HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

(ethoxymethoxy)cyclododecane

EC No 261-332-1

CAS No 58567-11-6

Member State(s): Finland

Dated: 24 June 2015

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1. HAZARD SUBJECT TO ASSESSMENT

The substance (ethoxymethoxy)cyclododecane 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]

3.1 Assessment of PBT/vPvB properties – comparison with the criteria of Annex XIII

3.2 Persistence

The substance is not readily biodegradable based on an OECD 301 B test (Measured biodegradation < 5 % after 28 days) and an OECD 301 C test (biodegradation 0 % (BOD) and 3 - 4 % (GC) after 28 days). Thus the P screening criterion is fulfilled and the substance is considered as potentially P.

3.3 Bioaccumulation

The Episuite BCFBAF predictions based on a log Kow values of 5.4 are between 1689 - 13 980 depending on the used model. It is noted that BCF values exceeding the vB criterion are only predicted when no biotransformation is expected.

Steady-state BCF values (690 and 729 (lipid corrected)) measured in a 28-day flow-through bioconcentration study in Carp in accordance with OECD 305 test guideline are below the B criteria[2]. The study has some weaknesses, as it measured only uptake and possible growth dilution could not be fully assessed due to lacking data on fish weights. However, it is noted, that there is no method for correcting steady-state BCF values for growth dilution. Growth dilution is relevant especially for the depuration phase. It is considered unlikely that correction

[1] Assessments of PBT properties are based on Annex XIII to the REACH Regulation.
[2] CERI 2004. Bioconcentration flow through Fish Test, OECD 301. Test no. 2004143. 31.8.2014. Study code 44216

for growth dilution would increase the measured BCF-values to such extent that the B/vB criteria would be exceeded. Therefore, based on the experimental BCF values the substance does not fulfil the B/vB criteria.

The substance is structurally similar to cyclododecane. A mean BCF value of 13 700 has been measured in carp for cyclododecane indicating that cyclododecane meets the B/vB criteria. In addition, cyclododecane is potentially P as it is not readily biodegradable.[3] Therefore, the possibility that EMCDD could be biodegraded to cyclododecane was investigated by EAWAG Aquatic Research Biocatalysis/Biodegradation Database[4]. Cyclododecane is not identified in the predicted pathways. Neither have completely cyclic structures (without any functional groups attached) been identified in studies with other non-aromatic cyclic structures, for instance dodecylcyclohexane.[5] Therefore, the formation of cyclododecane as a relevant metabolite is considered unlikely.

3.4 Toxicity

3.4.1 Fulfilment of the T criterion based on human health classification:

- Carcinogenic Cat 1A or 1B: not classified
- Mutagenic Cat 1A or 1B: not classified
- Toxic to reproduction cat 1A, 1B or 2: not classified
- STOT-RE cat 1, cat 2: not classified

A testing proposal for pre-natal developmental toxicity study has been submitted.

3.4.2 Fulfilment of the T criterion based on ecotoxicity data:

The following EC50 values have been derived from short term toxicity tests: Er50 = 53 mg/l and > 2 mg/l (algae); EC50 = 1.6 mg/l (*Daphnia magna*), EL50 = 1.9 mg/l (zebra fish) and LC50 = 0.77 mg/l (Japanese rice-fish). The T screening criteria of 0.1 mg/l is thus not fulfilled.

3.5 Summary and overall conclusions on the PBT, vPvB properties

Based on the experimental BCF values the substance does not fulfil the B/vB criteria.
The formation of a potential PBT/vPvB-substance, cyclododecane, is considered unlikely based on predicted metabolic pathways. Therefore, the substance is not considered PBT/vPvB based on the available information.

[3] Annex XV dossier 2008. http://www.echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/3537/term?searchname=Cyclododecane&searchecnumber=206-033-9
[4] http://eawag-bbd.ethz.ch/predict/
[5] Koma, D., Sakashita, Y., Kubota,K., Fujii, Y., Hasumi, F., Chung, S.Y., Kubo; M. 2005. Degradation pathways of cyclic alkanes in Rhodococcus sp. NDKK48. Appl Microbiol Biotechnol (2005) 66: 92–99.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indicate a preliminary timetable, for any follow-up actions proposed. Please delete the whole section in case the outcome is the first option (substance deemed not to have PBT/ED properties). Where the Authority has identified further follow-up actions but does not wish to continue working on the substance, this should be indicated here.

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**
e.g. RMOA	Month / Year	Member State Authority/ECHA