Eye Irrit. 2, H319, $C \ge 5 \%$

Skin Sen. 1, H317

STOT SE 3, H335, $C \ge 5 \%$

Note D¹

Self-classification:

The frequency of hazard classifications among all C&L notifications (occurring in at least 10% of notifications) was retrieved from ECHA dissemination site [accessed 12/2020] and is given below. In total, 4574 notifiers provided information on their hazard classifications (49 aggregated notifications). Two notifiers reported ethyl acrylate as not meeting GHS hazard criteria.

Hazard classifications occurring in at least 10% of notifications:

Hazard code	Hazard statement	% of notifications
H225	Highly Flammable liquid and vapor	100
H302	Harmful if swallowed	100
H312	Harmful in contact with skin	100
H315	Causes skin irritation	100
H317	May cause an allergic skin reaction	100
H319	Causes serious eye irritation	100
H331	Toxic if inhaled	55.1
H332	Harmful if inhaled	47.4
H335	May cause respiratory irritation	99.7

¹ Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

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H412 Harmful to aquatic life with long lasting 53.6 effects

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

[B.] Justification that action is needed at Community level is required.

Reason for a need for action at Community level:

- Change in existing entry due to changes in the criteria (DSD-CLP)
- Disagreement by DS with current self-classification

Further detail on need of action at Community level

There is a harmonised classification entry in Annex VI to Regulation (EC) No 1272/2008 containing a minimum classification and it is concluded that a refinement of the classification based on available data is justified. Differences in self-classification between different notifiers in the C&L Inventory and registration dossier are discovered.

Ethyl acrylate is an important industrial chemical. To minimize uncertainties in classification and ensure a high level of protection of workers, classification for acute toxicity has been evaluated.

5 IDENTIFIED USES

Ethyl acrylate is manufactured and/or imported in the European Economic Area in 100 000 – 1 000 000 tonnes per year. Identified uses are in articles, in formulation or re-packing, at industrial sites and in manufacturing (Table 8).

Table 8: Registered uses of ethyl acrylate (according to ECHA dissemination database, November 2020)

Manufacture	Manufacture and distribution
	Manufacture of intermediates at downstream user sites
	Manufacture of intermediates at production sites
	Polymerization at downstream user sites
	Polymerization at production sites
	Use as laboratory agent
Formulation	Formulation for natural gas injection
	Formulation into mixture
	Mixing into a formulation
	Formulation into solid matrix

Uses at industrial sites	Manufacture of intermediates at downstream user sites
	Manufacture of intermediates at production sites
	Polymerization at downstream user sites
	Polymerization at production sites
	Manufacture of pulp, paper and paper products
	Use as odourant in natural gas
Article service life	Manufacture of intermediates at downstream user sites
	Polymerization at downstream user sites
	Polymerization at production sites
	Consumer use; Paper articles
	Use as laboratory agent

DATA SOURCES

Systematic searches for publications and other relevant data were performed based on the following databases:

- U.S. National Library of Medicine, Pubmed.gov²
- TOXNET³, ChemIDplus⁴, IPCS⁵, eChemPortal⁶, EPA Comptox Dashboard⁷, EPA Chemview⁸
- Chemical Abstracts, Medline, Biosis, Embase, SciSearch, PQScitech (at host STN International Europe⁹)

in addition to unspecific databases (e.g., google scholar).

The REACH registration dossier for ethyl acrylate, available from ECHA's disseminated database (accessed 2019) has been analysed for study references, which then have been considered as data sources for this CLH report.

Relevant reviews and monographs with toxicological risk assessments on ethyl acrylate were analysed for study references. Used reviews are OECD (2005), McLaughlin et al. (1993), IARC (1979) and more recent

[04.01-MF-003.01]

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² https://www.ncbi.nlm,nih.gov/pubmed assessed at 14.2.2019

³ https://toxnet.nlm.nih.gov/ assessed at 14.2.2019

⁴ https://chem.nlm.nih.gov/chemidplus/ assessed 23.1.2019

⁵ http://www.inchem.org/ assessed 23.1.2019

⁶ http://www.echemportal.org/echemportal/page.action?pageID=9 assessed 23.1.2019

⁷ https://comptox.epa.gov/dashboard/ assessed 23.1.2019

⁸ https://chemview.epa.gov/chemview assessed 23.1.2019

⁹ http://www.stn-international.de/index.php?id=123 assessed 14.2.2019

IARC assessments (IARC, 1999), EFSA (2017), MAK Commission (Hartwig and MAK Commission, 1987) and more recent MAK evaluations (Hartwig and MAK Commission, 2018).

Whenever relevant information in secondary sources were identified, it was attempted to retrieve the respective primary sources.

7 PHYSICOCHEMICAL PROPERTIES

Table 9: Summary of physicochemical properties

Property	Value	Reference	Comment
Physical state at 20°C and 101,3 kPa	Liquid	(ECHA Dissemination, 2019)	Visual observation
Melting/freezing point	-71.2 °C	(ECHA Dissemination, 2019)	Reported from handbook, measured
Boiling point	99.8 °C	(ECHA Dissemination, 2019)	Measured at 1013 hPa
Density	0.95 g/cm ³	(ECHA Dissemination, 2019)	Reported from handbook, measured at 20 °C
Vapour pressure	40 hPa	(ECHA Dissemination, 2019)	Measured at 20.9 °C
Surface tension	not surface active	(ECHA Dissemination, 2019)	Reported from secondary source (authoritative data base),
Water solubility	20 g/L	(ECHA Dissemination, 2019)	Reported from secondary source (peer-reviewed data base), measured at 20 °C
Partition coefficient n-octanol/water	1.18	(ECHA Dissemination, 2019)	Measured at 25 °C
Flash point	9 ℃	(ECHA Dissemination, 2019)	Reported from secondary source (authoritative data base), measured at 1013.25 hPa
Flammability	Highly flammable	(ECHA Dissemination, 2019)	Reported from secondary source
Explosive properties	Non-explosive	(ECHA Dissemination, 2019)	Reported from expert judgment
Self-ignition temperature	372 °C	(ECHA Dissemination, 2019)	Reported from secondary source (peer-reviewed data base), measured at 1013.25 hPa
Oxidising properties	No oxidising properties	(ECHA Dissemination, 2019)	Reported from expert judgment
Granulometry	Not applicable		
Stability in organic solvents and identity of relevant degradation products	stable	(ECHA Dissemination, 2019)	Reported from expert judgment
Dissociation constant	No	(ECHA Dissemination, 2019)	Reported from expert judgment
Viscosity	0.5351 mPa*s	(ECHA Dissemination, 2019)	Reported from handbook, measured at 25 °C

8 EVALUATION OF PHYSICAL HAZARDS

Not performed for this substance.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Evaluation not performed for this substance.

