Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

2,2'-ethylenedioxydiethyl dimethacrylate

EC Number: 203-652-6
CAS Number: 109-16-0

CLH-O-0000007059-70-01/F

Adopted

26 November 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

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: 2,2'-ethylenedioxydiethyl dimethacrylate
EC number: 203-652-6
CAS number: 109-16-0
Dossier submitter: Finland

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
04.02.2021	France		MemberState	1
Comment received				
Based on results of the LLNA, criteria for Skin Sens. 1B are fulfilled. The EC3 value is however 91.6%, indicating a low potency. Concerning the GPMT assays, which were all score with reliability 3, 2 are positive, and 3 negative. Based on human data and according to CLP guidance document, there is a high frequency of occurrence of skin sensitisation based on the available studies on selected patients (in general > 2%) and the high number of published cases (> 100). Assessment of exposure data is lacking from the CLH report (refer to table 3.3 of CLP guidance). Considering the high frequency of occurrence of skin sensitisation based on human data, if no adequate exposure data is available, a subcategorisation as Skin Sens. 1A cannot be excluded. In this context, subcategorisation may be not possible. Thus, it should be discussed at the RAC level if classification as Skin Sens. 1 instead of 1B as proposed is more appropriate.				
Dossier Submitter's Response				
Thank you for your comment. The assessment of human exposure is not included in the CLH report because there is no adequate data available. Proposed sub-categorization as 1B is based on reliable LLNA. In this case, our view is that insufficient human exposure data would not overtake animal data. However, we agree it is the RAC to consider the most appropriate classification.				
RAC's response				
Thank you for comment. RAC agrees with the opinion of Dossier Submitter. It is noted that according to Regulation (EC) 1272/2008 point 3.4.2.2.4.2.: "*Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in*				

order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitisation are usually derived from case-control or other, less defined studies."

Date	Country	Organisation	Type of Organisation	Comment number
11.01.2021	Germany		MemberState	2
Comment received				
We agree with the classification of the 2,2'-ethylenedioxydiethyl dimethacrylate as Skin Sens 1B, H317. The argumentation that the human patch-test data suggest at least a categorization as skin sensitiser with high frequency is plausible. Finally, the key-LLNA clearly confirms the subcategorization as Skin Sens 1B, H317.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for comment.				

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2021	Germany	<confidential>	Company-Manufacturer	3
Comment received				
With reference to the CLH dossier regarding 2,2'-ethylenedioxyethyl dimethacrylate (EC number 203-625-6), we agree with the harmonised classification as Skin Sens 1B, H317, mainly based on animal data, namely LLNA data, proposed by the Finnish MSCA. We also agree to the proposed assessment on human data supporting the classification and labelling in a weight of evidence approach and not allowing a sub-categorisation due to the absence of exposure information. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2021-02-03_Comment on CLH Dossier TRGDMA_Comment_final_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2021-02-03_Comment on TRGDMA_final.pdf				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Thank you for comment.				

PUBLIC ATTACHMENTS
1. 2021-02-03_Comment on CLH Dossier TRGDMA_Comment_final_public.pdf [Please refer to comment No. 3]

CONFIDENTIAL ATTACHMENTS
1. 2021-02-03_Comment on TRGDMA_final.pdf [Please refer to comment No. 3]