

HAZARD ASSESSMENT OUTCOME DOCUMENT

for

**3,7,11,15-tetramethylhexadec-1-en-3-ol
(Isophytol)**

EC No 208-008-8

CAS No 505-32-8

Member State(s): Germany

Dated: 22 April 2021

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1. HAZARD SUBJECT TO ASSESSMENT

Isophytol (EC 208-008-8) 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 REASONING¹

Persistence

Isophytol is expected to undergo rapid biodegradation in the environment. Based on a weight-of-evidence, it was concluded that the substance did not screen for P/vP. Three experimental studies on ready biodegradability showed that the mineralisation was $\geq 60\%$. Results from three BIOWIN calculations for isophytol did not yield a clear indication. In addition, data from two similar alcohols have been also shown to biodegrade in ready biodegradation assays and they support the overall conclusion for the substance.

Bioaccumulation

Isophytol did not screen as potential P/vP, and therefore the potential for bioaccumulation was not assessed.

Toxicity

Even though the substance did not screen as potential P/vP the Toxicity was assessed. Isophytol showed acute toxicity to aquatic invertebrates and due to its properties, it might be highly toxic for aquatic organisms over longer exposure periods. Therefore, the Toxicity cannot be concluded and further evaluation is needed.

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