Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

triethylamine

EC Number: 204-469-4
CAS Number: 121-44-8

CLH-O-0000007001-91-01/F

Adopted

10 June 2021

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. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: triethylamine
CAS number: 121-44-8
EC number: 204-469-4
Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2020	Germany		MemberState	1
Comment received				
Please delete the statement "not applicable", which is given for the purity in table 2 of the report. Instead we would prefer a purity of 100 % as the ideal substance should be evaluated.				
Dossier Submitter's Response				
No amendments in the original document are done at this stage of the process. However, it can be confirmed that the dossier refers to the pure substance triethylamine.				
RAC's response				
Noted				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2020	Germany		MemberState	2
Comment received				
The Austrian CA proposes to change the current Annex VI entry from Acute Tox. 4 (H312, H332) to Acute Tox. 3 (H311, H331). The proposal for Acute Tox. dermal classification (Cat. 3, H311) is based on a WoE approach with three available studies of limited reliability. LD50 values of 420 mg/kg bw, 580 mg/kg bw and a range from 200 - 2000 mg/kg bw were reported. The large dose spacing of one study (200 - 2000 mg/kg bw) is considered to not contradict the other results with regard to classification. The consistency of the results is given. We agree with Acute Tox. 3 (H311) classification as well as a dermal ATE of 420 mg/kg bw.				

The proposal for Acute Tox. (inhalation) classification (Cat.3, H331) is based on one study judged to be reliable without restrictions resulting in LC50 (1h): 14.5 mg/L and therefore an ATE of 7.2 mg/L. Several additional studies judged to be not reliable are available. We agree that Acute Tox. 3 (H331) is warranted. Acute Tox. oral classification (Cat.4, H302) is warranted with an acute toxicity point estimate of 500 mg/kg bw.
Dossier Submitter's Response
Thank you for your support.
RAC's response
RAC has taken note of your comments.

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	3
Comment received				
Acute toxicity by oral route: None of the available studies is reliable due to insufficient level of details and/or methodological deficiencies. Most of the studies are performed with the substance in dilution. Thus, could you please confirm that the LD50 are expressed as mg of substance and not mg of solution? All LD50, except one in mouse (without any details on the protocol and results), are in the range of Category 4. Therefore, we can agree with the classification proposal based on the dataset of very low quality. In this context, FR agrees that the generic ATE of 500 mg/kg is appropriate. Acute toxicity by dermal route: All LD50 are in the range of Category 3. However, it is not clear why an ATE of 420 mg/kg was chosen since all studies are rated with Klimisch score of 3. In this context, the generic ATE of 300 mg/kg seems more appropriate. Acute toxicity by inhalation: We agree with the proposal as category 3 with an ATE of 7.2 mg/L.				
Dossier Submitter's Response				
Acute toxicity by oral route: Thank you for your support of Category 4 for acute oral toxicity. The available information in the study reports is very limited but the given LD_{50} values can be read as mg substance/kg bw. Acute toxicity by dermal route: The ATE was chosen based on the lowest LD_{50} value derived from a study. However, due to a limited reliability of the studies, also a generic ATE of 300 mg/kg (CLP regulation, Table 3.1.2) can be followed. Acute toxicity by inhalation: Thank you for your support.				
RAC's response				
RAC has taken note of your comments. RAC agrees that for acute toxicity by dermal route, the generic ATE of 300 mg/kg seems more appropriate.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2020	Germany		MemberState	4
Comment received				
The Austrian CA proposes to add classification as Eye Dam 1 (H318) to Annex VI. Several available studies judged to be reliable with restrictions indicate severe irreversible effects on eyes. Furthermore, triethylamine is classified as Skin Corr. 1A and therefore "shall be considered as leading to serious eye damage (Category 1)" according to Regulation (EC) No 1272/2008. The German CA agrees with classification as Eye Dam 1 (H318).				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
RAC has taken note of your comments.				

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2020	France		MemberState	5
Comment received				
Eye damage/ eye irritation: We agree that the substance fulfils criteria for classification as Eye Dam. 1: based on the studies presented in the CLH report but also implicit as the substance is already classified for Skin Corrosion. In this context, even if justified, this classification will not be indicated in the label.				
Dossier Submitter's Response				
Thank you for your support. The correct labelling is given in Table 6 of the CLH Dossier.				
RAC's response				
RAC has taken note of your comments.				