10 EVALUATION OF HEALTH HAZARDS

Acute toxicity

10.1 Acute toxicity - oral route

Table 10: Summary table of animal studies on acute oral toxicity

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD ₅₀	Reference
Acute oral toxicity, comparable to OECD 401	Rat, CRCD, male only 10 males per dose group	Source: No information	710, 840, 1000, 1190, 1410, 1680, 2000 and 2380 mg/kg bw	1120 mg/kg bw (95% CI: 1010 - 1240)	Rohm and Haas Company (1984) in (OECD, 2005)
GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2	5.03F	Purity: 99 %	Single application via gavage Vehicle: Methocel, no further information 14 days observation	Mortalities: 0: 0/10 710: 1/10 840: 1/10 1000:2/10 1190: 6/10 1410: 8/10 1680: 10/10 2000: 10/10 2380: 10/10	[Study 001 in REACH registration]
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rat, strain not specified, male only 5 animals per dose group	Ethyl acrylate Source: no information Purity: no information	291, 462, 732, 1162 and 1881 mg/kg bw Single application via gavage Vehicle: aqueous emulsion with 5% or 0.5% Traganth (conflicting reporting in secondary sources) 7 days observation	554 mg/kg bw Mortalities: 1881: 5/5 1162: 5/5 732: 3/5 462: 2/5 291: 0/5	BASF AG (1958) in (OECD, 2005) [Study 002 in REACH registration]
Acute oral toxicity, Similar to OECD 401	Rat, strain not specified, male only 10 males per dose	Ethyl acrylate Source: no information Purity: no	795, 1000, 1260, and 1580 mg/kg bw Single application	1020 mg/kg bw (95% CI: 950 - 1100) Mortalities:	Pozzani et al. (1949) [Study 005 in REACH

Method, guideline,	Species, strain, sex, no/group	Test substance,	Dose levels, duration of	Value LD ₅₀	Reference
deviations if any	sex, no/group		exposure	121250	
GLP: no	group	information	via gavage	795: 0/10	registration]
Reliability			Vehicle: 1%	1000: 4/10	
(REACH			"Tergitol" 7	1260: 10/10	
registration): 2			Observation:14	1580: 10/10	
Reliability (this assessment): 3			days		
Acute oral toxicity,	specified, male	Ethyl acrylate Source: no	18, 73, 291, 461, 731, 1159, 4609	461 – 731 mg/kg bw	Anonymous (1958a)
Not similar to guideline	and females 1-5 animals /	information Purity: Source: no	mg/kg bw Single application	(treatment in 10% olive oil)	[Study 003 in REACH
GLP: no	dose, sex ratio not specified,	information	via gavage	Mortalities:	registration]
Reliability	1 -		4609 and 1159	20% Olive oil	
(REACH	See mortality table for details		mg/kg bw in 20% Olive oil.	4609: 2/2	
registration): 2			1159, 731, 461	1159: 2/2	
Reliability (this assessment): 3			and 291 mg/kg	10% Olive oil	
, , , ,			bw in 10% Olive oil.	1159: 3/3	
			731, 291, 73 and	731: 4/5	
			18 mg/kg bw in	461: 2/5	
			1% distilled water	291: 0/5	
			Observation:7 days	1% Distilled	
			days	water	
				731: 0/1	
				291: 0/1	
				73: 0/1	
				18: 0/1	
Acute oral	Rat, F344/N, male	Ethyl acrylata	55, 10, 225, 450,	> 900 mg/kg bw	NTP (1986)
toxicity,	and female	Source: Rohm and	or 900 mg/ kg bw	> 900 mg/kg ow	
Similar to OECD	5 males and 5	Haas	Single application	N.C. and all Control	[Study 004 in REACH
401	females per group	(Philadelphia, PA)	via gavage	Mortalities:	registration]
GLP: no		Batch: 37201	Vehicle: aqueous	900 mg/kg bw: males 1/5,	
Reliability		Purity: 99%	ethanol	females: 0/5	
(REACH registration): 2			Observation: 14 days	No other deaths	
Reliability (this assessment): 3 (No LD50 determined)			aujo	occurred	
Acute oral	Mouse, B6C3F1, male and female	Ethyl acrylate	100, 225, 450,	900 - 1800 mg/kg	NTP (1986)
toxicity,		Source: Rohm and	900 or 1800 mg/ kg bw	bw	[Study 006 in
Similar to OECD 401	5 males and 5 females per group	Haas (Philadelphia, PA)	Single application	Mortalities:	REACH registration]
GLP: no		Batch: 37201	via gavage	1800: 4/5 males,	
Reliability			Vehicle: aqueous	,	

