

## COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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**Last data extracted on 21.07.2020**

**Substance name: Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane**

**CAS number: -**

**EC number: -**

**Dossier submitter: Norway**

### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	1
Comment received				
The DE CA supports the proposed classification as Muta. 2 (H341) and Repr. 1B (H360F). No EC-number is mentioned in the CLH report. According to the ECHA dissemination site the EC number of 701-135-4 is assorted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.07.2020	France		MemberState	2
Comment received				
<p>In the context of our national priority work for identifying the working plan on classification in 2019, we assessed a substance named: "1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with (chloromethyl)oxirane" (CAS number 30499-70-8; EC number 608-489-8). <a href="https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.111.042">https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.111.042</a></p> <p>After exchanges with ECHA, it was found that it is the same substance as "Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane", which is the substance of interest here.</p> <p>Both consist on the same final UVCB substance obtained by 2 different synthesis ways.</p> <p>In addition, according to ECHA website, "Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane" is associated with EC n°701-135-4 and CAS n°30499-70-8.</p> <p>Therefore, we are of the opinion that it is important to specify EC/CAS numbers in the classification entry to avoid confusion on the identity of the substance, and consequently</p>				

possible misclassification.

## MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	3
Comment received				
The DE CA supports the proposed classification as Muta. 2 based on positive results obtained in a valid in vivo somatic cell genotoxicity test (Comet Assay, OECD TG 489) supported by positive results from in vitro mutagenicity assays.				

Date	Country	Organisation	Type of Organisation	Comment number
02.07.2020	France		MemberState	4
Comment received				
Based on the positive effects in somatic cells in mammals in vivo (comet assay), supported by positive results from 3 in vitro tests (Ames test, chromosomal aberration study in mammalian cells and gene mutation study in mammalian cells), we agree with the proposal of classification Muta. 2.				

## TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	5
Comment received				
The DE CA supports the proposed classification as Repr. 1B (H360F) based on clear evidence from valid experimental studies (OECD TG 422) with rats showing severe effects on male fertility in the absence of relevant systemic toxicity.				

Date	Country	Organisation	Type of Organisation	Comment number
02.07.2020	France		MemberState	6
Comment received				
Data provide clear evidence of an adverse effect on male fertility in the absence of other toxic effects. Although the underlying mode of action is unclear, the data do not allow ruling out the relevance of this effect for humans. Thus, we agree with the proposal of classification in Category 1B, H360F.				
Although no developmental effects were observed in the available studies, only doses without any toxic effects were tested. In the absence of relevant developmental toxicity studies, we agree that no classification can be proposed.				

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Sweden		MemberState	7
Comment received				
The Swedish CA agrees with the proposed classification as Repr. 1B, H360F for adverse effects on fertility, expressed as impaired male rat fertility in the absence of marked general toxicity.				

Minor comment on section 10.10.4: We consider that information on the PNDT study performed according to OECD TG 414 in rats that is briefly mentioned in section 10.10.5 and available in Annex I to the CLH-report should have been presented in tabular form (table 15) as well to facilitate a transparent assessment of developmental toxicity.