

**SUMMARY REPORT OF THE 36<sup>th</sup> PBT EXPERT GROUP MEETING**

The 36<sup>th</sup> PBT Expert Group (PBT EG) meeting took place in Helsinki on 16-17 April 2024. PBT EG members provided advice on the assessment of three CoRAP substances, and one substance with SVHC intention. PBT EG members supported the assessment outcome of two CoRAP substances, perfluamine as vPvB and an organothiophosphate substance as PBT. PBT EG members advised on further testing to support the bioaccumulation assessment of the third CoRAP substance, linear siloxane L6. For the linear siloxane L3, PBT EG members agreed that there is sufficient evidence to support a vPvB conclusion. The outcomes of the substance discussions are listed in the table below.

In addition to the substance discussions, learnings from SVHC cases with bioaccumulation assessment relying on toxicokinetic information in air-breathing organisms and use of QSAR predictions in the PBT- assessment was presented. ECHA provided a short overview of the CLH process and an update of the status of the CLP Guidance on new hazard classes (PBT/vPvB and PMT/vPvM). It's foreseen that the guidance will be published in 2024.

35 participants representing 14 Member States, Norway, Switzerland, Commission and 5 accredited stakeholder organisations (CEFIC, Concawe, CropLife Europe, ECETOC and EEB) participated.

**Main outcomes of the substance discussions****Closed session**

- EC 203-497-4; Octamethyltrisiloxane (SVHC intention; assessed by NO): The substance (L3) belongs to the group of linear siloxanes. The PBT EG supported the vPvB conclusion. vP conclusion was based on the OECD TG 308 study resulting in a half-life of > 180 days. Bioaccumulation potential was confirmed in both aquatic and dietary OECD TG 305 studies with resulting  $BCF_{kgL}$ 's > 5000. Growth correction and lipid correction for decreasing fish weight and lipid content (negative growth) was discussed.

**Open session**

- EC 206-420-2; perfluamine (CoRAP 2020, assessed by BE): Based on the refined P assessment as recommended in the 25<sup>th</sup> PBT EG meeting, the PBT EG supported the vP conclusion. The assessment was based, among others, on the fact that perfluoroalkyl moieties strongly resist degradation, the substance has high intrinsic thermodynamic stability and also C-N bond in this kind of structure is known to resist degradation. It was noted that comparison with the similar PFAS substance would further strengthen the conclusion. Information on bioaccumulation potential including e.g. half-life > 40 days in fish and  $BCF_{kgL}$  > 5000, provides evidence on vB properties.
- EC 209-909-9; O,O,O-triphenyl phosphorothioate (CoRAP 2016, assessed by NL): Based on results of newly conducted OECD TG 309 and OECD TG 210 studies, the PBT EG supported the vP and the T conclusions. Furthermore, while acknowledging a number of shortcomings of available bioaccumulation in fish study, potentially leading to underestimation of the bioaccumulation potential, the PBT EG confirmed the general agreement reached in the 13<sup>th</sup> PBT EG meeting by supporting B

3 May 2024

conclusion for the substance. Overall, the PBT EG supported the PBT conclusion.

- EC 203-499-5; Tetradecamethylhexasiloxane (CoRAP 2024, assessed by ES): Grouping approach on linear siloxanes, namely L2, L3, L4, L5 and L6 supports the conclusion that degradation half-life of L6 is above vP criteria. The need for further testing to clarify bioaccumulation and toxicity concern was discussed. Use of the same grouping and benchmarking approach taking into account the possible limited uptake of the substance in biota was examined. It was considered that further bioaccumulation testing via dietary exposure would help to clarify the bioaccumulation potential. However, it was also noted that taking into account the low reliability of an estimated uptake rate constant, grouping approach and a trend analysis of depuration rate constants could already provide adequate information on bioaccumulation potential. It was also recommended to further explore the toxicity to sediment organisms and mammals.

### **Learnings from previous PBT assessments**

ECHA presented its recent experience in using toxicokinetic information addressing the bioaccumulation concern in air breathing species. The presentation included a short overview of the tiered assessment approach described in the recently updated ECHA Guidance, Chapter R.11: PBT assessment, as well as practical advice on the interpretation of information derived from OECD TG 417 toxicokinetic studies. Case examples of substances that bioaccumulate in air-breathers but not in aquatic species, such as bis(4-chlorophenyl) sulphone (BCPS) and several perfluorinated substances, were presented. These examples confirm the importance of also considering bioaccumulation potential in air-breathers.

### **General PBT assessment related guidance and approach development topics**

ECHA is planning to set up a new bioaccumulation working group under the PBT EG umbrella to further explore the use of fish *in vitro* clearance assay methods in aquatic bioaccumulation assessment. This informal group would consist of experts from Member States, academia, industry and CROs. The aim is to prepare a technical report with recommendations on the use of the *in vitro* assays for aquatic bioaccumulation assessment.

ECHA presented results of a comparison of recently submitted and curated data on ready biodegradability, bioaccumulation and long-term fish toxicity with QSAR predictions by EpiSuite™, VEGA QSAR, CATALOGIC and iSafeRat. It was observed that combination of BIOWIN models recommended in ECHA Guidance on IR&CSA, Chapter R.11 predicts well the degradation potential, that the BCF model with zero biotransformation rate was conservative regarding the BCFs of the aqueous exposure studies in all cases, and that many tested substances fall outside the applicability domain of chronic/long-term aquatic species toxicity models.

3 May 2024

**Substances discussed at the 36<sup>th</sup> PBT EG meeting:**

MS	EC number	Substance Name	Outcome	Session	CoRAP year
NO	203-497-4	Octamethyltrisiloxane	vPvB	Closed	
BE	206-420-2	perfluamine	vPvB	Open	2020
NL	209-909-9	O,O,O-triphenyl phosphorothioate	PBT	Open	2016
ES	203-499-5	Tetradecamethylhexasiloxane	Testing needed	Open	2024