HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Rosin, hydrogenated

EC No 266-041-3

CAS No 65977-06-0

Member State(s): Finland

Dated: 30 March 2015

Version 1.2

1. HAZARD SUBJECT TO ASSESSMENT

Rosin, hydrogenated was originally selected for hazard assessment in order to clarify suspected hazard properties:

PBT/vPvB

1. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted has led the assessing Authority to the following conclusions, 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 conclusion is based on the REACH and CLP data as well as other available relevant information.

2. BASIS FOR REASONING[1]

Rosin, hydrogenated is a UVCB substance derived by hydrogenation from rosin. Rosin acids, a class of tricyclic carboxylic acids, are the predominant components of rosin (> 85%). Typical constituents are abietic acid, dehydroabietic acid, isopimaric acid, neoabietic acid and palustric acid. The assessment of Rosin, hydrogenated (CAS 65997-06-0) was conducted together with Rosin (CAS 8050-09-7) and Rosin acids, sodium salts (CAS 61790-51-0) as members of one catefgory. Data have been read across between these substances. The conclusions of the assessment can be applied, in principle, to all category members. Abietic, isopimaric and neoabietic acids were selected as representative structures for which Episuite QSAR predictions were run.

Persistence. In the registration dossiers, results from 13 ready biodegradation tests are available. The test materials used are rosin and rosin acids, their K-, Ca- and Zn- salts and hydrogenated forms of rosin acids. In four tests the substance degraded to the extent that the criteria for ready biodegradation were fulfilled. In two tests, the substance was readily biodegradable, but failed the 10-day window. In six tests, the substance was not readily biodegradable. Of these, in four tests degradation was > 45 %; in two tests degradation was 13.6 % and 0.9 %. In an OECD 302B inherent test, 73.3 % of the substance (rosin, K-salt) degraded within 28 days.

The Episuite Biowin predictions for biodegradation indicate that individual constituents of the substance are not readily biodegradable. However, the results do not allow a screening assignment (P) in accordance with ECHA PBT guidance (R.11) Table R. 11-2.

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

In conclusion it can be stated that no final conclusion on P is possible based on the available data. Nevertheless, taking into account the percentages of degradation in the ready and inherent biodegradation test results, it seems unlikely that the P/vP-criterion would be fulfilled. However, no definitive conclusion can be made based on the available data.

Bioaccumulation. Bioaccumulation studies show BCF-values (23 - 330) clearly below the B/vB criteria[2]. In addition, the studies show that resin acids are metabolised in fish and mussels to conjugates and depurated rapidly (half-lives < 4 days).

QSAR predictions for the representative structures are below the B criterion with the exception of neoabietic acid for which a BCF value just above the B criterion (2017) is predicted by the Arnot-Gobas model (lower trophic, including biotransformation) using a worst-case logD values of 4.62. Furthermore, because the substance occurs in both ionized and unionized forms within the environmentally relevant pH -range, the measured BCF values were normalized to environmentally relevant pH-values. These normalized values exceed the B criteria for two representative structures. It is noted that a lot of uncertainty is related to such normalization and therefore the non-normalised measured BCFs are considered more reliable to represent the whole environmentally relevant pH -range.

Toxicity. In the registration dossiers, an array of acute toxicity tests for fish, aquatic invertebrates (*Daphnia magna*) and algae are available. The lowest EC50 value reported was 1.6 mg/l for *Daphnia magna*. In literature lower levels have been reported. For fish (*Salmo gairdneri*) LC50 values between 0.4 - 1.1 mg/l (Leach and Thakore, 1976; Chung et al. 1979 as cited in Peng et al. 2000) and for *Daphnia magna* 48-hour LC50 values between 0.07 - 1.28 mg/l (Peng et al. 2000).[3] Based on the available data, it can be concluded that EC/LC50 values from acute ecotoxicity tests are generally above the screening criterion of 0.1 mg/l. For one constituent, isopimaric acid, a *Daphnia magna* EC50 value is 0.07 mg/l and below the screening criterion. It is noted that both measured and predicted BCF values for isopimaric acid are below the B criterion even when worst case estimates were used (< 1608). ECOSAR QSAR predictions for individual constituents (abietic, isopimaric and neoabietic acid) show EC/LC50 values above the screening level 0.1 mg/l.

The substance has not been classified as Carcinogenic Cat 1A or 1B; mutagenic Cat 1A or 1B; Toxic to reproduction cat 1A, 1B or 2; STOT-RE cat 1, cat 2.

In conclusion, the substance is not considered to meet the PBT/vPvB criteria based on the available, mainly screening level, information. This conclusion covers the relevant constituents.

[2] Niimi, A. J. and Lee, H.B., 1992. Free and Conjugated concentrations of nine resin acids in rainbow trout (Oncorhynchus mykiss) following waterborne exposure. Environmental Toxicology and Chemistry, Vol. 11, pp. 1403-1407.
Burggraaf S, Langdon AG, Alistair LW, Roper DS. 1996. Accumulation and depuration of resin acids and fichtelite by the freshwater mussel *Hyridella Menziesi*. Environ Toxicol Chem 15(3):369–375.

[3] Peng, G., Roberts, J.C., 2000. Solubility and toxicity of resin acids. Wat. Res. Vol. 34, No. 10, pp. 2779 - 2785.