Committee for Risk Assessment

RAC

Annex 3

Records

of the targeted public consultation following the submission of an unpublished acute toxicity study in *Daphnia magna* that would potentially change the classification proposal for hazards to the aquatic environment

1-isopropyl-4-methylbenzene; p-cymene

EC Number: 202-796-7
CAS Number: 99-87-6

CLH-O-0000001412-86-273/F

Adopted

15 March 2019

ANNEX 3 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 1-ISOPROPYL-4-METHYLBENZENE; P-CYMENE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

The proposal for the harmonised classification and labelling (CLH) of (1-isopropyl-4-methylbenzene; p-cymene, EC 202-796-7; CAS 99-87-6) was submitted by the The Netherlands and was subject to a public consultation, from 21/05/2018 to 20/07/2018. The comments received by that date are compiled in Annex 2 to the opinion.

During the public consultation, the lead registrant of p-cymene under the REACH Regulation indicated the availability of an unpublished acute toxicity study in *Daphnia magna* (Hill, 2018) that would potentially change the classification proposal for hazards to the aquatic environment. The study is included in the REACH registration dossier update which is not yet disseminated on the ECHA website. Therefore, it is provided in the form of a robust study summary in IUCLID format. A target consultation was launched from 28/01/2019 to 11/02/2019 and the comments received are listed below.

Substance name: 1-isopropyl-4-methylbenzene; p-cymene
EC number: 202-796-7
CAS number: 99-87-6
Dossier submitter: The Netherlands

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
11.02.2019	United Kingdom		MemberState	1
Comment received				
1-isopropyl-4-methylbenzene; p-cymene (EC 202-796-7; CAS 99-87-6) We agree the new acute toxicity to Daphnia magna study is reliable and should be considered for hazard classification. One minor point for clarification is the solvent concentration. Considering this new data would result in no Aquatic Acute classification.				
RAC's response				
Thank you for the support. The solvent concentration is not known.				

Date	Country	Organisation	Type of Organisation	Comment number
08.02.2019	Germany		MemberState	2
Comment received				
A valid study on acute daphnia toxicity of p-Cymene from 2018 was submitted. Therein an EC50 (48 h) of 3.7 mg / L (measured) was determined. It is not plausible why a solubilizer (DMF; without indication of the concentration used) was used in the test at a water solubility of the substance of 23 mg / L. Therefore it is the opinion of the DE CA that the QSAR calculation of the acute invertebrate toxicity against Mysida (EC50 = 0.327 mg / L) should remain the ERV for the classification as acute hazardous to the aquatic environment (H400) due to acute toxicity at < 1mg / L.				
RAC's response				
The use of DMF is allowed according to the Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. OECD Environmental Health and Safety Publication. Series on Testing and Assessment. No. 23. Paris 2000. The test report does				

not give information on the concentration of DMF used and has no justification of the use included. Although the water solubility of p-cymene is 23 mg/L in the water solubility test it can be much lower in the aquatic toxicity test media. It is said in the test report that water solubility is immiscible. A solvent control has also been included in the test regime. DMF has also been used in one of the two *Daphnia* tests on alpha-terpinene. RAC sees no reason to doubt the results of this new *Daphnia* study.