HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Diundecyl phthalate, branched and linear (DIUP)

EC No 287-401-6

CAS No 85507-79-5

Member State(s): Denmark

Dated: 20 December 2019

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1. HAZARD SUBJECT TO ASSESSMENT

DIUP 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.	**X**
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
DIUP is not expected to undergo significant abiotic degradation (based on predicted information and distribution modelling). The major route of degradation is therefore expected to be biotic. Two readily biodegradation studies are available for DIUP with one showing readily biodegradability and the other one being just below the cut-of criteria of >60 %. DIUP is therefore not persistent in surface water. However, some uncertainty remains with regard to the sediment compartment since slow degradation is observed for other phthalates (e.g. DEHP) and DIUP could therefore potentially be P/vP in sediment

Bioaccumulation
DIUP is concluded not to be B or vB. This is based on a combination of the following information:

- A dietary bioaccumulation study in fish showing a fast tissue elimination half-life
- QSAR predictions indicating a low potential for bioaccumulation.
- Consideration on structural features of DIUP.
- Information from other phthalate esters of which none of the tested substances are displaying high bioaccumulation potential in fish.

Toxicity
Toxicity has not been assess since the substance is concluded not to meet the criteria for P and B.

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