Committee for Risk Assessment

RAC

Annex 1

Background document

to the Opinion proposing harmonised classification and labelling at EU level of

Ethyl acrylate

EC Number: 205-438-8
CAS Number: 140-88-5

CLH-O-0000006958-55-01/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

18 March 2021

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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Version number: 01 **Date: December 2019**

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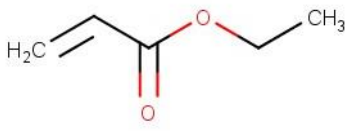
ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON ETHYL ACRYLATE

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 international chemical name(s)	Ethyl prop-2-enoate
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	
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 multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
Ethyl acrylate EC 205-438-8 CAS 140-88-5	Not applicable	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 ≥ 5 % Skin Sen. 1 (H317) STOT SE 3 (H335), C ≥ 5 % Note D	Flam. Liq. 2 (H225) Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 3 (H331) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Skin Sen. 1 (H317) STOT SE 3 (H335)

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

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and 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/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	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)	Other information	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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	Flam. Liq. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Skin Irrit. 2 Eye Irrit. 2 Skin Sen. 1 STOT SE 3	H225 H302 H312 H332 H315 H319 H317 H335	GHS02 GHS07 Dgr	H225 H302 H312 H332 H315 H319 H317 H335		Eye Irrit. 2; H319: C ≥ 5 % STOT SE 3; H335: C ≥ 5 % Skin Irrit. 2; H315: C ≥ 5 %	Note D
Dossier submitters proposal	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	**Modify** Acute Tox. 4 Acute Tox. 4 Acute Tox. 3 **Retain** Flam. Liq. 2 Skin Irrit. 2 Eye Irrit. 2 Skin Sen. 1 STOT SE 3	**Modify** H302 H312 H331 **Retain** H225 H315 H319 H317 H335	**Modify** GHS06 **Retain** GHS02 Dgr	**Modify** H302 H312 H331 **Retain** H225 H315 H319 H317 H335		**Add** Oral: ATE = 1120 mg/kg bw Dermal: ATE = 1800 mg/kg bw Inhalation: ATE = 9 mg/L (vapours) **Retain** Eye Irrit. 2; H319: C ≥ 5 % STOT SE 3;	**Retain** Note D

										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. 4 Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sen. 1 STOT SE 3	H225 H302 H312 H331 H315 H319 H317 H335	GHS02 GHS06 Dgr	H225 H302 H311 H332 H315 H319 H317 H335		Oral: ATE = 1120 mg/kg bw Dermal: ATE = 1800 mg/kg bw Inhalation: ATE = 9 mg/L (vapours) Eye Irrit. 2; H319: C ≥ 5 % STOT SE 3; H335: C ≥ 5 % Skin Irrit. 2; H315: C ≥ 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-repeated exposure	hazard class not assessed in this dossier	No
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 ≥ 5 %
Skin Sen. 1, H317
STOT SE 3, H335, C ≥ 5 %
Note D[1]

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.

H412	Harmful to aquatic life with long lasting effects	53.6

RAC general comment
Ethyl acrylate is manufactured and/or imported in Europe in a quantity of 100000 to 1000000 tonnes per year. It is used in the manufacture of paints, textiles, non-woven fibres and in formulation or repacking.

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

6 DATA SOURCES

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

- U.S. National Library of Medicine, Pubmed.gov[2]
- TOXNET[3], ChemID*plus*[4], IPCS[5], eChemPortal[6], EPA Comptox Dashboard[7], EPA Chemview[8]
- Chemical Abstracts, Medline, Biosis, Embase, SciSearch, PQScitech (at host STN International Europe[9])

[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

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 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/cm³	(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 °C	(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

Property	Value	Reference	Comment
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 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2	Rat, CRCD, male only 10 males per dose group	Ethyl acrylate Source: No information Purity: 99 %	710, 840, 1000, 1190, 1410, 1680, 2000 and 2380 mg/kg bw Single application via gavage Vehicle: Methocel, no further information 14 days observation	1120 mg/kg bw (95% CI: 1010 - 1240) 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	Rohm and Haas Company (1984) in (OECD, 2005) [Study 001 in REACH registration]
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability	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%	554 mg/kg bw Mortalities: 1881: 5/5 1162: 5/5	BASF AG (1958) in (OECD, 2005) [Study 002 in REACH registration]

