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HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

2,2’-[(3,3’-dichloro[1,1’-biphenyl]-4,4’-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]

EC No 226-939-8

CAS No 5567-15-7

Member State(s): Belgium

Dated: 30 November 2015

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1. HAZARD SUBJECT TO ASSESSMENT

2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide], commonly identified by the trade name Pigment Yellow 83 (PY 83), 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

No experimental information on hydrolysis or photodegradation is available for PY 83. On theoretical grounds one can state that if hydrolysis takes place under environmentally relevant conditions, this would only occur very slowly. Therefore one may state that PY 83 is not transformed abiotically.

In ready biodegradation studies on PY 83 and other similar substances little or no biodegradation was observed (≤ 6 % after 28 days for PY 83). Consequently, with the currently available data PY 83 should be considered as not readily biodegradable. Simulation tests are not conducted and BIOWIN estimations suggest a low potential for biodegradation. Consequently, PY 83 is considered to probably meet the P-criterion and potentially the vP-criterion.

Bioaccumulation

For PY 83 no experimental studies with regard to bioaccumulation are available. For analogous Pigment Yellow substances experimental studies of very low reliability are available, all

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

indicating that these substances are not bioaccumulative.

This conclusion is confirmed and better substantiated by measured and estimated data on relevant physico-chemical properties (log K_{ow}, solubility in octanol and molecular dimensions).

In a series of toxicokinetic studies with mammals, absorption was very low or could not be detected at all, indicating absence of the potential to bioaccumulate in mammals.

Also the absence of chronic toxic effects in mammals in any study with PY 83 and its analogues suggests no bioaccumulative potential.

Therefore one may state that PY 83 does not meet the B (and vB) criterion.

Toxicity

Fulfillment of the T criterion based on human health classification:

- Carcinogenic Cat 1A or 1B: no harmonized classification
- Mutagenic Cat 1A or 1B: no harmonized classification
- Toxic to reproduction cat 1A, 1B or 2: no harmonized classification
- STOT-RE cat 1, cat 2: no harmonized classification

The substance does not fulfil the T-criterion for human health.

Fulfillment of the T criterion based on ecotoxicity data:

Regarding aquatic toxicity a series of studies is available for PY 83 and its Pigment Yellow analogues. All these studies are executed (far) above the water solubility limit. In these studies chronic toxicity is not observed for aquatic invertebrates, so one may state that PY 83 does not meet the ecotoxicity T criterion. Based on the results of the acute aquatic tests also the screening T criterion is not met. Moreover no toxicity is found in long-term studies with sediment and soil organisms.

Therefore it is appropriate to conclude that PY 83 is not T.

Summary and overall conclusions on the PBT, vPvB properties

PY 83 is not considered to be a PBT or vPvB substance as the substance does not meet the B-criterion. PY 83 is considered to probably meet the P-criterion and potentially the vP-criterion but further examination is not deemed necessary in view of the conclusion on B. Further, according to the currently available results, PY 83 does not meet the T criterion, nor for human health nor for the environment.