

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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Last data extracted on 29.04.2020

Substance name: ethyl acrylate

CAS number: 140-88-5

EC number: 205-438-8

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/cm ³ and not 0.95 g/cm ³ given in the CLH dossier.				
The purity in table 2 has to be replaced by 100 %, as the ideal substance should be evaluated.				

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				

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).

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.				

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2020	Germany		MemberState	5
Comment received				
<p>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.</p> <p>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-potheseize 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 val-ues 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 %).</p>				

PUBLIC ATTACHMENTS

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