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			or 0.5% Traganth (conflicting reporting in secondary sources) 7 days observation	732: 3/5 462: 2/5 291: 0/5	
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rat, strain not specified, male only 10 males per dose group	Ethyl acrylate Source: no information Purity: no information	795, 1000, 1260, and 1580 mg/kg bw Single application via gavage Vehicle: 1% "Tergitol" 7 Observation:14 days	1020 mg/kg bw (95% CI: 950 - 1100) Mortalities: 795: 0/10 1000: 4/10 1260: 10/10 1580: 10/10	Pozzani et al. (1949) [Study 005 in REACH registration]
Acute oral toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rat, strain not specified, male and females 1-5 animals / dose, sex ratio not specified, See mortality table for details	Ethyl acrylate Source: no information Purity: Source: no information	18, 73, 291, 461, 731, 1159, 4609 mg/kg bw Single application via gavage 4609 and 1159 mg/kg bw in 20% Olive oil. 1159, 731, 461 and 291 mg/kg bw in 10% Olive oil. 731, 291, 73 and 18 mg/kg bw in 1% distilled water Observation:7 days	461 – 731 mg/kg bw (treatment in 10% olive oil) Mortalities: 20% Olive oil 4609: 2/2 1159: 2/2 10% Olive oil 1159: 3/3 731: 4/5 461: 2/5 291: 0/5 1% Distilled water 731: 0/1 291: 0/1 73: 0/1 18: 0/1	Anonymous (1958a) [Study 003 in REACH registration]
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH	Rat, F344/N, male and female 5 males and 5 females per group	Ethyl acrylate Source: Rohm and Haas (Philadelphia, PA) Batch: 37201 Purity: 99%	55, 10, 225, 450, or 900 mg/ kg bw Single application via gavage Vehicle: aqueous ethanol Observation: 14	> 900 mg/kg bw Mortalities: 900 mg/kg bw: males 1/5, females: 0/5 No other deaths	NTP (1986) [Study 004 in REACH registration]

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance,**	**Dose levels, duration of exposure**	**Value LD_{50}**	**Reference**
registration): 2 Reliability (this assessment): 3 (No LD50 determined)			days	occurred	
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH registration):: 2 Reliability (this assessment): 3 (No LD50 determined)	Mouse, B6C3F1 , male and female 5 males and 5 females per group	Ethyl acrylate Source: Rohm and Haas (Philadelphia, PA) Batch: 37201 Purity: 99%	100, 225, 450, 900 or 1800 mg/ kg bw Single application via gavage Vehicle: aqueous ethanol Observation: 14 days	900 - 1800 mg/kg bw Mortalities: 1800: 4/5 males, 3/5 females No other deaths occurred	NTP (1986) [Study 006 in REACH registration]
Acute oral toxicity, Comparable to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Mouse, CF1, male only 5 animals per dose group	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	1800 mg/kg bw Mortalities: 1000: male: 0/5, female: 0/5 1400: male: 0/5, female: 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	Rabbit, strain and sex not specified 2 animals per dose group	Ethyl acrylate Source: No information Purity: No	184, 368 and 736 mg/kg bw Single application via gavage Vehicle: aqueous	> 184 - <= 368 mg/kg bw Mortalities: 184: 0/2	BASF AG (1960) in (OECD, 2005) [Study 009 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): 3		information	emulsion in traganth (10% or 20%), without further specification 8 days observation time	368: 1/2 736: 2/2	registration]
Acute oral toxicity, Similar to OECD 401 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Mouse, ddY, male only 4 animals per dose group	Ethyl acrylate Source: No information Purity: no information	4 dose levels, no further information Single application via gavage Vehicle: No information Observation time: no information	1800 mg/kg bw (95% CI: 1228 - 2638) No information on mortalities	Tanii and Hashimoto (1982) [Study 010 in REACH registration]
Acute oral toxicity, Similarity to guideline unknown GLP: not specified Reliability (REACH registration): 3 Reliability (this assessment): 3	Rat, Wistar, sex not specified No information on group size	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	Rat, strain not specified 2 animals, sex not stated	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	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%,	> 736 mg/kg bw Mortalities: No mortality occurred at either dose level.	BASF AG (1960) in (OECD, 2005) [Study 013 in REACH registration]

