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 17.01.2023

Substance name: 2,3-epoxypropyl o-tolyl ether
CAS number: 2210-79-9
EC number: 218-645-3
Dossier submitter: Denmark

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
12.01.2023	France		MemberState	1
Comment received				
Page 5 mentions that the substance has a chiral atom and shows stereochemistry. Do you have the ratio of the stereoisomer? Could you please specify if the impurities can contribute to the proposed classification of the substance (concentration, notified and harmonised classification)?				

Date	Country	Organisation	Type of Organisation	Comment number
10.01.2023	Germany		MemberState	2
Comment received				
SID and phys chem: In chapter 1.2 of the report a typical concentration in table 2 and two impurities in table 3 are stated. If this information is confidential, please transfer it to a confidential annex. Further, the stated impurities seem to not impact the classification of 2,3-epoxypropyl o-tolyl ether and the proposed classification applies to the main constituent. In that case, the impurities should be deleted (instead of a transfer to a confidential annex) because they are not relevant.				

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
10.01.2023	Germany		MemberState	3
Comment received				
We agree with the dossier submitter's proposal for classification of 2,3-epoxypropyl o-tolyl ether (EPOTE) as a skin sensitiser category 1A, H317. The results of the LLNA showed a dose-response relationship of EPOTE, when considering the stimulation index (SI) (0.5, 1, 2.5 % corresponding to a SI of 1.58, 2.09, 6.34). At the highest dose tested, the SI amounts to 6.34, justifying classification of EPOTE as a potential skin sensitizer. In addition, the determined estimated concentration three (EC3) amounts to 1.3 % and justifies the classification of EPOTE as a skin sensitizer subcategory 1A. The test substance used had a purity of ca. 90 %, the impurities were not characterised and the dose calculation was not adjusted to purity.				

The proposed subcategorisation in Skin Sens. 1A can be supported. However, it is worth noting that the relevant LLNA test was performed with a 90 % pure substance and it is not clear whether the results obtained can be attributed to the 90 % constituent (2,3-epoxypropyl o-tolyl ether EC 218-645-3) or the impurity(-ies).

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
12.01.2023	France		MemberState	4
Comment received				
Skin sensitization: FR agrees with the proposal of subcategorization Skin Sens. 1A on the basis of the recent and reliable LLNA test (2018) that displays an EC3 value ≤ 2% and as the other animal studies and the human data available do not contradict this result. Based on the EC3 value of 1.3% the substance potency should be considered as strong, therefore the generic concentration limit of 0.1% (w/v) is supported (table 3.9 of CLP guidance).				