Kemikalieinspektionen
Swedish Chemicals Agency

HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Retinyl propionate

EC No 230-363-2

CAS No 7069-42-3

Member State(s): Sweden

Dated: 30 March 2015

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Version 1.2

1. HAZARD SUBJECT TO ASSESSMENT

Retinyl propionate 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: With a degradation of 45% in 28 d in a ready biodegradability test according to OECD guideline 301 B retinyl propionate does not meet the criterion for being ready biodegradable and thus potentially fulfils the P/vP-criteria of REACH Annex XIII. However, retinyl propionate is an ester of retinol which degraded to 81% during 28 days of incubation under similar conditions in a test performed according to the same guideline. The ester bond is not considered to be very stable and therefore the degradability of the two substances is not expected to differ much. In addition, Biowin predictions give similar results for the two substances except for Biowin 2 which predicts a higher probability for fast degradation of retinyl propionate than for retinol. This also indicates that retinyl propionate is more degradable than the result of the ready tests shows. It is therefore concluded that retinyl propionate does not fulfil the P/vP criteria of REACH.

Bioaccumulation: Retinyl propionate has an estimated log Kow>4.5. Thus, Retinyl propionate potentially fulfils the B/vB criteria of REACH Annex XIII. However, no experimental bioaccumulation data are available. Retinyl propionate is a form of vitamin A which is essential for vertebrates with several important functions e.g. for growth and development, for the maintenance of the immune system and good vision. Vitamin A also functions as retinoic acid (an irreversibly oxidized form of retinol), which is an important hormone-like growth factor for epithelial and other cells. Vitamin A is regulated by active mechanisms in the body including

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

storage in the liver but is also stored in kidney and fat. Stored vitamin A can cover the need for the vitamin for a couple months in the absence of vitamin A in the food. Retinyl propionate may therefore fulfil the B/vB criterion of REACH.

Toxicity: Retinyl propionate is classified as a Reprotoxicant category 1B and thus, the T-criterion of REACH Annex XIII is fulfilled.

In conclusion: Retinyl propionate does not fulfil the PBT/vPvB criteria of REACH Annex III