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD ₅₀	Reference
(REACH registration):: 2 Reliability (this assessment): 3 (No LD50 determined)		Purity: 99%	ethanol Observation: 14 days	3/5 females No other deaths occurred	
Acute oral toxicity, Comparable to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	only	Ethyl acrylate Source: Rohm and Haas Purity: No information	1000, 1400, 2000, 2800 and 4000 mg/kg bw Single application via gavage Vehicle: peanut oil Observation:10 days	Mortalities: 1000: male: 0/5, female: 0/5 1400: male: 0/5 2000: male: 4/5, female: 4/5 2800: male: 5/5, female: 5/5 4000: male: 5/5, female: 5/5	Rohm and Haas Company (1950) in (OECD, 2005) [Study 007 in REACH registration]
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rabbit, strain not specified, female only Different group sizes, see mortality table for details	Ethyl acrylate Source: no information Purity: no information	120, 180, 280, 420, 620, and 940 mg/kg bw Single application via gavage No vehicle Observation time: No information	280 - 420 mg/kg bw Mortalities: 120: 0/1 180: 0/3 280: 0/4 420: 2/2 620: 1/1 940: 1/1	Treon et al. (1949) [Study 008 in REACH registration]
Acute oral toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	sex not specified 2 animals per dose group	Source: No information Purity: No information	Single application via gavage Vehicle: aqueous emulsion in traganth (10% or 20%), without further specification 8 days observation time	> 184 - <= 368 mg/kg bw Mortalities: 184: 0/2 368: 1/2 736: 2/2	BASF AG (1960) in (OECD, 2005) [Study 009 in REACH registration]
Acute oral toxicity, Similar to OECD 401	only	Ethyl acrylate Source: No information Purity: no	4 dose levels, no further information Single application	1800 mg/kg bw (95% CI: 1228 - 2638) No information on	Tanii and Hashimoto (1982) [Study 010 in REACH

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD50	Reference
GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3		information	via gavage Vehicle: No information Observation time: no information	mortalities	registration]
Acute oral toxicity, Similarity to guideline unknown GLP: not specified Reliability (REACH registration): 3 Reliability (this assessment): 3	not specified	Ethyl acrylate Source: No information Purity: No information	No information on dose groups Single application via gavage Vehicle: polyethylene glycol, no further information 7 days observation time	1020 mg/kg bw No information on mortalities	Paulet and Vidal (1975) [Study 011 in REACH registration]
Acute oral toxicity, Not similar to guideline GLP: no Reliability (REACH registration): - Reliability (this assessment): 3	specified	Ethyl acrylate Source: Rohm and Haas No information on purity	Single dose: 2000 mg/kg bw Single application via gavage Vehicle: 10% in corn oil Observation time: No information	> 2000 mg/kg bw Mortalities: 2000 mg/kg bw: 0/2	Dow Chemical Company (1986)
Acute oral toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 3	Cat, strain not specified, sex not specified 1 animals per dose group	Ethyl acrylate Source: No information Purity: No information	184, 368 and 736 mg/kg bw Single application via gavage Vehicle: aqueous emulsion in traganth (10% and 20%, respectively), no further information 8 days observation time	> 736 mg/kg bw Mortalities: No mortality occurred at either dose level.	BASF AG (1960) in (OECD, 2005) [Study 013 in REACH registration]
Acute oral toxicity, Similarity to guideline unknown GLP: not	information	Ethyl acrylate Source: no information Purity: no information	No information on dose groups No information on vehicle No information on post exposure	800 mg/kg bw No information on mortalities	Sobczak and Baranski (1979) [Study 012 in REACH

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD50	Reference
specified Reliability (REACH registration): 4 Reliability (this assessment): 4 (no translation available)			observation time		registration]
Acute oral toxicity, no further information Reliability (this assessment): 4	No information	Ethyl acrylate Source: no information Purity: no information	No information	2080 mg/kg bw No information on mortalities	Secondary source: Union Carbide (1971) in (IARC, 1979)

10.1.1 Short summary and overall relevance of the provided information on acute oral toxicity

No GLP-conform guideline study is available. Among the available studies, one study in rats stands out regarding reliability (RL 2) and adequacy as basis for classification (Rohm and Haas Company (1984) in OECD (2005), key study in the REACH registration). This study determined an LD₅₀ of 1120 mg/kg bw. NTP investigated the acute toxicity of ethyl acrylate in rats and mice. The studies did not identify a LD₅₀ within the tested concentration range, thus can not be used for classification directly. However the highest tested concentration in rats (900 mg/kw bw with 1/10 deaths) provides a reliable lower bound for the LD₅₀ (NTP, 1986). Several other studies have been performed in rodents with sufficient dose groups and group sizes, primarily limited in reliability by lacking characterization of test item purity. The LD₅₀ range of these studies is 461 - 1800 mg/kg bw. If studies with more deviations from guideline criteria and studies that are only reported without experimental details in secondary sources are considered as well, the range of LD₅₀ values extends to > 184 to 2800 mg/kg bw and comprises various species.

No human studies with relevance for comparison with the classification criteria are available.

10.1.2 Comparison with the CLP criteria

According to Table 3.1.1 of Regulation (EC) No. 1272/2008 a substance shall be classified as

- Acute Tox 4 (oral) if the LD₅₀/ATE values are > 300 and ≤ 2000 mg/kg bw.
- Acute Tox 3 (oral) if the LD₅₀/ATE values are > 50 and ≤ 300 mg/kg bw.

No GLP-conform guideline study is available. The most appropriate study for classification (Rohm and Haas Company (1984) in OECD, 2005) corresponds to category 4 (LD₅₀: 1120 mg/kg bw). This classification is supported by a large body of studies with slightly lower reliability. Further, two studies of limited reliability

report a lower bound of possible LD_{50} which falls into the boundaries of category 3. Due to the significantly lower quality of these studies, this is not a reason to deviate from category 4.

10.1.3 Conclusion on classification and labelling for acute oral toxicity

Based on the criteria for classification in Regulation (EC) No. 1272/2008, ethyl acrylate has to be classified in category 4 for acute oral toxicity (Acute Tox 4, H302).

Based on the most appropriate study for comparison with the classification criteria, an ATE value of 1120 mg/kg bw is indicated.

