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HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

1,1’-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (BTBPE)

EC No 253-692-3

CAS No 37853-59-1

Country: Switzerland

Dated: 20 December 2022

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1. HAZARD SUBJECT TO ASSESSMENT

1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (BTBPE) was originally selected for hazard assessment in order to clarify suspected hazard properties:

PBT/vPvB

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	**Tick box**
According to the authority's assessment the substance does not have PBT/vPvB properties based on the currently available information	
According to the authority's assessment the substance has PBT/vPvB properties.	×
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING[1]

Persistence: BTBPE was shown to be not readily biodegradable. Further tests in mesocosms showed that BTBPE had negligible degradation in the sediment phase in a water–sediment mesocosms study and that it was persistent in soil amended with biosolids. The latter study was run over three years and the BTBPE concentrations were found to be stable over the whole study period. Benchmarking of the results using available information on persistence of the studied substances including POP-BDEs supported the conclusion of this study. This proves that the half-life of BTBPE in soil is higher than the threshold of 120 days for persistent chemicals and also higher than the threshold of 180 days for very persistent chemicals. Hence, BTBPE fulfils the criteria for P/vP.

Bioaccumulation: The only measured bioconcentration factors for BTBPE are between 5 and 57. However, the test duration was most probably too short considering the high log K_{OW}. Moreover, the exposure concentrations in the test were higher than the water solubility of BTBPE. The reliability of these data is therefore highly questionable. The main evidence for the bioaccumulation of BTBPE is the study of Tomy *et al.* (2007). The calculated biomagnification factor for rainbow trout is questionable due to discrepancies in the presented data. However, the measured depuration rate of 0.0128±0.002 day^{-1} is unaffected by the inconsistencies. Using the 13 models from the OECD BCF Estimation Tool and the depuration rate, it is concluded that BTBPE is very bioaccumulative. There are further indications from field studies that BTBPE is able to undergo biomagnification and trophic magnification, although several field studies have some shortcomings that may impact their validity.

Toxicity: The available acute toxicity studies indicate no acute toxicity of BTBPE to fish. However, these test are not meaningful, because chemicals with an octanol–water partition coefficient greater (K_{OW}) than 10^6 are not expected to reach sufficiently high internal concentrations for exerting effects within the test duration of acute tests with fish and invertebrates, even though they might be intrinsically toxic (Kwon *et al.*, 2016). Studies with chronic aqueous exposure are lacking. A dietary exposure study showed that a BTBPE

[1] Assessments of PBT properties are based on Annex XIII to the REACH Regulation.

concentration of 605±167 µg/g lipid in the feed impacted the transcription of more than 30 genes in juvenile rainbow trout, but no adverse effects were seen in the fish.

In conclusion, BTBPE is considered to meet the vPvB criteria of REACH Annex III.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not viewed as a commitment by the authority. Any commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
RMOA	01/2022	Spain
SVHC	01/2022	Spain