

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public 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: allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester

CAS number: 96-05-9

EC number: 202-473-0

Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2020	Germany		MemberState	1
Comment received				
The purity in table 2 has to be replaced by 100 %, as the ideal substance should be evaluated.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
23.04.2020	France		MemberState	2
Comment received				
Acute Toxicity by oral route: We agree with the proposal as Acute Tox 4. You rate all the studies with Klimisch score 3 or 4. Rohm & Hass (1975) study seems of better quality compared to all other studies (only data on purity lacking, all other data available allowing adequate assessment of the study). If it is the case, the ATE could be set at 470 mg/kg instead of 401 mg/kg.				
Acute toxicity by dermal route: We agree with the proposal as Acute Tox 3. You rate the studies with Klimisch score 3 or 4 and choose the highest LD50 without clear justification. FR is of opinion to choose the generic ATE of 300 mg/kg				
Acute Toxicity by inhalation: We agree with the proposal as Acute Tox 2 and the selected ATE. We note that in the Degussa study, the tested concentrations induce either no mortality or a full mortality. This lead to a very large 95% CI. However, the LC50 value is supported by the Huntingdon study. Therefore, the ATE is considered appropriate.				

Date	Country	Organisation	Type of Organisation	Comment number
17.04.2020	Germany	Evonik Resource Efficiency GmbH	Company-Importer	3
Comment received				

We agree with the proposed classification and labelling of Allyl methacrylate as Acute Tox 4, H302, Acute Tox 3, H311 and Acute Tox 2, H330.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment AMA_Evonik Resource Efficiency GmbH_Public comment on proposed classification.pdf

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment AMA_Evonik Resource Efficiency GmbH_Confidential comment on proposed classification.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2020	Belgium		MemberState	4

Comment received

Acute oral toxicity :

The 2 Smirnova et al. (1990)'s studies are poorly reported, no information on purity of the substance, strain and number of animals unknown, no information on dose levels, no information on vehicle and no information on mortalities. Results of these studies cannot be confirmed. However, the other available studies have also deficiencies. Purity is not available for the Rohm and Haas (1975)'s study. Purity, dose levels and information on mortality are not available for the Smith et al. (1969)'s study. Purity, vehicle, dose levels, vehicle and information are not available for Anonymous (1981)'s study.

BECA is surprised that the 2 most recent studies (1990), with lowest LD50, are the least detailed. BECA ask more information on these 2 studies (purity, strain and number of animals, dose levels, vehicle and information on mortalities).

If no more information is provided by the registrant, BECA is in favour of taking into account the lowest LD50, 57 mg/kg bw, and then BECA is in favour of a classification as Acute Tox. 3 with an ATE value of 57 mg/kg bw.

Acute dermal toxicity :

Two studies are available in the CLH dossier. These 2 studies are poorly reported and a lot of information are lacking. For the 2 studies, purity, vehicle, dose levels and information on mortalities are not reported.

BECA supports a classification as Acute Tox. 3 for the dermal route. However, as both studies have deficiencies, BECA considers that the lowest LD50 must be take into account and then BECA is in favour of an ATE value of 210 mg/kg bw.

Acute inhalation toxicity :

BECA supports the proposal to classify Allyl methacrylate as Acute Tox. 2 and supports the proposed ATE value of 1.47 mg/L.

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2020	Germany		MemberState	5

Comment received

Allyl methacrylate induced acute toxicity in rats after oral, dermal and inhalation exposure. All studies on oral exposure were considered of limited reliability (reliability 3) or as not as-signable (reliability 4) in this assessment. Two studies performed similar to OECD TG 401 on rats are limited in their reliability, due to lacking information on the purity of the test sub-stances. Studies reveal LD values of 470 and 401 mg/kg bw. Other studies with oral exposure to rats and mice were not assignable. The DE CA supports classification of allyl methacrylate for acute oral toxicity as Acute Tox 4 (H302), with an

ATE value of 401 mg/kg. Value is based on the lowest LD50 from studies with rats performed similar to OECD TG 401.

The DE CA supports classification for acute dermal toxicity (Acute Tox. 3, H311) using an ATE = 467 mg/kg bw, based on the LD50 value from one study with deficiencies, but adequately for concluding on a harmonized classification and ATE value. A second study on dermal ex-posure of allyl methacrylate was not assignable.

Furthermore, it is supported to classify allyl methacrylate for acute inhalation toxicity, category 2 (Acute Tox. 2, H330) with an ATE = 1.47 mg/L (vapours), based on the lowest LC50-value from the key study.

PUBLIC ATTACHMENTS

1. AMA_Evonik Resource Efficiency GmbH_Public comment on proposed classification.pdf [Please refer to comment No. 3]

CONFIDENTIAL ATTACHMENTS

1. AMA_Evonik Resource Efficiency GmbH_Confidential comment on proposed classification.pdf [Please refer to comment No. 3]