



HAZARD ASSESSMENT OUTCOME DOCUMENT

for

Alcohols, lanolin

EC No 232-430-1

CAS No 8027-33-6

Member State(s): Sweden

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1. HAZARD SUBJECT TO ASSESSMENT

Alcohols, lanolin 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

Alcohols, lanolin is an UVCB consisting of a mixture of alcohols derived from the hydrolysis of lanolin. Its main constituents are Cholesterol, Lanosterol, Dihydrolanosterol, Cholesta-3,5-dien-7-one and unidentified long chain- and sterol alcohols. In addition, Desmosterol, Lathosterol, Cerebrosterol, Agnosterol and Dihydroagnosterol has been identified (but not quantified) as constituents of Alcohols lanolin. The constituents with identified structures all fulfil the screening criteria for P/vP based on BIOWIN predictions.

Alcohols, lanolin is not readily biodegradable (39% degradation after 28 days). The study has however been performed at a concentration which is almost three orders of magnitude higher than the water solubility of the main constituents cholesterol and the results indicate that relevant biodegradation is taking place considering the low bioavailability of the substance. However, Alcohols lanolin is a UVCB substance with possibly several 100 constituents and the observed biodegradation may indeed represent the biodegradation of only some constituents.

The main constituent Cholesterol has been shown to be inherently biodegradable (67% degradation in 14 days and 74% in 28 days) in a study according to OECD guideline 302C (modified MITI Test). According to the ECHA guidance chapter R.11 on PBT assessment a level of 70% mineralization (O₂ uptake) must be reached within 14 days, and the log phase should be no longer than 3 days in order for a substance to be regarded as non-persistent. Cholesterol almost achieved the 70%-threshold despite having been tested at a concentration three orders of magnitude higher than its water solubility. The length of the log phase has however not been declared in the registration dossier. In addition, it has been shown that

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

Cholesterol is fully mineralised by a large number of bacterial species including *Rhodococcus*, *Pseudomonas*, *Chrysobacterium*, species of *Mycobacteria* and *Nocardia*.

No information is available for the other known constituents of Alcohols, lanolin. However, given the close structural similarity between Cholesterol and the other identified constituents of Alcohols, lanolin it can be assumed that also Lanosterol, Dihydrolanosterol, Desmosterol, Lathosterol, Cerebrosterol, Agnosterol and Dihydroagnosterol have a degradability comparable to Cholesterol. More so because they all, similar to Cholesterol, have the 3 β - hydroxyl group that is required for the activity of Cholesterol oxidases or 3 β -hydroxysteroid dehydrogenase/isomerases that catalyses the first step in the degradation of Cholesterol. Cholesta-3,5-dien-7-one on the other hand lacks the 3 β - hydroxyl group and may not be oxidised by these enzymes. It has however, been identified as an intermediate when 7-ketocholesterol is degraded by *Pseudomonas aeruginosa*. This bacteria species and several others isolated from soil and sewage sludge have been shown to mineralise 7-ketocholesterol. Cholesta-3,5-dien-7-one is therefore considered to have a degradability comparable to Cholesterol.

The large number of the unidentified constituents that together constitutes ca. 45% of Alcohols, lanolin consists to ca 50% of sterols similar to those identified and 50% long chain aliphatic alcohols (C14-C36). The sterols are assumed to have a similar biodegradability as Cholesterol.

Cholesterol and more so its biohydration product Coprostanol is known to be very recalcitrant to degradation in anaerobic/anoxic sediments. This may also be the case for the other sterols. This is however, not considered to be determinative for the P-assessment of the sterol constituents of Alcohols, lanolin.

Long chain aliphatic alcohols with chain lengths C6 – C22 have been assessed in the OECD SIDS programme. The whole category is considered to show very high levels of biodegradability. For the very long chained alcohols (>C22) no information, neither on their share of the long chain aliphatic alcohol fraction of Alcohols, lanolin nor on their degradability, is available.

Overall, based on the available information the constituents of Alcohols lanolin are not considered to meet the P/vP criteria of Reach annex XIII with a caveat for the fraction (unknown how big) of very long chain alcohols (C>20) for which no information is available.

Bioaccumulation

The constituents of Alcohols lanolin with identified structures all have high predicted log K_{ow}-values (7.61-10.88), which are all above the B-screening log K_{ow} of 4.5 indicating B/vB-properties. However, BCF-predictions of substances with predicted log K_{ow}-values above 8 are associated with large uncertainties.

In the registration dossier for the UVCB Alcohols, lanolin, an OECD 305 (Burri, 2014) biomagnification study on fish for its main constituent, Cholesterol, is used to fill the data requirement for the registered substance. The study resulted in a "Lipid corrected kinetic dietary (BMFKL)" of 4.0470 which is an indication of high bioaccumulation potential. It is worth noticing that the 14 day exposure to food containing 1000 mg cholesterol/kg did not increase the total cholesterol levels in the treated fish, instead they were lower than in the unexposed control fish. This indicates that the high exposure of Cholesterol via the diet in this study decreased the indigenous de novo synthesis of Cholesterol and puts a question mark to the relevance of the measured BMF-value. It is likely that the experimental result obtained for Cholesterol is valid also for the other identified constituents of Alcohols, lanolin, of which some are intermediates in the biosynthesis pathway of Cholesterol from Lanosterol, but no definitive conclusions can be drawn

Dry weight BAF factors from 30 – 217 (dry weight) were measured in earthworms exposed to
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soil amended with dried sewage sludge. However, the worms were also exposed simultaneously to other sterols with similar properties. In soil 23 - 49% of the total measured sterol content was Cholesterol whereas in the worms 87 - 97% of the total sterol content was Cholesterol. This large difference in Cholesterol/total sterol ratio between soil and worms cannot be explained by lipid partitioning since these sterols have very similar Log Kow values and molecular structures. Either Cholesterol is actively taken up by the worm or, more plausible, metabolism in the worm tissue or by the gut microflora leads to the formation of Cholesterol within the worm. Overall, it is not possible to draw any firm conclusions regarding the bioaccumulation of cholesterol in earthworms from this study.

The long chain aliphatic alcohols that constitutes ca 25% of Alcohols, lanolin are not expected to bioaccumulate. Long chain aliphatic alcohols with a chain length from C6-C22 have a low potential for bioaccumulation according to OECD, 2006. Alcohols with longer chain lengths are expected to have lower bioavailability and thus, even lower potential for bioaccumulation.

In summary, the available information is not sufficient to enable a definitive conclusion if any of the constituents of Alcohols, lanolin are bioaccumulative to the extent that they fulfil the B/vB criteria of Reach Annex XIII.

Toxicity

Due to the scarcity of data it is not possible, to conclude on the T criterion based on ecotoxicity data. The human health data does not allow a definitive conclusion on the human T-criterion because there is insufficient information for assessing the effects on fertility of Alcohols, lanolin.

Overall conclusion:

Overall, based on the available information, Alcohols lanolin is not considered to fulfil the PBT/vPvB criteria of Reach annex XIII. The constituents of Alcohols, lanolin are not considered to fulfil the P/vP-criteria, with a caveat for the fraction of very long chain aliphatic alcohols (C>22) for which no information is available. These very long chain aliphatic alcohols are however, considered to have a low bioaccumulation potential and thus not fulfil the B/vB criteria.