

Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

2,4,6-triisopropyl-*m*-phenylene diisocyanate

EC Number: 218-485-4
CAS Number: 2162-73-4

CLH-O-0000006862-68-01/F

Adopted
17 September 2020

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 2,4,6-TRIIISOPROPYL-M-PHENYLENE DIISOCYANATE

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: 2,4,6-triisopropyl-m-phenylene diisocyanate

EC number: 218-485-4

CAS number: 2162-73-4

Dossier submitter: Germany

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
24.10.2019	Sweden		MemberState	1
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 such substance specific data is available for TRIDI and although the CLP criteria cannot directly be applied, the Swedish CA supports the WoE approach taken by the DS. Hence, classification of TRIDI as Resp. Sens. 1, H334 is supported based on; 1) the general mechanistic knowledge on the biological effects of diisocyanates. For example, the (di)isocyanate structure is an alert for respiratory sensitisation (REACH guidance on IR/CSA, Table R.7.3-3, and OECD QSAR toolbox v.4.3), and 2) read-across of human and non-human respiratory data from structurally similar diisocyanates HDI, MDI and TDI. All three source substances have harmonised classifications as Resp Sens. 1. In addition the Swedish CA finds that the molecular size (285 Da) and volatility (although quite low, i.e. 0.19 Pa) do not contradict that respiratory uptake of TRIDI occurs.				
Dossier Submitter's Response				
We thank the SE CA for their support.				
RAC's response				
Noted.				

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Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	2
Comment received				
Despite the lack of data on respiratory sensitization with TRIDI, 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
24.10.2019	Sweden		MemberState	3
Comment received				
No substance specific human or animal data on skin sensitization is available for TRIDI. However, the Swedish CA agrees with the DS that there is sufficient evidence for skin sensitization potential of TRIDI by the presence of the diisocyanate structure in combination with evidence of strong skin sensitizing properties from a number of structural analogue diisocyanates. In addition, the molecular size of TRIDI (285 Da) indicates potential for skin absorption. Hence, the Swedish CA supports classification of TRIDI as Skin Sens. 1, H317.				
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	4
Comment received				
Skin Sensitization: Despite the lack of data on skin sensitization with TRIDI, 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				
Thank you for your comment. RAC also agrees with the classification proposed by the Dossier Submitter.				