10.2 Acute toxicity - dermal route

Table 11: Summary table of animal studies on acute dermal toxicity

3.6 (1 1	g ·	TD 4 1 4	D 1 1	T 7 1	D C
Method, guideline,	Species, strain, sex, no/group	Test substance,	Dose levels duration of	Value LD ₅₀	Reference
deviations if any	sex, no/group		exposure of	LD50	
Acute dermal toxicity, Comparable to OECD 402 GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 2	Rat, CD, male only, 6 males per dose group	Ethyl acrylate No information on source Purity: 99%	2000, 2514, 3162, 3976 and 5000 mg/kg bw Occlusive application 24 h exposure 14 d observation	3049 mg/kg bw (95% CI: 2300-3846) Mortalities: 5000: 5/6 3976: 5/6 3162: 3/6 2514: 3/6 2000: 0/6	Rohm and Haas Company (Testing Facility) (1986a) in (OECD, 2005) [Study 001 in REACH registration]
Acute dermal toxicity, Similar to OECD 402 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2	Mouse, CD-1 6 males per dose group	Ethyl acrylate No information on source, Batch No: 070381 Purity: 99%	2400, 3200 and 4000 mg/kg bw Occlusive application 24 h exposure 14 d observation	2997 mg/kg bw (95% CI: 2419 - 3609) Mortalities: 2400 mg/kg bw: 1/6 3200 mg/kg bw: 3/6 4000 mg/kg bw: 6/6	Rohm and Haas Company (Testing Facility) (1986) in (OECD, 2005) [Study 007 in REACH registration]
Acute dermal toxicity, Similar to OECD 402	Rabbit, strain not specified 10 animals per dose group	Ethyl acrylate Commercial grade equivalent to product on open market	1580, 2000 and 2520 mg/kg bw Occlusive application	1800 mg/kg bw (95% CI: 1647 - 1950) Converted using a density of 0.92	Pozzani et al. (1949) [Study 005 in REACH

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Value LD ₅₀	Reference
GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2 Acute dermal toxicity, Not similar to guideline GLP: no Reliability	Rat, Charles River (CD), male only 4 animals per dose group	No information on source Ethyl acrylate No information on source Purity: 99%	24 h exposure 14 d observation Only dose: 5000 mg/kg bw Non-Occlusive application 24 h exposure 14 d observation	g/mL Mortalities: 1580 mg/kg bw: 1/10 2000 mg/kg bw: 5/10 2520 mg/kg bw: 10/10 > 5000 mg/kg bw Mortalities: 5000 mg/kg bw: 0/6	Rohm and Haas Company (Testing Facility) (1986d) in (OECD, 2005) [Study 002 in REACH
toxicity, Not similar to guideline (Limit test) GLP: no Reliability (REACH registration): 2	Mouse, CD-1 6 males per dose group	Ethyl acrylate No information on source Purity: 99% Batch No: 070381	Only dose: 5000 mg/kg bw Non-occlusive application 24 h exposure 14 d observation	> 5000 mg/kg bw No mortalities at limit dose	Rohm and Haas Company (Testing Facility) (1986d) in (OECD, 2005) [Study 008 in REACH registration]
Reliability (this assessment): 3 Acute dermal toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 3	Rat, no further information 1 male and 4 females per dose group	Ethyl acrylate No information on source No information on purity	Single dose: 1840 mg/animal Non-occlusive application, but animals placed in a tub with substance 4 h exposure 8 d observation	No LD ₅₀ determined Mortalities: 1840 mg/animal: 4/5 animals died	Anonymous (1958b) [Study 009 in REACH registration]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability	Rabbit, no information on strain or sex 2 animals per dose group	Ethyl acrylate No information on source No information on purity	Only dose level: 184 mg/kg bw, reported as 0.2 mL/kg bw Occlusive application	> 184 mg/kg bw Mortalities:	Anonymous (1958c) [Study 004 in REACH registration]

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of	Value LD50	Reference
(REACH registration): 2 Reliability (this assessment): 3			24 h exposure 14 d observation	184 mg/kg bw: 0/2	
Acute dermal toxicity, Similar to OECD 402 GLP: not specified Reliability (REACH registration): 2 Reliability (this assessment): 3 Acute dermal toxicity,	Rabbit, strain not specified Group size not explicitly stated, 6-10 animals per dose implied Rabbit, no further information No information on group size	Ethyl acrylate No information on source No information on purity Ethyl acrylate No information on source No information on purity	Dose range 0.53 – 1.80 g/kg bw, progression by coefficient 1.5 (4 dose groups implied) Occlusive application 24 h exposure 14 d observation Repeated application of 3-5 mL Occlusive application 2 to 6 h exposure Observation time not specified	LD ₅₀ not specified Lowest dose with mortality: 1200 mg/kg bw no CI given Mortalities: no information No LD ₅₀ determined Mortalities: 3 or 24 applications with a total dose of 5.4 – 40.7 g/kg were survived 30 or 38 applications with a total dose of 49.8 – 69.1 g/kg were lethal for all animals	Czajkowska (1981) (Sokal et al., 1980) [Study 006 in REACH registration] Treon et al. (1949) [Study 010 in REACH registration]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (this assessment): 3	Rabbit, male albino 2 or 4 animals per dose group	Test substance identity unclear: could be formulation Source: Union Carbide, South Charleston, "Taft-Product" Reg #511-01-1811, Batch No. 03661 No information on purity	0.25, 0.5, 1.0, 4.0 mL/kg Occlusive application 24 h exposure Observation time not specified, but all deaths occurred within 2 days	460 mg/kg bw (95% CI: 290 – 750) reported as 0.50 mL/kg bw (95% CI: 0.314 – 0.816) and converted with a density of 0.92 g/mL Mortalities: 0.25 ml/kg bw: 0/4 0.5 ml/kg bw: 2/4	Union Carbide Corporation (1989)

