

## COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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**Last data extracted on 08.02.2021**

**Substance name: 2,2'-ethylenedioxydiethyl dimethacrylate**

**CAS number: 109-16-0**

**EC number: 203-652-6**

**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				
<p>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.</p> <p>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 &gt; 2%) and the high number of published cases (&gt; 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.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
11.01.2021	Germany		MemberState	2
Comment received				
<p>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.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
03.02.2021	Germany	<confidential>	Company-Manufacturer	3
Comment received				
<p>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</p>				

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

#### 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]