Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

1,5-naphthylene diisocyanate

EC Number: 221-641-4
CAS Number: 3173-72-6

CLH-O-0000006855-63-01/F

Adopted

17 September 2020

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1,5-NAPHTHYLENE 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.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: 1,5-naphthylene diisocyanate
EC number: 221-641-4
CAS number: 3173-72-6
Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	Covestro Deutschland AG	Company-Manufacturer	1
Comment received				
Comments on the use of the split entry concept of NDI in referring on an unpublished expert opinion (Pauluhn 2010) with cited IGF study, an unpublished acute Inhalation study in rats according OECD No 403 (Bayer 1995) like referred by the dossier submitter and a Currenta study 2019 (attached) ECHA note – An attachment was submitted with the comment above. Refer to public attachment NDI classification public.zip				
Dossier Submitter's Response				
The comment by the manufacturer is noted. The DS was faced with the task of verifying the existing minimum classification as Acute Tox. 4* for all possible NDI materials, not for one material alone. It is noted that ECHA's Guidance on the Application of the CLP Criteria refers to the split-entry concept, but does not provide a workable definition of the thoracic fraction. The upper limit of 50 µm for the thoracic fraction used by the DS was not derived from the Plant Protection Regulation, but from norm EN 481, Table 1. According to this table, which gives numerical approximations of the thoracic fraction, 50 µm marks the lowest particle size without contribution to the thoracic fraction (vs. 0.1% of the particles at 40 µm, 1.0% at 30 µm, 3.0% at 25 µm etc. contribute to that fraction). Moreover, as pointed out in the classification dossier, the 50 µm limit has been used in previous cases where the split-entry concept was applied. The DS notes further that EN 481 also describes the thoracic fraction as a cumulative (log)normal distribution with a median of 11.64 µm and a geometric standard deviation of				

1.5 and therefore the 50 µm limit chosen in previous cases might be considered as quite conservative.

However, it is also immediately obvious that it is not acceptable to use 10 µm as the upper limit of the thoracic fraction (acc. to Table 1 of EN 481, 55.5% of the particles with a diameter of 11 µm and still 9.1% of the particles with 20 µm diameter contribute to the thoracic fraction). In the Currenta study submitted with the manufacturers comment, almost 74% of the test material had a particle size of 10-50 µm.

The DS notes that the proposal from the manufacturer to define classification borders based on % thoracic fraction rather than a specific particle size cut-off would bear a considerable risk of under-classification if the 10 µm limit was used. The DS would therefore rather prefer if the classification borders would be defined based on an upper limit particle size. If % thoracic fraction would be used, then a clear definition would be needed to allow for a correct and unambiguous determination of that fraction.

Forwarded to RAC for further consideration.

RAC's response

RAC agrees with the DS that it would be logical to maintain consistency between the split-entries, unless there is a reason to deviate from the previous ones. In addition, RAC agrees that it is preferable to clearly define a specific particle size cut-off, rather than to define the limit based on % thoracic fraction. Especially, when there is no clear-cut definition for the thoracic fraction available, but it is rather a spectrum. In the comment by the Company-Manufacturer, it was not evident which particle sizes they refer to as the thoracic fraction, but often, as indicated also by the DS, 10 µm is viewed as such.

In this case however, it should also be noted that in Bayer 2003, NDI at particle size 10.1 µm (MMAD, GSD 2.8 µm) caused 100% lethality at the dose level of 1050 mg/m^3 (1.05 mg/L, the only dose level tested with this particle size). While not directly applicable to classification purposes, this result would indicate at least a category 3 classification for the acute inhalation toxicity of this particle size, considering the classification criteria. Therefore, it appears evident that 10 µm could not be used as a limit in this case.

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	<confidential>	Company-Importer	2

Comment received

On 26th of August 2019, the public consultation of the proposed harmonized classification of NDI, dossier submitter Germany, was launched. It is open until 25th of October 2019. <confidential> comments this proposal as follows:

As member of the joint registration, we have been informed by Covestro Deutschland AG (lead registrant) about their position and the related background. <confidential> agrees to the comments submitted by Covestro and supports their argumentation completely.

In order to have also a harmonization of different legal regulations like e.g. ADR 2019, we suggest – if the ECHA follows Covestro's proposal of a split-entry concept for NDI – to use already ready existing values especially for the definition of the diameter of inhalable dust. As reference, the ADR 2019 (chapter 2.2.61.1.3) describes the principle requirement for the testing of a substance for acute toxicity by inhalation. It is defined by min 10 wt% of inhalable dust with an aerodynamic radius of <10µm. In consequence we suggest to define the particle size accordingly by <10 µm instead of <50µm as proposed.

For setting the max border level of inhalable dust content we also follow the argumentation of Covestro for the determination of acute toxicity of mixtures follows the additivity formula according to the CLP Regulation (EC) No 1272/2008.
Dossier Submitter's Response
Cf. the DS's response above. An upper limit of 10 µm does not appear sufficiently conservative based on norm EN 481. Forwarded to RAC for further consideration.
RAC's response
Please see RAC's response for comment number 1.

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	<confidential>	Company-Importer	3
Comment received				
In order to have also a harmonization of different legal regulations like e.g. ADR 2019, we suggest – if the ECHA follows Covestro's proposal of a split-entry concept for NDI – to use already ready existing values especially for the definition of the diameter of inhalable dust. As reference, the ADR 2019 (chapter 2.2.61.1.3) describes the principle requirement for the testing of a substance for acute toxicity by inhalation. It is defined by min 10 wt% of inhalable dust with an aerodynamic radius of <10µm. In consequence we suggest to define the particle size accordingly by <10 µm instead of <50µm as proposed. For setting the max border level of inhalable dust content we also follow the argumentation of Covestro for the determination of acute toxicity of mixtures follows the additivity formula according to the CLP Regulation (EC) No 1272/2008.				
Dossier Submitter's Response				
See the DS response for comment above.				
RAC's response				
Please see RAC's response for comment number 1.				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	Covestro Deutschland AG	Company-Manufacturer	4
Comment received				
see attached documents ECHA note – An attachment was submitted with the comment above. Refer to public attachment NDI classification public.zip				
Dossier Submitter's Response				
See the DS response for comment above.				
RAC's response				
Please see RAC's response for comment number 1.				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	France		MemberState	5
Comment received				
Based on data available, FR agrees with the classification proposal for acute toxicity				
Dossier Submitter's Response				
The DS thanks 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
25.10.2019	Germany	Covestro Deutschland AG	Company-Manufacturer	6
Comment received				
no comments, we agree with the dossier submitter ECHA note – An attachment was submitted with the comment above. Refer to public attachment NDI classification public.zip				
Dossier Submitter's Response				
The DS thanks the manufacturing company 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	7
Comment received				
Based on data available, FR agrees with the classification proposal for skin sensitisation				
Dossier Submitter's Response				
The DS thanks 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.				

Date	Country	Organisation	Type of Organisation	Comment number
24.10.2019	Sweden		MemberState	8
Comment received				
The Swedish CA agrees with the proposed classification of NDI as Skin Sens. 1A, H317.				
Dossier Submitter's Response				
The DS thanks 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.				

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PUBLIC ATTACHMENTS
1. NDI classification public.zip [Please refer to comment No. 1, 4, 6]