**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: 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. | | | | |

**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).<br><br>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.<br><br>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.<br><br>Acute Tox. oral classification (Cat.4, H302) is warranted with an acute toxicity point estimate of 500 mg/kg bw. | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 23.03.2020 | France | | MemberState | 3 |
| Comment received | | | | |
| Acute toxicity by oral route:<br>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.

**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.<br><br>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.<br><br>The German CA agrees with classification as Eye Dam 1 (H318). | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 23.03.2020 | France | | MemberState | 5 |
| Comment received | | | | |
| Eye damage/ eye irritation:<br>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. | | | | |