

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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Last data extracted on 04.11.2019

Substance name: 1,5-naphthylene diisocyanate

CAS number: 3173-72-6

EC number: 221-641-4

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				
<p>Comments on the use of the split entry concept of NDI in referring on an unpublished expert opinion (Pauluhn 2010) with cited IGF study, an unpublished acute Inhalation study in rats according OECD No 403 (Bayer 1995) like referred by the dossier submitter and a Currenta study 2019 (attached)</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment NDI classification public.zip</p>				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	<confidential>	Company-Importer	2
Comment received				
<p>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:</p> <p>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.</p> <p>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.</p> <p>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.</p>				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2019	Germany	<confidential>	Company-Importer	3
Comment received				
<p>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.</p> <p>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.</p>				

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				

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				

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				

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				

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.				

PUBLIC ATTACHMENTS

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