Method, guideline,	Species, strain, sex, no/group	Test substance,	Dose levels duration of	Value LD ₅₀	Reference
deviations if any	sex, norgroup		exposure	11030	
			•	1.0 ml/kg bw: 4/4	
				4.0 ml/kg bw: 2/2	
Acute dermal toxicity,	Rabbit, male albino	Test substance identity unclear:	0.5, 1.0 mL/kg bw	580 mg/kg bw (95% CI: 355 –	Union Carbide Corporation (1989)
Not similar to guideline	4 animals per dose group	could be formulation	Occlusive application	947) reported as	
GLP: no		Source: Union Carbide, South	24 h exposure	0.63 mL/kg bw	
Reliability (this assessment): 3		Charleston, Reg #511-01-0560, Batch No. 06024 No information on purity	Observation time not specified, but all deaths occurred within 1 day	(95% CI: 0.386 – 1.03) and converted with a density of 0.92 g/mL	
				Mortalities:	
				0.5 mL/kg bw: 1/4	
				1.0 mL/kg bw: 4/4	
Acute dermal toxicity,	Rabbit, strain and sex not specified	Ethyl acrylate Source: Rohm	126 & 252 mg/kg bw	> 126 & < 252 mg/kg bw	Dow Chemical Company (1986)
Not similar to	2 animals per	and Haas	No information	Mortalities:	
guideline	dose	No information	on exposure	126 mg: 0/2	
GLP: no		on purity	duration	252 mg: 2/2	
Reliability (this assessment): 3			Application as 12.6% in Dowanol 50B	202 mg. 212	
			No information on occlusion		
			No information on observation time		
Acute dermal	No information	Ethyl acrylate	No information	1950 mg/kg bw	Secondary source:
toxicity,		No further		No further	Union Carbide
No further information		information		information	(1971) (in IARC, 1979)
Reliability (this assessment): 4					

10.2.1 Short summary and overall relevance of the provided information on acute dermal toxicity

A GLP-conform study, closely following the guideline criteria on rats is available. The LD_{50} of this study was 3049 mg/kg bw (95% CI: 2300 - 3846 mg/kg bw (Rohm and Haas Company (Testing Facility) (1986a) in OECD, 2005)). A study on mice, not according to GLP, but still of adequate reliability, determined a LD_{50} of

2997 mg/kg bw (95% CI: 2419 - 3609 mg/kg bw, Rohm and Haas Company (Testing Facility) (1986b) in OECD (2005)). Pozzani et al. (1949) report a LD₅₀ of 1800 mg/kg bw in rabbits. This study does not analytically determine the purity of the test substance, however the test substance is stated to be the usual commercial grade from the open market. Otherwise, the study adheres to the principles of the OECD Guideline for acute dermal toxicity, therefore it is deemed relevant for classification. Further studies are available, but often used non-occlusive application or application methods significantly deviating from guideline methods. Among the unreliable studies, two studies on rabbits by Union Carbide (Union Carbide Corporation, 1989) merit explicit discussion. These studies determined LD₅₀ which correspond to a stricter toxicity category (460 - 580 mg/kg bw), yet they contain an ambiguous test substance description ("taft product") that leaves doubts whether the tested substance might have been a formulation.

No human studies with relevance for comparison with the criteria in Regulation (EC) No. 1272/2008 are available.

10.2.2 Comparison with the CLP criteria

According to Table 3.1.1 of regulation (EC) No. 1272/2008 a substance shall be classified as

- Acute Tox 4 (dermal) if the LD₅₀/ATE values are > 1000 and ≤ 2000 mg/kg bw
- Acute Tox 3 (dermal) if the LD₅₀/ATE values are $> 200 \le 1000$ mg/kg bw.

No GLP-conform guideline study is available. Two studies of good quality determined LD $_{50}$ of 2997 mg/kg bw (in mice) and 3049 mg/kg bw (in rats). Pozzani et al. (1949) report a LD $_{50}$ of 1800 mg/kg bw in rabbits. Although the rabbit study is of lower quality than these two studies on rodents, it is still considered of sufficient reliability to be used for classification. According to the Regulation (EC) No. 1272/2008, both rats and rabbits are the preferred species for classification of dermal toxicity and in case experimental data is available for several species, the most appropriate LD $_{50}$ shall be chosen among valid test results. Although the rodent studies are of better quality and it is acknowledged that these studies correspond to non-classification according to the classification criteria, the study with rabbits indicates a potentially higher sensitivity of rabbits. Therefore, it is inappropriate to dismiss the lower LD $_{50}$ obtained in rabbits. On the other hand, the results reported in the studies with the unclear test substance identity (Union Carbide Corporation, 1989) are not considered reliable enough to be used for classification. Therefore a classification is proposed based on the study results on rabbits by Pozzani et al. (1949), which correspond to category 4.

10.2.3 Conclusion on classification and labelling for acute dermal toxicity

Based on the criteria for classification in Regulation (EC) No. 1272/2008, ethyl acrylate has to be classified in category 4 for acute dermal toxicity (Acute Tox. 4, H312).

Based on the LD_{50} used for classification an ATE value of 1800 mg/kg bw is indicated.