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD_{50}	Reference
registration): 3 Reliability (this assessment): 3			respectively), no further information 8 days observation time		
Acute oral toxicity, Similarity to guideline unknown GLP: not specified Reliability (REACH registration): 4 Reliability (this assessment): 4 (no translation available)	Rat, no further information No information on group size	Ethyl acrylate Source: no information Purity: no information	No information on dose groups No information on vehicle No information on post exposure observation time	800 mg/kg bw No information on mortalities	Sobczak and Baranski (1979) [Study 012 in REACH 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 LD_{50} of 1120 mg/kg bw. NTP investigated the acute toxicity of ethyl acrylate in rats and mice. The studies did not identify a LD_{50} 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 LD_{50} (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 LD_{50} 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 LD_{50} 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 LD_{50}/ATE values are > 300 and ≤ 2000 mg/kg bw.
- Acute Tox 3 (oral) if the LD_{50}/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 (LD_{50}: 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

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance,**	**Dose levels duration of exposure**	**Value LD_{50}**	**Reference**
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	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	Rohm and Haas Company (Testing Facility) (1986) in (OECD, 2005) [Study 007 in REACH registration]

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Value LD_{50}	Reference
assessment): 2				3200 mg/kg bw: 3/6 4000 mg/kg bw: 6/6	
Acute dermal toxicity, Similar to OECD 402 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2	Rabbit, strain not specified 10 animals per dose group	Ethyl acrylate Commercial grade equivalent to product on open market No information on source	1580, 2000 and 2520 mg/kg bw Occlusive application 24 h exposure 14 d observation	1800 mg/kg bw (95% CI: 1647 - 1950) Converted using a density of 0.92 g/mL Mortalities: 1580 mg/kg bw: 1/10 2000 mg/kg bw: 5/10 2520 mg/kg bw: 10/10	Pozzani et al. (1949) [Study 005 in REACH registration]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rat, Charles River (CD), male only 4 animals per dose group	Ethyl acrylate No information on source Purity: 99%	Only dose: 5000 mg/kg bw Non-Occlusive application 24 h exposure 14 d observation	> 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 registration]
Acute dermal toxicity, Not similar to guideline (Limit test) GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	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]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability	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	No LD_{50} determined Mortalities:	Anonymous (1958b) [Study 009 in REACH registration]

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance,**	**Dose levels duration of exposure**	**Value LD_{50}**	**Reference**
(REACH registration): 3 Reliability (this assessment): 3			4 h exposure 8 d observation	1840 mg/animal: 4/5 animals died	
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	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 24 h exposure 14 d observation	> 184 mg/kg bw Mortalities: 184 mg/kg bw: 0/2	Anonymous (1958c) [Study 004 in REACH registration]
Acute dermal toxicity, Similar to OECD 402 GLP: not specified Reliability (REACH registration): 2 Reliability (this assessment): 3	Rabbit, strain not specified Group size not explicitly stated, 6-10 animals per dose implied	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	LD_{50} not specified Lowest dose with mortality: 1200 mg/kg bw no CI given Mortalities: no information	Czajkowska (1981) (Sokal et al., 1980) [Study 006 in REACH registration]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 3	Rabbit, no further information No information on group size	Ethyl acrylate No information on source No information on purity	Repeated application of 3-5 mL Occlusive application 2 to 6 h exposure Observation time not specified	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	Treon et al. (1949) [Study 010 in REACH registration]
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (this	Rabbit, male albino 2 or 4 animals per dose group	Test substance identity unclear: could be formulation Source: Union Carbide, South Charleston, „Taft-	0.25, 0.5, 1.0, 4.0 mL/kg Occlusive application 24 h exposure Observation time	460 mg/kg bw (95% CI: 290 – 750) reported as 0.50 mL/kg bw	Union Carbide Corporation (1989)

