HAZARD ASSESSMENT OUTCOME DOCUMENT

for

2,6-di-tert-butylphenol EC No 204-884-0 CAS No 128-39-2

Member State(s): Belgium

Dated: 30 March 2015

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1. HAZARD SUBJECT TO ASSESSMENT

2,6-di-tert-butylphenol 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	Х
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

2,6-di-*tert*-butylphenol may meet the definitive P and vP criteria. The parent compound is not readily biodegradable and results from simulation tests are not available. However, it is reasonable to expect that 2,6-di-*tert*-butylphenol is oxidized in aquatic media and possibly the transformation products do biodegrade to a relevant extent. Further testing would be needed to examine the rate of abiotic and biological degradation and the identity of the transformation products that are formed in relevant quantities. However, considering the conclusion on the bioaccumulation potential of 2,6-di-*tert*-butylphenol, such testing is not deemed necessary for the PBT-assessment.

Bioaccumulation

2,6-di-*tert*-butylphenol does not fulfil the definitive B criterion. Both experimental and predicted BCF-values are well below the cut-off value for bioaccumulation for aquatic organims as given in Annex XIII of REACH. This conclusion applies for the parent compound and it is reasonable to expect that also the potential transformation products do not meet the definitive B-criteria.

Toxicity and ecotoxicity

- Carcinogenic Cat 1A or 1B: no harmonized classification
- Mutagenic Cat 1A or 1B: no harmonized classification

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

- EC No. 204-884-0
- Toxic to reproduction cat 1A, 1B or 2: no harmonized classification
- STOT-RE cat 1, cat 2: no harmonized classification

Regarding chronic aquatic toxicity only a test on algae is available for 2,6-di-*tert*-butylphenol. According to this test the ecotox T-criterion is not met. However, long-term tests on fish or invertebrates are not available and therefore a definitive conclusion regarding the fulfilment of the T property cannot be drawn. Acute tests on 2,6-di-*tert*-butylphenol and the 2,4-analogue point out that the screening criterion for ecotox T is not met. Considering the opinion on the bioaccumulation potential of 2,6-di-*tert*-butylphenol, further testing of the T-property is not deemed necessary for the PBT-assessment.

Conclusion

2,6-di-*tert*-butylphenol is not considered to be a PBT substance as the substance does not meet the definitive B-criterion. Definitive conclusions on P & T-properties cannot be drawn but further testing is not deemed necessary for the purpose of the PBT-assessment. This conclusion applies to the parent compound and there is no indication that transformation products are PBT.