Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

1,3-bis(isocyanatomethyl)benzene

EC Number: 222-852-4
CAS Number: 3634-83-1

CLH-O-0000006846-62-01/F

Adopted

17 September 2020

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1,3-BIS(ISOCYANATOMETHYL)BENZENE

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.

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Substance name: 1,3-bis(isocyanatomethyl)benzene;
EC number: 222-852-4
CAS number: 3634-83-1
Dossier submitter: Germany

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
11.10.2019	Finland		MemberState	1
Comment received				
FI CA is the of opinion that category approach based on structural similarity to monomeric diisocyanates, consistency of the effects, reliability and adequacy of the source data and common underlying mechanism etc. is justified for the substance with limited test data avail-able for itself. It has been shown that the respiratory sensitization property depends on the diisocyanate groups in the structure of the molecule. We agree that data rich diisocyanates HDI, MDI and TDI with harmonized classification for sensitization as Resp. Sens 1 can be used as source substances. The proposed classification as Resp. Sens 1, H334 is supported for Bis(isocyanatomethyl)benzene.				
Dossier Submitter's Response				
We thank the FI CA for their support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
24.10.2019	Sweden		MemberState	2
Comment received				
As stated in section 3.4.2.1 of Annex I to the CLP Regulation, classification for respiratory sensitisation is typically based on human data with supportive evidence from e.g. animal data. No human data is available for XDI and although the CLP criteria cannot directly be applied to XDI, the Swedish CA supports the WoE approach taken by the DS. Hence, classification of XDI as Resp. Sens. 1, H334 is supported based on sufficient evidence of the hazardous property, including the following pieces of information; 1) general mechanistic knowledge on the biological effects of diisocyanates. For example, the diisocyanate structure is an alert for respiratory sensitisation (REACH guidance on				

IR/CSA, Table R.7.3-3, and OECD QSAR toolbox v.4.3), 2) read-across of human and non-human data of the hazardous property from structurally similar diisocyanates HDI, MDI and TDI. All three source-substances have harmonised classifications as Resp Sens. 1. and, 3) clear evidence of the skin sensitising potential of m-XDI which demonstrate the potential of the substance to initiate an immunological response.
Dossier Submitter's Response
We thank the SE CA for their support.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	3
Comment received				
Despite the lack of data on respiratory sensitization with m-XDI, the current knowledge on hypersensitivity induced by isocyanates can allow proposing a classification for this substance.				
Dossier Submitter's Response				
We thank the FR CA for their support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
11.10.2019	Finland		MemberState	4
Comment received				
For skin sensitisation endpoint three GPMT studies are available. Despite of limitations, all of the reported results are consistent with an extreme skin sensitisation potential of the substance. Thus, suggested classification of Skin Sens. 1A, H317 is supported.				
Dossier Submitter's Response				
We thank the FI CA for their support.				
RAC's response				
Thank you for your comment. RAC also agrees with the classification proposed by the Dossier Submitter.				

Date	Country	Organisation	Type of Organisation	Comment number
24.10.2019	Sweden		MemberState	5
Comment received				
The proposal to classify m-XDI as a skin sensitizer is based on an OECD TG 406 compliant GPMT study in which it was reported that an intradermal induction dose of 0.01% resulted in a 100% sensitization rate. The skin sensitizing property of m-XDI is also supported by several less reliable studies. The Swedish CA hence agrees with the proposed classification as Skin Sens 1A, H317 with a specific concentration limit of 0.001%.				
Dossier Submitter's Response				
We thank the SE CA for their support.				

RAC's response
Thank you for your comment. RAC also agrees with the classification proposed by the Dossier Submitter.

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	6
Comment received				
Skin Sensitization: We agree with the proposal.				
Dossier Submitter's Response				
We thank the FR CA for their support.				
RAC's response				
Thank you for your comment. RAC also agrees with the classification proposed by the Dossier Submitter.				