HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

2-(4-tert-butylbenzyl)propionaldehyde

EC No 201-289-8

CAS No 80-54-6

Member State(s): Sweden

Dated: 13 May 2016

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1. HAZARD SUBJECT TO ASSESSMENT

2-(4-tert-butylbenzyl)propionaldehyde 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: Available studies show that 2-(4-tert-butylbenzyl)propionaldehyde (Lysmeral) has a slow hydrolysis rate but is prone to oxidation. Calculations indicate that Lysmeral will be photodegraded in the atmosphere with a calculated half-life of 11.66 hours. The available screening tests for biodegradation shows that Lysmeral fulfils the criteria for being ready biodegradable and therefore does not fulfil the P criterion.

Bioaccumulation: Lysmeral has an estimated log Kow of 4.2 - 4.735. The value of 4.735 obtained in a slow stirring test according to OECD guideline 123 is considered to be the most reliable estimation, thus the screening B-criterion of log K_{ow}>4.5 is met. No experimental BCF studies with fish have been carried out. The BCF for aquatic organisms was calculated with BCFBAF v.3.00 and v 3.01 which gave BCF values between 274.3 L/kg and 618 (regression method) depending on logKow-value used. The Arnot-Gobas method gave a BCF (upper trophic) of 1274 when the highest log Kow (4.7) was used as input in the calculation.

Despite the absence of experimental BCF data the available information indicates that the substance may not be bioaccumulative to the extent that the B-criterion is fulfilled. However, as the screening B-criterion is met and in the absence of experimental BCF studies in fish Lysmeral must be considered to potentially fulfil the B-criterion of Reach.

Toxicity: The T-criterion is fulfilled based on Lysmeral being classified as Repro cat 2.

In conclusion, Lysmeral is considered not to meet the PBT/vPvB criteria of Reach Annex XIII.

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