COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during 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 07.04.2020

Substance name: di-n-butylamine
CAS number: 111-92-2
EC number: 203-921-8
Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
02.04.2020	Germany		MemberState	1
Comment received				
In Table 6 the column „Specific Conc. Limits, M-factors and ATE" the ATE for inhalation should be amended to read: "Inhalation: ATE = 1.15 mg/L (vapours)" in the subsequent RAC Oppinion, if agreed upon.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	2
Comment received				
Acute toxicity: For the acute toxicity by oral, dermal, and inhalation routes, FR agrees with the classification proposal of the DS. However, for the oral and dermal routes, considering the quality of the studies available, FR would be of the opinion to use the generic ATE for the classification of mixture, that is to say : - Acute oral toxicity : 100 mg/kg - Acute dermal toxicity : 300 mg/kg				

Date	Country	Organisation	Type of Organisation	Comment number
02.04.2020	Germany		MemberState	3
Comment received				
The Austrian CA proposes to change the current Annex VI entry from Acute Tox. 4 (H302, 312, 332) to Acute Tox. 3 (H301, H311) and Acute Tox. 2 (H330). The proposal for Acute Tox. oral classification (Cat. 3, H301) is based on a WoE approach. Based on the lowest LD50 (Schmidt et al.1974) used for classification an ATE value of 220 mg/kg bw is indicated. We agree with Acute Tox. 3 (H301) classification as well as an oral ATE of 220 mg/kg bw. The proposal for Acute Tox. dermal classification (Cat.3, H311) is based on one available study similar to OECD TG 402. LD50 of 768 mg/kg bw is reported. We agree with Acute Tox. 3 (H311) classification as well as a dermal ATE of 768 mg/kg bw.				

The proposal for Acute Tox. inhalative classification (Cat.2, H330) is based on a guideline- and GLP-conform study, which results in a LC50 of 1.15 mg/L (4 h exposure).

The German CA agrees with Acute Tox. 2 (H330) classification as well as an inhalative ATE of 1.15 mg/L.

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	4
Comment received				
FR agrees with the proposal of the DS for these endpoints.				

Date	Country	Organisation	Type of Organisation	Comment number
02.04.2020	Germany		MemberState	5
Comment received				
The Austrian CA proposes to add classification as Skin Corr. 1B (H314) to Annex VI. The proposal for Skin Corr. classification (Cat 1B, H314) is based on one study similar to OECD TG 404, which reports necrosis 24 h after start of exposure (3 min or 1h) in 2 of 2 animals tested. Furthermore, necrosis as well as severe erythema and moderate edema were observed in a Draize test after 4h exposure. Another skin irritation study with an exposure duration of 24h showed heavy necrosis after 24h. The German CA agrees with Skin Corr. 1B (H314) classification.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	6
Comment received				
FR agrees with the proposal of the DS for these endpoints.				

Date	Country	Organisation	Type of Organisation	Comment number
02.04.2020	Germany		MemberState	7
Comment received				
The Austrian CA proposes to add classification as Eye Dam. 1 (H318) to Annex VI. Two studies are available for the evaluation of Eye Dam. classification, whereby one study is similar to OECD TG 405. Severe effects in the eyes of rabbits such as conjunctivae chemosis and necrosis, cornea ulceration, cornea opacity were observed. However, due to limited reporting, no final conclusion can be drawn based on the documented scoring. The proposed classification of Di-n-butylamine as Skin Corr. 1B implicitly entails a classification as Eye Dam. according to Regulation (EC) No 1272/2008 "Skin corrosive substances shall be considered as leading to serious eye damage (Category 1)". In conclusion, the German CA agrees with Eye Dam. 1 (H318) classification.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
02.04.2020	Germany		MemberState	8
Comment received				
The Austrian CA proposes to add classification as STOT SE 3 (H335) to Annex VI. The proposal for STOT SE 3 is based on one study in rats equivalent to OECD TG 403. This study determined a LC50 of 1.15 mg/L (4 h exposure) and observed transient effects (reduced respiratory rate, abnormal respiratory movement, gasping). During the observation period, previously exposed rats showed abnormal breathing, lethargy, ataxia, prone posture and intermittent convulsions till day 2 with normal appearance on day 3. Tissue changes were not investigated. No further animal tests are available to be used as part of weight of evidence evaluation and no human data is reported to apply the Criteria for respiratory tract irritation (3.8.2.2.1. of Regulation (EC) No 1272/2008,). On the basis of limited data available and taking into account the substance properties as Skin Corr. 1B and Acute Tox. inhalative Cat. 2, the described effects on the respiratory system seem to be associated with the aforementioned irritating properties. However, the available acute toxicity data is not sufficient to conclude on respiratory tract irritation. In addition, "a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation and so the additional Category 3 is considered to be superfluous" according to the CLP guidance (ECHA, 2017). The proposed "classification as acutely toxic and corrosive is considered to cover and communicate the specific toxicological effect(s) adequately" (CLP Guidance, ECHA, 2017). In conclusion, the German CA does not agree with STOT SE 3 (H335) classification.				

Date	Country	Organisation	Type of Organisation	Comment number
03.04.2020	Germany	BASF SE	Company-Manufacturer	9
Comment received				
Please see the attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment 202003_Comments on CLH report_111-92-2.docx				

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	10
Comment received				
FR agrees with the proposal of the DS for these endpoints.				

PUBLIC ATTACHMENTS
1. 202003_Comments on CLH report_111-92-2.docx [Please refer to comment No. 9]