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance,**	**Dose levels duration of exposure**	**Value LD_{50}**	**Reference**
assessment): 3		Product“ Reg #511-01-1811, Batch No. 03661 No information on purity	not specified, but all deaths occurred within 2 days	(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 1.0 ml/kg bw: 4/4 4.0 ml/kg bw: 2/2	
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (this assessment): 3	Rabbit, male albino 4 animals per dose group	Test substance identity unclear: could be formulation Source: Union Carbide, South Charleston, Reg #511-01-0560, Batch No. 06024 No information on purity	0.5, 1.0 mL/kg bw Occlusive application 24 h exposure Observation time not specified, but all deaths occurred within 1 day	580 mg/kg bw (95% CI: 355 – 947) reported as 0.63 mL/kg bw (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	Union Carbide Corporation (1989)
Acute dermal toxicity, Not similar to guideline GLP: no Reliability (this assessment): 3	Rabbit, strain and sex not specified 2 animals per dose	Ethyl acrylate Source: Rohm and Haas No information on purity	126 & 252 mg/kg bw No information on exposure duration Application as 12.6% in Dowanol 50B No information on occlusion No information on observation time	> 126 & < 252 mg/kg bw Mortalities: 126 mg: 0/2 252 mg: 2/2	Dow Chemical Company (1986)
Acute dermal toxicity, No further	No information	Ethyl acrylate No further	No information	1950 mg/kg bw No further	Secondary source: Union Carbide (1971) (in IARC,

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Value LD_{50}	Reference
information Reliability (this assessment): 4		information		information	1979)

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 LD_{50} 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 LD_{50} 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 LD_{50}/ATE values are > 1000 and ≤ 2000 mg/kg bw**
- **Acute Tox 3 (dermal) if the LD_{50}/ATE values are > 200 ≤ 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

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**
Acute inhalation toxicity, Similar to OECD 403 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 2	Rat, Sprague-Dawley 10 males per dose group	Ethyl acrylate, as vapour Purity: 98-98.5% Source: Aldrich Chemical Co., (Milwaukee, Wis.)	6.3, 8.1, 9.9, 11.4 and 12.3 mg/L (analytically determined) 4 h exposure, whole body 14 days post exposure observation	9 mg/L (95% CI: 7.7 – 10.5 mg/L) Mortalities 6.3 mg/L: 1/10 8.1 mg/L: 6/10 9.9 mg/L: 7/10 11.4 mg/L: 7/10 12.3 mg/L: 9/10	Oberly and Tansy (1985) [Study 004 in REACH registration]
Acute inhalation toxicity, Equivalent to OECD 403 GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 2	Rat, Sprague-Dawley, males and females 5 animals per dose group Male/female ratio not specified	Ethyl acrylate, as vapour Purity: 99.8% Impurities: inhibitor Methoxyphenole (MEHQ, 14 ppm), water (0.03%) Source: Union Carbide, Hahntown, LA	23.2, 29.5 and 35.3 mg/L, 1 h exposure, whole body 14 days post exposure observation	25.8 mg/L (95% CI: 21.7 – 30.6 mg/L) Mortalities 23.2 mg/L: 2/5 29.5 mg/L: 3/5 35.3 mg/L: 5/5	Anonymous (1989) [Study 002 in REACH registration]
Acute inhalation toxicity,	Rat, strain not specified	Ethyl acrylate, as vapour	1.2, 2.0, 3.1, 4.1 and 6.1 mg/L	> 6.1 mg/L	Silver and Murphy (1981)

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**
No guideline followed GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3 (No LC_{50} determined)	6 males per dose group	Purity: 98.5% Impurities: hydroquinone monomethyl ether as stabilizer Source: No information	(analytical) 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: 0/6 6.1 mg/L: 1/6	[Study 005 in REACH registration]
Acute inhalation toxicity, similar to OECD 403 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rat, strain and sex not specified 6 animals per dose group	Ethyl acrylate, as vapour Purity: No information Source: No information	4.1, 8.2 and 16.3 mg/L (nominal) 4h exposure, whole body Post exposure observation not specified	> 4.1 & < 8.2 mg/L Mortalities 4.1 mg/L: 0/6 8.2 mg/L: 5/6 16.3 mg/L: 6/6	Pozzani et al. (1949) [Study 009 in REACH 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	Guinea pig, strain not specified, sex not specified 2 animals per	Ethyl acrylate, as vapour Purity: No	Single dose 4.83 mg/L (analytical) 7 h exposure	< 4.83 mg/L LC100 = 4.83 mg/L	Treon et al. (1949)