10.3 Acute toxicity - inhalation route

Table 12: Summary table of animal studies on acute inhalation toxicity

Acute inhalation (Rat, Sprague-Dawley) Acute inhalation (Rat, Sprague-Dawley) Similar to OECD 403 GLP: no Reliability (Risassessment): 2 Acute inhalation toxicity, Dawley Acute inhalation (Rat, Sprague-Dawley) Acute inhalation (Rat, Sprague-Dawley, males sessment): 2 Acute inhalation (Rat, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation (Rat, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation (Rat, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation (Rat, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Dawley, males and fermales to OECD 403 Acute inhalation (Rat, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Sprague-Dawley, males and fermales to OECD 403 Acute inhalation toxicity, Sprague-Dawley, Male/Temale ratio not specified (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ratio not specified (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ratio not specified (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ration (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ration (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ration (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Male/Temale ration (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Metalities (MEHQ, 14 ppm), water (0.03%) Acute inhalation toxicity, Sprague-Dawley, Metalities (MEHQ, 14 ppm), Metalities (MEHQ, 14 ppm), Metalities (MEHQ	Method,	Species, strain,	Test substance, ,	Dose levels,	Value	Reference
Acute inhalation Coxicity, Darticle size Coxicity, Dawley Dawley Coxicity, Dawley	guideline,	_	form and	duration of		
Acute inhalation toxicity, Similar to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation to OECD 403 (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation Rat, strain not specified Acute inhalation Rat, strain and sex Ethyl acrylate, as stabilizer Reliability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassibilizer sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as sassessment): 4 (A may spost exposure observation and sex exposure whole body inhalation specified and sassessment): 4 (A may spost exposure observation and sex exposure whole body inhalation specified and specified a	deviations if any			exposure	LCsu	
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GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation toxicity,		-	•	•	9	REACH
Reliability (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation toxicity, Dawley, males and females OteCD 403 5 animals per dose group GLE whole body male/female ratio not specified on toxicity, water (0.03%) Reliability (this assessment): 2 Reliability (REACH registration): 2 Reliability (REACH assessment): 2 Reliability (REACH registration): 2 Reliability (this assessment): 3 Ro LCso determined) Rat, strain and sex Ethyl acrylate, as vapour observation observation observation on the properties observation observation on the properties observation observation on the properties observation on the properties observation on the properties observation o	GLP: no		Chemical Co.,	· r · · · · ,		registration]
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Acute inhalation toxicity, Equivalent to OECD 403 GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 2 Route inhalation toxicity, No guideline followed GlDP: no guideline followed (REACH registration): 2 Reliability (this assessment): 2 Reliability (REACH registration): 3 Reliability (REACH registration): 4 Reliability (REACH registration): 5 Reli						
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toxicity, Equivalent to OECD 403 GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 2 Rough inhalation toxicity, No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (REACH registration): 3 Reliability (REACH registration): 4 REACH registration] REACH registration] Solver and (A.1 mg/L) Mortalities 1.2 mg/L: 0/6 2.0 mg/L: 0/6 3.1 mg/L: 0/6 4.1 mg/L: 0/6 6.1 mg/L: 1/6 Reliability (REACH registration) REACH registration] Reliability (REACH registration) REACH registration] Reliability (REACH registration) REACH registration] Reliability (REACH registration) Reliability (REACH registration) Reliability (REACH registration) Reliability (REACH registration						
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Equivalent to OECD 403 OECD 404 OECD 404 OECD 404 OECD 405 OECD 405 OECD 404 OECD 40		, 1 0			25.8 mg/L	
Equivalent to OECD 403 GLP: yes Reliability (this assessment): 2 Reliability (prior toxicity, negliability (prior toxicity) (prior	,	•	-		,	` ´ ´
GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 2 Acute inhalation followed GLP: no Reliability (REACH registration): 2 Reliability (REACH registration): 2 Reliability (this assessment): 2 Reliability (this assessment): 2 Acute inhalation followed GLP: no Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Reliability (this assessment): 3 Reliability (this assessment): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Rat, strain not specified Source: Union Carbide, Hahntown, LA 1.4 days post exposure observation Source: Union Carbide, Hahntown, LA 1.4 days post exposure observation 1.4 days post exposure observation Source: Union Carbide, Hahntown, LA 1.2, 2.0, 3.1, 4.1 and 6.1 mg/L Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Methoxyphenole (MEHQ, 14 ppm), water (0.03%) Source: Union Carbide, Hahntown, LA 1.2, 2.0, 3.1, 4.1 and 6.1 mg/L Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Methoxyphenole (MEHQ, 14 ppm), water (0.03%) Source: Union Carbide, Hahntown, LA Acute inhalation Rat, strain and sex Brupirties: inhibitor Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Acute inhalation Acute inhalation Acute inhalation Rat, strain and sex Brupirties: inhibitor Acute inhalation Acute in	-		•		30.6 mg/L)	
Reliability (REACH registration): 2 Reliability (this assessment): 2 Reliability (this assessment): 2 Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (this assessment): 3 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (REACH registration): 2 Reliability (REACH registration): 3 Reliability (REACH registration): 3 Reliability (REACH registration): 4 Revposure observation observation Revosure observation Revosure value (REACH registration): 3 Recipied (REACH registration): 4 Revposure value (REACH registration): 5 Revosure observation Revosure observation Revosure value (REACH registration): 5 Revosure observation Revosure value (REACH registration): 6 Revosure observation Revosure value (REACH registration): 7 Revosure value (REACH registrat		1		•		
REACH registration): 2 Reliability (this assessment): 2 Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Rat, strain not specified vapour assessment): 3 Rat, strain not specified vapour and 6.1 mg/L Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3	,	Male/female ratio			Mortalities	
Reliability (this assessment): 2 Rat, strain not toxicity, No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Rat, strain not specified Rat, strain not specified Purity: 98.5% Impurities: hydroquinone monomethyl ether as stabilizer Source: Union Carbide, Hahntown, LA Source: Union Carbide, Hahntown, LA Silver and Murphy (1981) Mortalities (analytical) Post exposure observation not specified 3.1 mg/L: 0/6 3.1 mg/L: 0/6 4.1 mg/L: 0/6 6.1 mg/L: 1/6 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 > 4.1 & < 8.2 Pozzani et al.		not specified	(MEHQ, 14 ppm),	observation	23.2 mg/L: 2/5	
Acute inhalation toxicity, No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Rat, strain not specified Rat, strain not specified Purity: 98.5% Impurities: hydroquinone monomethyl ether as stabilizer No information Rat, strain not strain not vapour Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 and 6.1 mg/L (analytical) A h exposure, whole body Post exposure observation not specified 1.2 mg/L: 0/6 3.1 mg/L: 0/6 4.1 mg/L: 0/6 6.1 mg/L: 1/6 Acute inhalation Rat, strain and sex Rehability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation	registration): 2		water (0.03%)		29.5 mg/L: 3/5	
Acute inhalation toxicity, Rat, strain not specified No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Rat, strain not specified Rat, strain not specified Vapour Bethyl acrylate, as vapour and 6.1 mg/L (analytical) (analytical) Acute inhalation Mortalities (analytical) Mortalities (analytical) Acute inhalation Mortalities (analytical) Acute inhalation Mortalities (analytical) Acute inhalation Acute inhalation Rat, strain and sex Rat, strain and sex Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 (analytical) Acute inhalation Mortalities (analytical) Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 Acute inhalation Rat, strain and sex Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 1.2, 2.0, 3.1, 4.1 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Acute inhalation	• ,				35.3 mg/L: 5/5	
Acute inhalation toxicity, No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Rat, strain not specified Rat, strain not specified Purity: 98.5% Purity: 98.5% Impurities: hydroquinone monomethyl ether as stabilizer Silver and Murphy (1981) Mortalities 1.2 mg/L: 0/6 2.0 mg/L: 0/6 3.1 mg/L: 0/6 4.1 mg/L: 0/6 6.1 mg/L: 1/6 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 Acute inhalation	assessment): 2		*			
toxicity, specified vapour and 6.1 mg/L No guideline followed group Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Acute inhalation Ro guideline followed group Specified vapour and 6.1 mg/L (analytical) Impurities: 4 h exposure, whole body Post exposure observation not specified Mortalities 1.2 mg/L: 0/6 2.0 mg/L: 0/6 3.1 mg/L: 0/6 4.1 mg/L: 1/6 Mortalities 1.2 mg/L: 0/6 3.1 mg/L: 0/6 6.1 mg/L: 1/6 Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 > 4.1 & < 8.2 Pozzani et al.	Acute inhalation	Rat strain not		12 20 31 41	> 6.1 mg/I	Silver and
followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 A mortaintes whole body whole body post exposure observation not specified REACH registration] REACH registration] REACH registration] 1.2 mg/L: 0/6 2.0 mg/L: 0/6 4.1 mg/L: 0/6 6.1 mg/L: 1/6					> 0.1 mg/L	
GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3		6 males per dose	Purity: 98.5%	(analytical)	Mortalities	
Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined) Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC ₅₀ determined)	followed	group	Impurities:	4 h exposure,		-
Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC_{50} determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 $> 4.1 \& < 8.2$ Pozzani et al.	GLP: no			whole body		registrations
registration): 2 Reliability (this assessment): 3 (No LC_{50} determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 $> 4.1 \& < 8.2$ Pozzani et al.						
Reliability (this assessment): 3 (No LC_{50} determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 $> 4.1 \& < 8.2$ Pozzani et al.			Source: No			
assessment): 3 (No LC_{50} determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 $>$ 4.1 & < 8.2 Pozzani et al.				•		
determined) Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 > 4.1 & < 8.2 Pozzani et al.	assessment): 3				6.1 mg/L: 1/6	
Acute inhalation Rat, strain and sex Ethyl acrylate, as 4.1, 8.2 and 16.3 > 4.1 & < 8.2 Pozzani et al.						
	·	Pat strain and say	Ethyl acrylete es	11 82 and 162	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Pozzani et al
toxicity, not specified vapour mg/L (nominal) mg/L (1949)	toxicity,			· ·		
similar to OECD 6 animals per Purity: No 4h exposure,		-	-			
dose group information whole body Mortalities [Study 009 in		dose group			Mortalities	[Study 009 in
GLP: no Source: No Post exposure REACH	GLP: no		Source: No	Post exposure		

