HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

A mixture of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide]

EC No 420-470-4

CAS No -

Member State(s): Spain

Dated: 6 July 2023

Disclaimer:

1. HAZARD SUBJECT TO ASSESSMENT

A mixture of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide] 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.	X

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

3. BASIS FOR REASONING[1]

The substance is a UVCB consisting of salts of calcium hydroxide with reaction products of alkylphenol, methylamine and formaldehyde. The main components are oligomers with two, three, four or more alkylphenol groups connected by alkylamine bridges (i.e. dimers, trimers, tetramers etc.). After the start of the PBT assessment by the evaluating authority, the registrant has inactivated the registration dossier of the substance as it fulfils the definition of a polymer and has registered the reactants of the substance instead to fulfill the registration obligations related to the polymeric substance.

Based on the assessment of the authority, the main fractions of the polymeric substance screen potentially P/vP with the monomers and dimers screening potentially B/vB, too. No final conclusion on the PBT/vPvB properties can be drawn based on the available information. Furthermore, there is some uncertainty on the composition of the polymeric substance, and hence, a comprehensive PBT assessment covering all the relevant constituents cannot be performed currently.

However, as the polymeric substance has no longer an active registration, no further information can be requested. The registered reactants do not have a PBT/vPvB concern. Therefore, no follow-up work is proposed for the polymeric substance at present.

<u>Persistence:</u>

No experimental data on abiotic degradation of the substance is available. Based on the

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

structure of the constituents hydrolysis is not expected. AOPWIN predicts low half-lives for the reaction with OH-radicals for example constituents but due to the low volatility of the constituents, phototransformation in air is not expected to be a significant degradation route.

Two ready biodegradation tests (OECD 301B and 301A) with the UVCB substance, which resulted in 0-4 % degradation after 28 days, are available in the inactivated registration dossier. However, the ready biodegradation tests are not considered applicable for the PBT assessment as the substance is a UVCB and the degradation of the different constituents can differ.

BIOWIN QSAR models were performed for example constituents of monomers, dimers, trimers and tetramers. Based on the BIOWIN predictions, the dimers, trimers and tetramers screen potentially P/vP. Depending on the level of branching of the alkylchain, the BIOWIN results of the monomers also fulfil the screening criteria or they are borderline cases for meeting the screening criteria as indicated in ECHA Guidance R.11. It is noted that the branching and length of the alkyl substitution groups of the phenols can vary which may affect the degradability, e.g. monomers with more branched alkyl chain are expected to have slower degradation.

Bioaccumulation

Log Kow values in the range of 4.8-8.1 were determined in an HPLC study included in the inactivated registration dossier. Since the substance is a complex UVCB it is not possible to know to which constituents/constituent groups the peaks detected in the HPLC study corresponded to.

The log Kow values predicted by KOWWIN and Chemicalize QSAR models for the example monomers are above 4.5 and fulfil the screening criteria for B/vB. The predicted log Kow values of the different (non-salt) trimers and tetramers are well above 10 and also the molecular weight and size of these types of constituents are high which could indicate limited uptake. The predicted log Kow of the dimer is also above 10 but this type of constituents are not as big and bulky as the trimers and tetramers and they could potentially be taken up more easily by the organisms.

BCFBAF QSAR model predicts BCF values above 2000 L/Kg for the example monomers based on the log Kow regression method and Arnot-Gobas method when assuming zero biotransformation but low BCF (<100) based on the Arnot-Gobas method when including biotransformation estimation. For the dimer, trimer and tetramer constituents the QSAR model predicts low BCFs (<10), which was expected due to their very high predicted log Kow values.

In a fish dietary bioaccumulation study included in the inactivated registration dossier, low BMF value (0.0037) is reported but on the other hand slow depuration of the test substance was observed (growth corrected depuration half-life 0.119 d^{-1}). This could indicate bioaccumulation potential. However, as the test substance was a solution of the UVCB substance with a dilution oil and the results were determined for the whole test substance, it is not possible to conclude on the bioaccumulation potential of individual constituents/constituent groups. Also the reliability of the study cannot be assessed due to lack of detailed information. Nevertheless, the study raises concern on potential bioaccumulation potential of at least some of the constituents of the UVCB substance and/or of the dilution oil.

Toxicity

The UVCB substance is not classified as Carcinogenic Cat 1A or 1B, Mutagenic Cat 1A or 1B, Toxic to reproduction cat 1A, 1B or 2, STOT-RE cat 1, cat 2. No reliable data on the ecotoxicity is available for the UVCB substance.

It is not possible to conclude whether the different constituents fulfil the criteria for T.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

No follow up action is required at present. However, if the registration dossier of the polymeric substance is reactivated in the future, it should be re-evaluated whether further information on PBT/vPvB properties of some of the constituents is needed.