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**
guideline GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	dose	information Source: No information	Post exposure observation not specified, all animals died		[Study 011 in REACH registration]
Acute inhalation toxicity, similar to OECD 403 GLP: yes Reliability (REACH registration): 2 Reliability (this assessment): 3	Monkey, strain not specified, males/females 3 animals per dose group	Ethyl acrylate, as vapour Purity: No information Source: No information	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]
Acute inhalation toxicity, similar to OECD 403 GLP: no Reliability (REACH registration): 2 Reliability (this assessment): 3	Rats, strain not specified, males and females 3 animals per dose group, sex ratio not specified	Ethyl acrylate, as vapour Purity: No information Source: No information	162 - 175 mg/l 4 – 30 min exposure, whole body Post exposure observation not specified	LC_{50} < 165 mg/L 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	Rats, 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	7.4 mg/L No information on mortalities	Lomonova and Klimova (1979) [Study 012 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**
registration): 3 Reliability (this assessment): 4 (no translation available)					
Acute inhalation toxicity, No information on guideline GLP: no Reliability (REACH registration): 3 Reliability (this assessment): 4 (no translation available)	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]
Acute inhalation toxicity, Not similar to guideline GLP: no Reliability (this assessment): 4 (no translation available)	Mouse, strain and sex not specified 4-15 animals per dose	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 LC_{50} 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 LC_{50} values are > 10.0 mg/L and ≤ 20.0 mg/L (4h exposure)
- Acute Tox. 3 (inhalation) if the LC_{50} values are > 2.0 mg/L and ≤ 10.0 mg/L (4h exposure)

Because of the study on rats with an LC_{50} of 9 mg/L, supported by the GLP-conform study, which determined a LC_{50} < 9.137 mg/L, and a study indicating a LC_{50} > 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 LC_{50} used for classification, an ATE value of 9 mg/L (vapours) is indicated.

RAC evaluation of acute toxicity

ACUTE TOXICITY – ORAL ROUTE

Summary of the Dossier Submitter's proposal

The table below shows the available acute oral studies.

Species	LD_{50} (mg/kg bw)	Dosing (mg/kg bw)	Results (mortality)	Reliability (DS)	Study	Remarks
rat (10 males per dose)	1120	710, 840, 1000, 1190, 1410, 1680, 2000, 2380 vehicle Methocel	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	2	1984	Comparable OECD TG 401; purity 99%
rat (5	554	291, 462,	291: 0/5	3	1958	Similar to

males per dose)		732, 1162, 1881 vehicle aqueous emulsion with 0.5 or 5% Traganth	462: 2/5 732: 3/5 1162: 5/5 1881: 5/5			OECD TG 401
rat (10 males per dose)	1020	795, 1000, 1260, and 1580 Vehicle not specified	795: 0/10 1000: 4/10 1260: 10/10 1580: 10/10	3	1949	Similar to OECD TG 401
rat (1-5 per dose)	461-731	18, 73, 291, 461, 731, 1159, 4609 Vehicle 10 or 20% olive oil	18: 0/1 73: 0/1 291: 0/1 731: 0/1 291: 0/5 461: 2/5 731: 4/5 1159: 3/3 1159: 2/2 4609: 2/2	3	1958a	
rat (5 per dose/sex)	>900	55, 10, 225, 450, or 900 vehicle aqueous ethanol	900: M 1/5, F 0/5	3	1986	Similar to OECD TG 401
mouse (5 per dose/sex)	900-1800	100, 225, 450, 900 or 1800 vehicle aqueous ethanol	1800: M 4/5, F: 3/5	3	1986	Similar to OECD TG 401
mouse (5 per dose)	1800	1000, 1400, 2000,2800, 4000 vehicle peanut oil	1000: M: 0/5, F: 0/5 1400: M: 0/5,F: 0/5 2000: M: 4/5, F: 4/5 2800: M: 5/5, F: 5/5 4000: M: 5/5, F: 5/5	3	1950	
rabbit (female)	280-420	120, 180, 280, 420, 620, 940 no vehicle	120: 0/1 180: 0/3 280: 0/4 420: 2/2 620: 1/1 940: 1/1	3	1949	
rabbit (2 per dose)	>184 - ≤ 368	184, 368, 736 vehicle aqueous emulsion in traganth (10% or 20%	184: 0/2 368: 1/2 736: 2/2	3	1960	
mouse (4 per dose)	1800	4 dose levels vehicle not specified		3	1982	Similar to OECD TG 401
rat	1020			3	1975	
rat (2 per dose)	>2000	Single dose, 2000 Vehicle PEG		3	1986	

