



HAZARD ASSESSMENT OUTCOME DOCUMENT

for

Retinol

EC No 200-683-7

CAS No 68-26-8

Member State(s): Sweden

Dated: 30 March 2015

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1. HAZARD SUBJECT TO ASSESSMENT

Retinol 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: Retinol does not fulfil the PBT/vPvB criteria of REACH Annex III. Although not readily biodegradable 81% degradation in 28 days in an OECD 301B study shows that the P/vP-criteria are not met.

Bioaccumulation: Retinol has a high estimated LogKow indicating that the substance has a high potential to bioaccumulate and thus potentially fulfils the B/vB criteria of REACH Annex XIII. However, no experimental bioaccumulation data are available. Retinol (vitamin A) is a vitamin 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 active 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. Retinol may therefore well fulfil the B/vB criterion of REACH.

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

In conclusion, Retinol is considered not to meet the PBT/vPvB criteria of REACH Annex III.

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