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, , form and particle size (MMAD)	Dose levels, duration of exposure	Value LC ₅₀	Reference
Reliability (REACH registration): 2 Reliability (this assessment): 3		information	observation not specified	4.1 mg/L: 0/6 8.2 mg/L: 5/6 16.3 mg/L: 6/6	registration]
Acute inhalation toxicity, Similar to OECD 403 GLP: yes Reliability (REACH registration): 1, key study Reliability (this assessment): 3	Rat, Wistar 5 males and 5 females per dose group	Ethyl acrylate, as vapour Purity: 99.94 % Source: No information Batch: 011577eda0	Only 1 dose: 9.137 mg/L 4 h exposure, head only 14 days post exposure observation	< 9.137 mg/L Mortalities m 4/5, f 2/5	Anonymous (2012) [Study 001 in REACH registration]
Acute inhalation toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rabbit, strain not specified, sex not specified 4 animals per dose	Ethyl acrylate, as vapour Purity: No information Source: No information	Single dose 4.83 mg/L (analytical) 7 h exposure Post exposure observation not specified, all animals died	< 4.83 mg/L LC100 = 4.83 mg/L	Treon et al. (1949) [Study 010 in REACH registration]
Acute inhalation toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Guinea pig, strain not specified, sex not specified 2 animals per dose	Ethyl acrylate, as vapour Purity: No information Source: No information	Single dose 4.83 mg/L (analytical) 7 h exposure Post exposure observation not specified, all animals died	< 4.83 mg/L LC100 = 4.83 mg/L	Treon et al. (1949) [Study 011 in REACH registration]
Acute inhalation toxicity, similar to OECD 403 GLP: yes Reliability (REACH registration): 2	Monkey, strain not specified, males/females 3 animals per dose group		75.68 ppm, corresponding to 0.31 mg/L 3 h and 6 h exposure, head only Post exposure time not specified	No mortalities after 3 h and 6 h exposure to 0.31 mg/L	Anonymous (1995) [Study 003 in in REACH registration]