cat (1 per dose)	>736	184, 368, 736 Vehicle 10% in corn oil		3	1960	
rat	800	vehicle aqueous emulsion in traganth (10% or 20%		4	1979	
no information	2080	no information		4	1971	

All studies show deficiencies; however, the available information is considered adequate for concluding on harmonized classification and on an ATE value. The most reliable study (Klimisch score 2) is the (first) study from 1984 with an LD_{50} of 1120 mg/kg bw. The NTP studies from 1986 did not result in an LD_{50} but could support a lower bound value of about 900 mg/kg bw.

The most appropriate study (1984; LD_{50} 1120 mg/kg bw) results in category 4 (Acute Tox 4 (oral) if the LD_{50}/ATE values are > 300 and ≤ 2000 mg/kg bw). This is supported by the LD_{50} values of studies in rodents with sufficient reliability. Only two studies with limited reliability would fall into the boundaries of category 3.

The DS proposed to classify ethyl acrylate as Acute Tox. 4; H302 with an ATE value of 1120 mg/kg bw.

Comments received during consultation

One MSCA agreed with the proposal as Acute Tox. 4 but proposing an ATE value of 554 mg/kg bw based on the study from 1958. In respond to this comment the DS considered that the converted ATE value of 500 mg/kg bw for Category 4 is in the same order of magnitude as the proposed ATE value of 554 mg/kg bw. Therefore, the DS proposed an ATE of 500 mg/kg bw.

Two other MSCAs were supportive of the classification as Acute Tox. 4 and the ATE of 1120 mg/kg bw.

Assessment and comparison with the classification criteria

There are 15 studies available, none of them according to guidelines or in conformity with GLP. LD_{50} values range from 280-2080 mg/kg bw from studies performed with rat, mouse, rabbit and cat, and using several different vehicles.

The most reliable study from 1984 results in an LD_{50} of 1120 mg/kg bw. This is supported by the NTP studies from 1986, which did not result in a LD_{50}, but show a lower boundary of 900 mg/kg bw. This leads to a classification as Acute Tox. 4 ($300 < LD_{50} \leq 2000$ mg/kg bw). The LD_{50} of the most reliable study results in an ATE of 1120 mg/kg bw.

RAC concludes that ethyl acrylate meets the criteria for cat 4 ($300 < ATE \leq 2000$ mg/kg bw) and should be classified as **Acute Tox. 4; H302 (Harmful if swallowed) with an ATE of 1120 mg/kg bw**.

ACUTE TOXICITY – DERMAL ROUTE

Summary of the Dossier Submitter's proposal

The table below shows the available acute dermal studies.

