Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester

EC Number: 202-473-0
CAS Number: 96-05-9

CLH-O-0000006957-57-01/F

Adopted

18 March 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON ALLYL METHACRYLATE; 2-METHYL-2-PROPENOIC ACID 2-PROPENYL ESTER

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: allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester
EC number: 202-473-0
CAS number: 96-05-9
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.				
Dossier Submitter's Response				
No amendments in the original document are done at this stage of the process. However, it can be confirmed that the dossier refers to the pure substance allyl methacrylate.				
RAC's response				
Noted.				

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.
Dossier Submitter's Response
Acute oral toxicity: Thank you for your support. The ATE value of 401 mg/kg bw is preferred as this lower value is supported by study results from secondary sources with LD_{50} values ranging from 57 – 421 mg/kg bw. Acute dermal toxicity: The classification is based on the most reliable study (Smyth, 1969), although also for this study relevant information is missing. The use of the generic ATE value of 300 mg/kg bw can be followed based on the limited reliability of both studies and the evidence from the second study. Acute inhalation toxicity: Thank you for your support.
RAC's response
Acute oral toxicity: Agreed with the DS that classification is preferably based on the most reliable (score 3) studies. Acute dermal toxicity: Agreed with the adaptation of the DS to use the generic ATE value of 300 mg/kg bw.

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_Confidental comment on proposed classification.pdf				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

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.

Dossier Submitter's Response

Acute oral toxicity:
It is correct that all available studies have their limitations. The study from Smirnova (1990) is only available in Russian language. The information given in the registration dossier and in the CLH report is taken from the OECD SIDS Dossier (secondary source). A translation of the study Smirnova (1990) has shown that only very limited information is reported in the study (2 page report) where allyl methacrylate has been tested in mice and rats für acute, subacute and chronic exposure (oral and inhal) as well as for its irritating and senitizing potential in rabbits and guinea pigs respectively. The number of animals used and the strains are not reported. Information on the dosing is missing but it is noted that for the dosing via gavage the test substance was applied as a 5% solution in oil. Single dosing also showed effects on the CNS (coordination, agressivity).
A classification based on this limited information is not supported.

Acute dermal toxicity: Due to the limited reliability a converted ATE of 300 mg/kg bw would be preferred. See response to comment No 2.

Acute inhalation toxicity: Thank you for your support.

RAC's response
Acute oral toxicity: Agreed with response of DS (also in comment 2). Acute dermal toxicity: Agreed with the adaptation of the DS to use the generic ATE value of 300 mg/kg bw, based on the availability of two studies of limited reliability.

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.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

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_Confidental comment on proposed classification.pdf [Please refer to comment No. 3]