# HAZARD ASSESSMENT OUTCOME DOCUMENT

EC No.: 271-089-3

for

# 1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (DTDP)

EC No 271-089-3 CAS No 68515-47-9

**Member State(s):** Denmark

Dated: 20 December 2019

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# 1. HAZARD SUBJECT TO ASSESSMENT

DTDP was originally selected for hazard assessment in order to clarify suspected hazard properties:

EC No.: 271-089-3

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<sup>1</sup>

#### **Persistence**

The registered substance 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.

DTDP is *not readily biodegradable*. When applying expert judgement and taking all available information into account it seems unlikely that the substance will persist in the environment under most environmental conditions. This is based on the results from the two biodegradation screening studies, available information on other phthalate esters and expected microbial degradation of the two ester groups in the molecule. The rate of biodegradation may, however, be rather low due to strong sorption potential (high hydrophobicity) which may make the availability of the substance low to degrading microorganisms. Based on borderline results in Biowin and results from DEHP, DTDP could therefore potentially be P/vP in sediment.

The degradation product (a representative mono phthalate ester) is predicted to be rapidly biodegradable. This is supported by test data on a structural analogue. Therefore, this degradation product is concluded to *not* meet the P criterion.

#### **Bioaccumulation**

Based on a dietary study with a constituent of the registered substance, QSAR estimates, the high log Kow and considerations of biotransformation rates the substance is concluded not to meet the criteria for B or vB.

### **Toxicity**

Not assessed as DTDP does not meet the criteria for P and B.

<sup>&</sup>lt;sup>1</sup> Assessments of PBT properties are based on Annex XIII to the REACH Regulation.