Species	LD_{50} (mg/kg bw)	Dosing (mg/kg bw)	Results (Mortality)	Reliability (DS)	Study	Remarks
rat (6 males per dose)	3049	2000, 2514, 3162, 3976, 5000	2000: 0/6 2514: 3/6 3162: 3/6 3976: 5/6 5000: 5/6	2	1986a	Comparable OECD TG 402/GLP; purity 99%
mouse (6 males per dose)	2997	2400, 3200, 4000	2400: 1/6 3200: 3/6 4000: 6/6	2	1986	Similar to OECD TG 402; purity 99%
rabbit (10 per dose)	1800	1580, 2000, 2520	1580: 1/10 2000: 5/10 2520: 10/10	2	1949	Similar to OECD TG 402
rat (4 per dose)	>5000	5000	0/6	3	1986d	
mouse (6 males per dose)	>5000	5000	no mortalities	3	1986d	
rat (1 male, 4 females per dose)	Not determined	1840	4/5	3	1958b	
rabbit (2 per dose)	>184	184	0/2	3	1958c	
rabbit (6-10 per dose)	Not specified	0.53-1.8	no information	3	1981	Similar to OECD TG 402
rabbit	Not determined			3	1949	
rabbit (2-4 per dose)	460	0.25, 0.5, 1.0, 4.0 mL/kg	0.25: 0/4 0.5: 2/4 1.0: 4/4 4.0: 2/2	3	1989	
rabbit (4 per dose)	580	0.5, 1 mL/kg	0.5: 1/4 1.0: 4/4	3	1989	
rabbit (2 per dose)	>126 & <252	126, 252	126: 0/2 252: 2/2	3	1986	
No information	1950			4	1971	

Thirteen studies are available, reporting a range for LD_{50} values between 126 and 252 to > 5000 mg/kg bw. Some studies used non-occlusive application or other applications. The rabbit studies from 1989 (with LD_{50} values leading to category 3) used an ambiguous test substance ('taft product').

Two studies of good quality resulted in an LD_{50} of 2997 mg/kg bw (in mice, 1986) and 3049 mg/kg bw (in rats, 1986a). Another study (1949) with rabbits, of somewhat lower quality, resulted in an LD_{50} of 1800 mg/kg bw.

The DS proposed to classify ethyl acrylate as Acute Tox. 4; H312 with an ATE value of 1800 mg/kg bw.

Comments received during consultation

Three MSCAs support the classification as Acute Tox. 3 and the ATE of 1800 mg/kg bw.

Assessment and comparison with the classification criteria

The three most reliable studies (Klimisch score 2), performed on rats (1986a), mice (1986), and rabbits (1949) lead to LD_{50} values of 3049, 2997 and 1800 mg/kg bw, respectively. It is noted that rabbits seem to be more sensitive than other species, also when taking into account the less reliable studies (noticing that these Klimisch score 3 rabbit studies are more recent).

RAC concludes that ethyl acrylate meets the criteria for cat 4 ($1000 < LD_{50} \leq 2000$ mg/kg bw) and should be classified as **Acute Tox. 4; H312 (Harmful in contact with skin) with an ATE of 1800 mg/kg bw.** The classification is supported by information from other rabbit studies.

ACUTE TOXICITY – INHALATION ROUTE

Summary of the Dossier Submitter's proposal

The table below shows the available acute inhalation studies.

Species	LC_{50} (mg/L)	Concentrations (mg/L)	Results (mortality)	Rel. (DS)	Study	Remarks
rat (10 males per dose)	9	6.3, 8.1, 9.9, 11.4, 12.3	6.3: 1/10 8.1: 6/10 9.9: 7/10 11.4: 7/10 12.3: 9/10	2	1985	Similar to OECD TG 403; purity 98-98.5%; 4h
rat (5 males per dose)	25.8 (1 h), converted 12.9	23.2, 29.5, 35.3	23.2: 2/5 29.5: 3/5 35.3: 5/5	2	1989	Equivalent to OECD TG 403/GLP; purity 99.8%; 1h
rat (6 males per dose)	> 6.1	1.2, 2.0, 3.1, 4.1 and 6.1	1.2: 0/6 2.0: 0/6 3.1: 0/6 4.1: 0/6 6.1: 1/6	3	1981	4h
rat (6 per dose)	> 4.1 & < 8.2	4.1, 8.2, 16.3	4.1: 0/6 8.2: 5/6 16.3: 6/6	3	1949	Similar to OECD TG 403; 4h
rat (5 males/females per dose)	<9.137	9.137	M 4/5, F 2/5*	3	2012	Similar to OECD TG 403/GLP; 4h
rabbit (1 male, 4 females per dose)	<4.83	4.83	all animals died	3	1949	7h
Guinea pig (2 per dose)	<4.83	4.83	all animals died	3	1949	7h
monkey (3 per dose)	-	0.31	no mortalities	3	1995	Similar to OECD TG 403;

