Summary report of the 35th PBT Expert Group meeting

11 December 2023

SUMMARY REPORT OF THE 35th PBT EXPERT GROUP MEETING

The 35th PBT Expert Group (PBT EG) meeting was held remotely on 21-22 November in Helsinki. PBT EG members provided advice on the assessment of one CoRAP substance, one dossier evaluation case and one substance with SVHC intention. The outcomes of the substance discussions are listed in the table below. In addition to the substance discussions, persistence assessment approaches on Concawe hydrocarbon UVCBs was discussed.

39 participants representing 16 Member States, Norway, Switzerland and 5 accredited stakeholder organisations (CEFIC, Concawe, CropLife Europe, ECETOC and EEB) participated.

Main outcomes of the substance discussions

Closed session

- EC 217-496-1; 1,1,1,3,5,5,5-heptamethyltrisiloxane (H-L3) (SVHC intention; assessed by NO): Read across from source substance L3 (EC 203-497-4) was discussed. Due to differences in hydrolysis rate of the source and target substance, some EG members supported data generation on the substance (H-L3).

- EC 258-649-2; dibenzylbenzene, ar-methyl derivative (dossier evaluation, assessed by ECHA): Persistence, bioaccumulation and toxicity of the UVCB substance with five constituent groups was discussed. Based on the available information it was considered that two of the constituent groups, dibenzyl toluene isomers and benzylphenylmethyl toluene isomers, would meet at least the B and T (environment) criteria. Conclusion was based on structural similarity, physico-chemical properties, BCF > 2000 in fish supported by QSAR predictions and NOEC < 0.01 mg/L in fish and invertebrates supported by QSAR predictions. The half-life of 2,5-dibenzyltoluene constituent was > 40 days in surface water. In conclusion, the substance was considered to meet at least the PBT criteria based on information on the 2,5-dibenzyltoluene constituent.

Open session

- EC 203-492-7; Hexamethyldisiloxane (L2) (CoRAP 2013, assessed by NO): Reliability of the OECD TG 210 study conducted with the substance was discussed. Elements discussed included late initiation of exposure, increased length of fish in a solvent control, unclarity with observed effects on appearance and behaviour etc. Concern on the late initiation of the study was acknowledged as it may have resulted in the lack of exposure during early sensitive life stages of tested fish.

General PBT assessment related guidance and approach development topics

Results of the comparison of experimental physicochemical data with COSMOtherm predictions was presented by Dr. Juliane Glüge, ETH Zürich, Switzerland. The quality of the data submitted by the registrants is very variable, certain ranges show values (compared to the COSMOtherm values) that are systematically too low or too high. This can be problematic, for example, as log K_{OW} is used as indicator for the bioaccumulation potential. Predictions of physicochemical properties including octanol-water partition coefficient for more than 4400 neutral organic substances registered under REACH were published.

The Persistence Assessment Tool (PAT) demonstration of the newly published tool was provided by Christopher Hughes, Environmental Chemistry and Toxicology, Ricardo. This software tool provides support to practitioners in the evaluation of persistence under regulatory frameworks. It provides guidance and structure to evaluate data quality, and a quantitative weight-of-evidence methodology to increase consistency, transparency and robustness of assessments.

Substances discussed at the 35th PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
NO	217-496-1	1,1,1,3,5,5,5-heptamethyltrisiloxane (H-L3)	Testing needed	Closed	
ECHA	258-649-2	dibenzylbenzene, ar-methyl derivative	PBT	Closed	
NO	203-492-7	Hexamethyldisiloxane (L2)	Refine assessment	Open	2013