Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

Adopted

18 March 2020

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON ETHYL ACRYLATE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: ethyl acrylate
EC number: 205-438-8
CAS number: 140-88-5
Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2020	Germany		MemberState	1
Comment received				
The density stated on ECHA dissemination site is 0.92 g/cm3 and not 0.95 g/cm3 given in the CLH dossier. The purity in table 2 has to be replaced by 100 %, as the ideal substance should be evaluated.				
Dossier Submitter's Response				
Thank you for the correction of the density given for the substance. The value should be 0.92 g/cm^3. The CLH dossier refers to the pure substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
14.04.2020	United Kingdom	IPI Global Ltd	Company-Manufacturer	2
Comment received				
page 3.It is very well recognized that closed loop system technology reduces the exposure of the operator below the threshold recommended by the EU as confirmed by our customers and the HSE study and that it is in agreement with the latest amended EU directives for CMD 2004[1] and in general with the (89/391/EEC) of 12 June 1989[2] and the 89/24/EC of 7 April 1998[3].				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ETHYL ACRYLATE.pdf
Dossier Submitter's Response
Thank you for the information on safe handling of ethyl acrylate in closed loop systems. Information no relevant for the classification process and the intrinsic properties of the substance.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2020	Belgium		MemberState	3
Comment received				
Acute oral toxicity : BECA supports a classification as Acute Tox. 4. However, BECA is not agree with the proposed ATE value of 1120 mg/kg bw. Even if the purity is unknown in the BASF AG (1958)'s study, this study is performed similarly to the OECD TG 401 and is well reported. BECA is then in favour to take into account the ATE value of this study. BECA proposed an ATE value of 554 mg/kg bw. Acute dermal toxicity : BECA supports the proposal to classify the substance as Acute Tox. 4 and the proposed ATE value of 1800 mg/kg bw. Acute inhalation toxicity : A recent study (Anonymous (2012)) tested only one dose level of 9.137 mg/L. 4 males out of 5 and 2 females out of 5 died in this study which result in a LC50 lower than 9.137 mg/L. Two studies, both performed by Treon et al. in 1949, revealed that all animals, exposed to 4.83 mg/L, died. Anonymous (1989b) revealed a LC50 of 5.8 mg/L. In Pozzani et al. (1949), no LC50 was determined but it was comprised between 4.1 and 8.2 mg/L. The key study used to classify the substance and to determine the ATE value of 9 mg/L was Oberly and Tansy (1985)'study. However, the reported results showed that 1/10, 6/10, 7/10, 7/10 and 9/10 respectively at 6.3, 8.1, 9.9, 11.4 and 12.3 mg/L. At 8.1 mg/L of exposure, more than half of the exposed animals die. Based on these information, BECA supports the proposal to classify ethyl acrylate as Acute Tox. 3. However, BECA is not agree with the proposed ATE value of 9 mg/L. Several studies, reported in the dossier, demonstrate that the ATE value must be lower. As no clear ATE can be defined, BECA is in favour of an estimated ATE value of 3 mg/L based on the CLP Regulation (Annex I Table 3.1.2).				
Dossier Submitter's Response				
Acute oral toxicity: Several studies, most of them with limited reliability, are available for evaluation of this endpoint. However, all of them indicate classification as Acute Tox 4. The most reliable study (Rohm, 1984) with the substance (99% purity) reports a LD_{50} of 1120 mg/kg bw. The proposed ATE value of 554 mg/kg bw (BASF, 1958) is in the same ordner of magnitude as the converted ATE value of 500 mg/kg bw for Category 4 (CLP, table				

3.1.2). Therefore an ATE value of 500 mg/kg bw, which is very conservative, can be followed by the dossier submitter.

Acute dermal toxicity: Thank you for your support.

Acute inhalation toxicity:
Thank you for your agreement on Acute Tox. 3, H 331.
It is correct that 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 values based on CLP (Table 3.1.2) would be 3 mg/L which is on the other hand lower than available information showing that no mortalities were seen at doses around 4 mg/L (except the studies by Treon, 1949 with an exposure duration of 7h). The dossier submitter therefore cannot support a converted ATE value but based on a weight of evidence approach a value of around 7 mg/L is indicated.

RAC's response

Acute oral toxicity:
Agreed with the evaluation.
However, RAC proposes to base the ATE on the only study comparable to OECD TG 401 and reliable with restriction (reliability 2) with an LD_{50} of 1120 mg/kg bw.

Acute inhalation toxicity:
Agreed with the evaluation.
It should be noted that the exposure duration in the Treon study (1949) was 7h instead of 4h. Furthermore, the LC_{50} (reported 5.8 mg/L) from the Anonymous (1989b) might be higher, as the reported mortality was 0.4 at 4.1 mg/L and 4/4 at 16.4 mg/L.
RAC proposes an ATE of 9 mg/L taking into account the results from the most reliable studies, but also some of the studies with a score of 3.

Date	Country	Organisation	Type of Organisation	Comment number
23.04.2020	France		MemberState	4
Comment received				
France agrees with the proposed categories and ATE for acute toxicity.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2020	Germany		MemberState	5
Comment received				
Ethyl acrylate induced acute toxicity in different species after oral, dermal, and inhalation exposure. The DE CA supports classification in category 4 for acute oral toxicity (Acute Tox 4, H302) using an ATE value of 1120 mg/kg bw, based on the only study comparable to OECD TG 401 and reliable with restriction (reliability 2) in rats with ethyl acrylate (purity 99 %). The DE CA supports classification for acute dermal toxicity in category 4 (Acute Tox. 4, H312) with an ATE value of 1800 mg/kg bw, derived from the lowest LD50 obtained in rabbits of a study similar to OECD TG 402 (reliability 2). Furthermore,				

classification for acute inhalation toxicity in category 3 is supported. The AU CA proposes an ATE value of 9 mg/L. However, during another study, using one dose at 9.1 mg/L, four out of five male rats died after inhalation exposure to ethyl acrylate (purity 99.9 %). Further studies with 4 hours exposure to rats consistently support a lower LC50 value (5.8 mg/L, > 4.1 & < 8.2 mg/L, but > 6.1 mg/L) while studies on rabbit and guinea pig hy-pothesize a much lower LC 50 value. However, studies are of lower reliability and uncertain-ties due to longer than 4 hour exposure. The DE CA does not support an ATE value of 9 mg/kg bw (vapours), but recommend an ATE value of 7 mg/L. This is based on the LC50 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 study of Oberly and Tansy (1985), performed similar to OECD TG 403 with 4 hours exposure to vapour of ethyl acrylate (purity: 98-98.5 %).
Dossier Submitter's Response
Thank you for your support. For discussion of ATE value for acute inhalation toxicity please see response to comment No 3.
RAC's response
Acute oral toxicity: Agreed with the evaluation, and the LD_{50} of 1120 mg/kg bw from the most reliable study to base the ATE on. Acute inhalation toxicity: Agreed with the evaluation of the DS. RAC proposes an ATE of 9 mg/L taking into account the results from the most reliable studies, but also some of the studies with a score of 3.

PUBLIC ATTACHMENTS
1. ETHYL ACRYLATE.pdf [Please refer to comment No. 2]