

**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-ethylhexanoic acid, monoester with propane-1,2-diol**

**EC Number: 285-503-5**  
**CAS Number: 85114-00-7**

CLH-O-0000007244-77-01/F

**Adopted**  
**16 March 2023**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 2-ETHYLHEXANOIC ACID, MONOESTER WITH PROPANE-1,2-DIOL

### 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-ethylhexanoic acid, monoester with propane-1,2-diol**

**EC number: 285-503-5**

**CAS number: 85114-00-7**

**Dossier submitter: Spain**

#### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
08.08.2022	Germany		MemberState	1
Comment received				
Comments are attached in the confidential attachement				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment DE-CA Comments-CAS-Nr-85114-00-7-Confidential.pdf				
Dossier Submitter's Response				
No proposal for any changes. Thank you for your full support to our CLH proposal.				
RAC's response				
Thank you for the detailed analysis. RAC agrees that classification as Repr. 1B; H360D is warranted.				

#### TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
11.08.2022	Finland		MemberState	2
Comment received				
We agree that the reported malformations of head, skull and brain in mice and rat, and particularly the reported exencephalies in mice, warrant classification for Repr. 1B; H360D. The data is supported by similar pattern of developmental findings reported for 2-ethylhexanoic acid, a likely hydrolysis product of the substance.				
Dossier Submitter's Response				
No proposal for any changes. Thank you for your full support to our CLH proposal.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 2-ETHYLHEXANOIC ACID, MONOESTER WITH PROPANE-1,2-DIOL**

RAC's response

Thank you for your comment. RAC agrees with the proposed classification as Repr. 1B; H360D.

**CONFIDENTIAL ATTACHMENTS**

1. DE-CA Comments-CAS-Nr-85114-00-7-Confidential.pdf [Please refer to comment No. 1]