Method, guideline,	Species, strain, sex, no/group	Test substance, , form and	Dose levels, duration of	Value LC ₅₀	Reference
deviations if any		particle size (MMAD)	exposure	2030	
Reliability (this assessment): 3					
Acute inhalation toxicity, similar to OECD 403 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	specified, males and females 3 animals per dose group, sex ratio not specified	Ethyl acrylate, as vapour Purity: No information Source: No information	body Post exposure observation not specified	Mortalities 4 min: 0/6 8 min: 2/6 15 min: 6/6 30 min: 6/6	Anonymous (1958d) [Study 008 in REACH registration]
Acute inhalation toxicity, No information on guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 3	Rats, no information on strain and sex 6 animals per dose	Ethyl acrylate, as vapour Purity: No information Source: No information	4.1 and 16.4 mg/L 4 h exposure No information on post exposure observation	5.8 mg/L mortalities 4.1 mg/L: 0/4 16.4 mg/L: 4/4	Anonymous (1989b) [Study 014 in REACH registration]
Acute inhalation toxicity, No information on guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 4 (no translation available)	Rats, no information of strain and sex No information on group sizes	vapour Purity: No information	No information on dose levels No information on exposure No information on post exposure observation	7.4 mg/L No information on mortalities	Lomonova and Klimova (1979) [Study 012 in REACH registration]
Acute inhalation toxicity, No information on guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 4 (no translation	mice, no information of strain and sex No information on group sizes	Ethyl acrylate, as vapour Purity: No information Source: No information	No information on dose levels No information on exposure No information on post exposure observation	16 mg/L No information on mortalities	Lomonova and Klimova (1979) [Study 013 in REACH registration]

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, , form and particle size (MMAD)	Dose levels, duration of exposure	Value LC ₅₀	Reference
available)					
Acute inhalation toxicity, Not similar to guideline GLP: no Reliability (this assessment): 4 (no translation available)	sex not specified	Ethyl acrylate, no further information	0.025, 0.05, 0.1, 0.5 mg/L No information on exposure No information post exposure observation	LC ₅₀ not determined Mortalities 0.025 mg/L: 2/4 0.05 mg/L: 4/7 0.1 mg/L: 7/10 0.5 mg/L: 6/15	Gabor et al. (1962)

10.3.1 Short summary and overall relevance of the provided information on acute inhalation toxicity

A GLP-conform guideline study is reported as key study in the REACH dossier, however only a single concentration level has been reported (Study 001 in ECHA (2019)). At 9.137 mg/L, 4/5 male and 3/5 female rats died, giving a strong indication that the LC₅₀ is < 9.137 mg/L. Yet the study can't be used as a basis for classification because of a missing lower bound of toxicity. The confidential information in the registration dossier has been checked to confirm that no information on additional concentration levels is available.

In addition, two inhalation studies in rats of adequate reliability with 4 h (Oberly and Tansy, 1985) and 1 h exposure (Study 002 in ECHA (2019)) are available. Oberly and Tansy (1985) report an LC_{50} of 9 mg/L (7.7 – 10.5 mg/L). The LC_{50} obtained after 1 h exposure has to be multiplied with a factor of 0.5 (for vapours) to be comparable with the criteria in Regulation (EC) No 1272/2008. After conversion, the study (Study 002 in ECHA (2019)) determines a 4 h LC_{50} of 12.9 mg/L. A further study (Silver and Murphy, 1981) did not test a sufficiently high concentration to determine a LC_{50} , but provides an indication for the lower bound of the LC_{50} , with only 1/6 deaths at 4 h exposure of 6.1 mg/L. Several studies of lower reliability determined LC_{50} concentrations in the range of 4.1 – 16 mg/kg bw.

No human studies with relevance for comparison with the classification criteria are available.

10.3.2 Comparison with the CLP criteria

According to Table 3.1.1 of Regulation (EC) No. 1272/2008 a substance shall be classified as

- Acute Tox. 4 (inhalation) if the LC₅₀ values are > 10.0 mg/L and ≤ 20.0 mg/L (4h exposure)
- Acute Tox. 3 (inhalation) if the LC₅₀ values are > 2.0 mg/L and $\le 10.0 \text{ mg/L}$ (4h exposure)

Because of the study on rats with an LC₅₀ of 9 mg/L, supported by the GLP-conform study, which determined a LC₅₀ < 9.137 mg/L, and a study indicating a LC₅₀ > 6.1 mg/L, ethyl acrylate has to be classified in category 3 for acute inhalative toxicity (Acute Tox. 3, H 331). The 1 h study which, after application of

the conversion factor to compare with 4 h exposures, corresponds to category 4 (12.9 mg/L) is not a reason to deviate from category 3, as the shorter exposure duration increases the uncertainty of the obtained value. The studies with lower reliability predominantly support a classification in category 3.

10.3.3 Conclusion on classification and labelling for acute inhalation toxicity

According to the criteria for classification in Regulation (EC) No. 1272/2008, ethyl acrylate has to be classified in category 3 for acute inhalative toxicity (Acute Tox. 3, H 331).

Based on the lowest LC₅₀ used for classification, an ATE value of 9 mg/L (vapours) is indicated.

10.4 Skin corrosion/irritation

Evaluation not performed for this substance.

10.5 Serious eye damage/eye irritation

Evaluation not performed for this substance.

10.6 Respiratory sensitisation

Evaluation not performed for this substance.

10.7 Skin sensitisation

Evaluation not performed for this substance.

10.8 Germ cell mutagenicity

Evaluation not performed for this substance.

10.9 Carcinogenicity

Evaluation not performed for this substance.

10.10 Reproductive toxicity

Evaluation not performed for this substance.

10.11 Specific target organ toxicity-single exposure

Evaluation not performed for this substance.

10.12 Specific target organ toxicity-repeated exposure

Evaluation not performed for this substance.

10.13 Aspiration hazard

Evaluation not performed for this substance.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

Evaluation not performed for this substance.

12 EVALUATION OF ADDITIONAL HAZARDS

Evaluation not performed for this substance.

13 ADDITIONAL LABELLING

Not applicable for this evaluation.

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