

**HAZARD ASSESSMENT
OUTCOME DOCUMENT**

for

o-(p-isocyanatobenzyl)phenyl isocyanate

EC No 227-534-9

CAS No 5873-54-1

Member State(s): Belgium

Dated: 13 July 2015

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1. HAZARD SUBJECT TO ASSESSMENT

o-(p-isocyanatobenzyl)phenyl isocyanate 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 REASONING¹

Persistence

It is demonstrated that hydrolysis of the parent compound 2,4'-MDI is the main transformation process taking place after release to the environment. Hydrolysis occurs readily and the half-life in heterogeneous medium for oligomeric MDI is estimated at ca. 20 hours. So one may conclude that the parent compound 2,4'-MDI is not P.

The main transformation products resulting from hydrolysis are the corresponding urea compounds. In a first instance 2,4'-MDA and the corresponding monourea is formed but as hydrolysis goes on longer urea chains are formed and the stable end products are inert and insoluble polyureas with high molecular weights. Based on this analysis it is appropriate to conclude that the oligomeric urea compounds are also not P and that only the polymeric urea forms probably meet the P criterion. A potential stable degradation product of 2,4'-MDI is 2,4'-MDA. Based on test results with 4,4'-MDA, 2,4'-MDA should be considered as potentially P.

Bioaccumulation

Because of the ready hydrolysis of the substance 2,4'-MDI in the environment it is not possible and not very relevant to determine whether 2,4'-MDI would meet the B-criterion (BCF

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

> 2000 l/kg).

In a study with radiolabelled 4,4'-MDI, BCF-values up to 200 l/kg are found. It should be noted that this value reflects the bioconcentration of water soluble hydrolysis products which includes 2,4'-diaminodiphenylmethane and low molecular weight ureas. This observation supports the statement that 2,4'-MDI, 2,4'-MDA and the oligomeric urea compounds do not meet the B-criterion. Also in a mesocosm study carried out with polymeric MDI, no MDI could be detected in fish which confirms that 2,4'-MDI and its transformation products are unlikely to be bioaccumulative.

It should also be noted that the transformation products that are (v)P, i.e. the polyurea compounds are high molecular weight compounds and therefore it is very unlikely that these compounds would show bioaccumulation potential.

Based on the measured BCF and log K_{ow} -values for 4,4'-MDA, one may conclude that also the potential degradation product 2,4'-MDA does not meet the definitive B-criterion.

Toxicity

Fulfillment of the T criterion based on human health classification:

- Carcinogenic Cat 1A or 1B: no harmonized C & L in this category
- Mutagenic Cat 1A or 1B: no harmonized C & L in this category
- Toxic to reproduction cat 1A, 1B or 2: no harmonized C & L in this category
- STOT-RE cat 1, cat 2: harmonized C & L as STOT-RE cat 2 (H373)

Based on the harmonized classification as STOT-RE cat 2, the parent compound 2,4'-MDI meets the T criterion.

Fulfillment of the T criterion based on ecotoxicity data:

Based on the results of the available toxicity tests with aquatic organisms 2,4'-MDI is not identified as T. It should be noted however that all the tests are conducted with polymeric MDI and therefore no definitive conclusion can be drawn in relation to the ecotox T character of both the parent compound 2,4'-MDI and its stable transformation products (polyureas). Available toxicity tests on aquatic organisms with 4,4'-MDA do not indicate that 2,4'-MDA would meet the environmental T-criterion.

Summary and overall conclusions on the PBT, vPvB properties

2,4'-MDI is not considered to be a PBT substance as the parent compound is not P. The parent compound is potentially bioaccumulative but further assessment is deemed not relevant. As the parent compound is classified as STOT RE cat. 2, it meets the T-criterion anyhow.

The relevant transformation products are the corresponding oligomeric and polymeric urea compounds. It is unlikely that the oligomeric urea compounds would meet the P criterion and therefore it is appropriate to state that oligomeric urea does not meet the PBT-criteria. Because of its high molecular weight one can state that polymeric urea shows no bioaccumulation potential and consequently does not meet the PBT-criteria. The degradation product 2,4'-MDA does not meet the B-criterion and consequently is not a PBT substance.