



HAZARD ASSESSMENT OUTCOME DOCUMENT

for

Rosin, maleated

EC No 232-480-4

CAS No 8050-28-0

Member State(s): Finland

Dated: 30 March 2015

Disclaimer:

The information and views set out in this document are those of the evaluating authority and do not necessarily reflect the position or opinion of the other Member States or ECHA. Neither ECHA nor the evaluating authority nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any formal regulatory activities that ECHA or the Member States may initiate at a later stage. Hazard assessments and their outcomes are compiled on the basis of information available by the date of the publication of the document.

1. HAZARD SUBJECT TO ASSESSMENT

Rosin, maleated 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

Rosin, maleated is an UVCB substance consisting of rosin acids, fumaropimaric acid and maleopimaric acid/anhydride. Fumaropimaric acid, maleopimaric acid and maleopimaric acid anhydride are all three probably in equilibrium with one another, with the equilibrium between acid and anhydride being pH dependant. Rosin, maleated is produced when rosin is reacted with maleic anhydride (or maleic acid, cis-butenedioic acid) or fumaric acid (trans-butenoic acid). For the hazard assessment of the rosin acid constituents please see also the Hazard Outcome document of Rosin (EC 232-475-7).

Persistence. Four ready biodegradability tests are available in the registration dossiers. In three of the tests less than 26 % biodegradation was observed during the test, indicating that the substance is not readily biodegradable. In one of the tests, the substance was readily biodegradable (63 % degradation), but failed the 10-day window. However, as the substance contains both rosin acid constituents as well as fumaropimaric acid and maleopimaric acid/anhydride constituents it is not possible to conclude on the ready biodegradability of the constituents.

Episuite Biowin-model results on maleopimaric acid/anhydride and fumaropimaric acid indicate that these constituents are not readily biodegradable. For maleopimaric acid anhydride the screening assignment is P (Biowin 3 value < 2.2 and Biowin 6 or Biowin 2 probability < 0.5).

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

In conclusion, it can be stated that based on the available information, Rosin, maleated meets the P-screening criterion and is potentially P.

Bioaccumulation. No experimental bioaccumulation data are available for fumaropimaric acid and maleopimaric acid (anhydride) constituents of rosin, maleated. The resin acid constituents of rosin, maleated are not expected to bioaccumulate significantly in aquatic organisms, based on Episuite QSAR predictions and two experimental studies on fish and mussels, showing low BCF values and metabolic transformation to conjugates and rapid depuration². Considering the fact that the adduct compounds (maleopimaric acid (anhydride) and fumaropimaric acid) are larger and more polar molecules than the rosin acids, it could be expected that their potential to bioaccumulate is lower. Direct read-across to the resin acids is, however, not possible for the maleopimaric acid (anhydride)/fumaropimaric acid constituents. Nevertheless, the predicted logD (pH specific logKow value) values for these constituents at environmentally relevant pH values are below the screening criterion 4.5, and the predicted BCF values are low compared to the B criteria. In conclusion, it can be stated that based on the available information, Rosin, maleated does not meet the screening criteria for B/vB.

Toxicity. Only acute ecotoxicity tests are available in the registration dossiers. In the tests (fish, *Daphnia magna* and algae), no effects were observed up to the solubility level of the substance with the exception of one test where an EC50 values for *Daphnia magna* was determined as 22 mg/l. Episuite Ecosar predictions on maleopimaric acid anhydride show EC/LC50 values between 3.6 - 23.7 mg/l and ChV values between 0.152 - 13.7 mg/l. The predictions can be considered as worst case in the sense that they are based on a worst case logD (logKow) prediction. The predicted values should be used with care, as no information on the model performance is available. In conclusion, the T screening criterion (EC50 value < 0.1 mg/l) is not met based on the available information.

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.

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.