						3, 6 h
rat (3 per dose)	<165	162 - 175	4 min: 0/6 8 min: 2/6 15 min: 6/6 30 min: 6/6	3	1958d	Similar to OECD TG 403; 4-30 min
rat (6 per dose)	5.8	4.1, 16.4	4.1: 0/4 16.4: 4/4	3	1989b	4h
rat	7.4		-	4	1979	Exposure duration not specified
mouse	16		-	4	1979	Exposure duration not specified
mouse (4-15 per dose)	Not determined	0.025, 0.05, 0.1, 0.5	0.025: 2/4 0.05: 4/7 0.1: 7/10 0.5: 6/15	4	1962	Exposure duration not specified

* Discrepancy: REACH dossier and Table 12 in CLH report provide F: 2/5, text in CLH report provides F: 3/5.

One GLP conform and guideline study in rats is available for ethyl acrylate, however only one single concentration is reported. At 9.317 mg/L 4/5 male and 3/5 females died, giving a strong indication that the 4h LC_{50} < 9 mg/L. In addition, two studies with adequate reliability (1985, 1989) reported LC_{50} values after 4h of exposure of 9 and 12.9 mg/L. An additional study (1981) provided an indication of the lower boundary with 1/6 deaths at 6.1 mg/L. Several studies of lower reliability reported 4h LC_{50} values in the range of 4.1-16 mg/L.

Overall, the data indicate a classification as category 3 (LC_{50} values > 2.0 mg/L and ≤ 10.0 mg/L, 4h exposure), based on LC_{50} of 9 mg/L, supported by the GLP conform study, which determined a LC_{50} < 9.137 mg/L, and a study indicating a LC_{50} > 6.1 mg/L.

The DS proposed to classify ethyl acrylate as Acute Tox. 3; H331 with an ATE value of 9 mg/L (vapours), based on the lowest LC_{50} value.

Comments received during consultation

One MSCA agreed with the proposal as Acute Tox. 3 and proposed ATE.

The other two MSCAs were in support of Acute Tox. 3, but not with the proposed ATE. One MSCA proposed a generic ATE of 3 mg/L (as other studies showed that it must be lower than 9 mg/L and no clear ATE can be defined). The other MSCA proposed an ATE of 7 mg/L, based on the LC_{50} values expected to be higher than 6.3 mg/L (mortality 1/10) and lower than 8.1 mg/L (mortality 6/10) of the 1985 study, performed similar to OECD TG 403 with 4 hours exposure to vapour of ethyl acrylate (purity: 98-98.5 %).

The DS responded that indeed other studies indicate a lower ATE value, although due to the used dosing no final value can be derived (but it may be between 6 and 7 mg/L). The converted ATE value would be 3 mg/L, while no mortalities were seen at doses around 4 mg/L (except in the 1949 study with 7h exposure). The DS cannot support a converted ATE, but proposed a value of around 7 mg/L based on a weight of evidence approach.

Assessment and comparison with the classification criteria

Thirteen acute inhalation studies (vapour) are available. Two reliable studies (Klimisch score 2) in rats result in 4h LC_{50} values of 9 and 12.9 mg/L. The lowest LC_{50} of 9 mg/L

results in a classification ($2 < LC_{50} \leq 10$ mg/l for vapours) as Acute Tox. 3.

From the studies (with Klimisch score 2) used for assessing the category 3, the lowest LC_{50} is 9 mg/L. Other studies (with Klimisch score 3) suggest that the LC_{50} might be lower. However, these studies have uncertainties and it is difficult to establish an overall LC_{50} on these studies. Therefore, RAC considers appropriate an ATE of 9 mg/L.

RAC concludes that ethyl acrylate meets the criteria ($2 < LC_{50} \leq 10$ mg/L) and should be classified as **Acute Tox. 3; H330 (Toxic if inhaled) with an ATE of 9 mg/L**.

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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