Rosin, Hydrogenated Rosin, and their Salts

CATEGORY JUSTIFICATION DOCUMENT

1 CATEGORY DEFINITION AND ITS MEMBERS

This document describes the "Rosin, Hydrogenated Rosin, and their Salts" category and its members as per ECHA guidance R6: QSARs and grouping of chemicals (2008), the ECHA Read-Across Assessment Framework[1], and the specific guidance for UVCBs[2]. Although this format is more applicable to analogue or chemical categories, the main headings of the guidance are included for this UVCB category to ensure consistency in reporting.

Table 1 Category UVCB Members

CAS Number	Registered Substance Name
8050-09-7	Rosin
65997-06-0	Rosin, hydrogenated
65997-05-9	Rosin, oligomers
91081-53-7	Rosin, reaction products with formaldehyde
61790-51-0	Resin acids and Rosin acids, sodium salts
61790-50-9	Resin acids and Rosin acids, potassium salts
92129-53-8	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt
68440-56-2	Resin acids and Rosin acids, magnesium salts
9007-13-0	Resin acids and Rosin acids, calcium salts
68334-35-0	Resin acids and Rosin acids, calcium zinc salts
9008-34-8	Resin acids and Rosin acids, manganese salts
61789-65-9	Resin acids and Rosin acids, aluminum salts
68554-12-1	Resin acids and rosin acids, hydrogenated, calcium salts
1192825-55-0	Resin acids and Rosin acids, dimers, calcium zinc salts
68990-02-3	Resin acids and Rosin acids, hydrogenated, sodium salts
91081-28-6	Resin acids and Rosin acids, reactions with formaldehyde, sodium salts

1.1 Category Definition

1.1.1 Category Hypothesis

The substances within this category consisting of rosin, hydrogenated rosin, and mono-, di-, and tri-valent salts of rosin or hydrogenated rosin. This is a series of structurally related compounds, each of which is present to a greater or lesser extent in every grade of material. The main constituents of all the category members share the same basic chemistry, primarily resin acids, consisting of diterpenic monocarboxylic acids (70 – 100% (ionic or non-ionic)) *[including dehydroabietic acid,*

[1] https://echa.europa.eu/documents/10162/13628/raaf_en.pdf

[2] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

methyldehydroabietic acid (when present), dimers and trimers]; fatty acids; and a neutral fraction. There are no other constituents present at concentrations > 10%. The organic structures of the mono-, di-, and tri-valent salts are identical to the equivalent free acids. There is a high degree of similarity in the constituents of the whole category. It is therefore expected that the substances will act in a very similar manner within biological systems. This is outlined in this document.

1.1.1.1 Brief Manufacturing Process Description

Rosin is a UVCB sub-type 3, where the source is biological (family: *pinaceae*, genus: *pinus*), with subsequent refinement. This process can be either distillation, fractional distillation, or extraction and solvent refining or purification. A batch/continuous process is used, in a partially closed system with a process temperature between 160 and 275 °C and under reduced pressure. Rosin can be further stabilized by catalytic disproportionation.

The hydrogenation of rosin is a continuous process. Molten rosin is fed together with pressurized hydrogen into a reactor filled with an appropriate hydrogenation catalyst. At the end of the reactor the residual hydrogen and the hydrogenated rosin are separated.

The reaction between Rosin and formaldehyde is carried out at elevated in the range of 140 - 200°C in a closed reactor with stirring, over the course of 2 - 6 hours.

Saponification of rosin; hydrogenated rosin; or rosin, reaction products with formaldehyde takes place in closed vessels where the reactions take place below 100°C with rosin (or specified derivative) and the relevant salt.

Oligomerization of rosin starts with Rosin that is molten or alternatively dissolved in a solvent. An acidic catalyst is added and the oligomerization (essentially dimerization) occurs. Once achieved, the solvent (if applicable) and catalyst are removed by distillation. Oligomerization is sometimes followed by a physical treatment to remove neutrals.

1.1.2 Applicability domain (AD) of the category

This category includes rosin and rosin monovalent-, divalent-, and trivalent salts. Members are composed primarily of resin acids, a class of tricyclic carboxylic acids, but also contains minor amounts of dimerized rosin and unsaponifiable matter. The category also includes oligomers of Rosin and Rosin formaldehyde adducts, both of which have higher levels of higher molecular weight dimers and trimers. There are five subcategories, defined in Table 2 to Table 6.

The chemistry of Rosin and its derivatives is highly complex. H4R has produced a reference document on analytical aspects. It also provides an insight into this chemistry. A copy is also given in the registration dossier.

Table 2 Category Constituents – Subcategory: Rosin; Rosin, hydrogenated; and Rosin, oligomers

Constituent Types	Rosin	Rosin, hydrogenated	Rosin, oligomers	Subcategory Boundary Conditions
Abietane type	0.1 – 100	0 – 20	0 – 60	0 – 100
Pimarane and isopimarane types	0 – 80	0 – 30	0 – 50	0 – 80
Labdane type	0 – 80	0 – 15	0 – 15	0 – 80
Fatty acids	0 – 10	-	0 – 10	0 – 10
Dihydro (combined)	0 – 45	10 – 85	0 – 10	0 – 85

Tetrahydro (combined)	0 – 25	0 – 60	0 – 5	0 – 60
Dehydroabietic acid	0 – 70	0 – 30	0 – 40	0 – 70
Neutral fraction (including decarboxylated rosin)	0 – 10	0 – 10	0 – 20	0 – 20
Dimers	0 – 20	0 – 20	5 – 70	0 – 70
Trimers and Higher Oligomers	0 – 15	-	0 – 50	0 – 50

Table 3 Category Constituents – Subcategory: Monovalent Salts of Rosin

Constituent Types	Resin acids and Rosin acids, sodium salts	Resin acids and Rosin acids, potassium salts	Resin Acids and Rosin Acids, hydrogenated sodium salts	Subcategory Boundary Conditions
Abietane type	0.1 – 100	0.1 – 100	0 – 20	0 – 100
Pimarane and isopimarane types	0 – 80	0 – 80	0 – 30	0 – 80
Labdane type	0 – 80	0 – 80	0 – 15	0 – 80
Fatty acids	0 – 10	0 – 10	-	0 – 10
Dihydro (combined)	0 – 45	0 – 45	10 – 85	0 – 85
Tetrahydro (combined)	0 – 25	0 – 25	0 – 60	0 – 60
Dehydroabietic acid	0 – 70	0 – 70	0 – 30	0 – 70
Neutral fraction (including decarboxylated rosin)	0 – 10	0 – 10	0 – 10	0 – 10
Dimers	0 – 20	0 – 20	0 – 20	0 – 20
Trimers and Higher Oligomers	0 – 15	0 – 15	-	0 – 15
Potassium (K) Content	-	7 – 12.0	-	0 – 12.0
Sodium (Na) Content	4 – 7.1	-	0.5 – 7	0 – 7.1

Table 4 Category Constituents – Subcategory: Divalent Salts of Rosin

Constituent Types	Resin acids and Rosin acids, magnesium salts	Resin acids and Rosin acids, calcium salts	Resin acids and Rosin acids, calcium zinc salts	Resin acids and Rosin acids, manganese salts	Resin acids and Rosin acids, Hydrogenated, calcium salts	Resin acids and Rosin acids, dimers, calcium zinc salts	Subcategory Boundary Conditions
Resin Acids	-	-	-	-	-	0 – 90	0 – 90
Abietane type	0.1 – 100	0.1 – 100	0.1 – 100	0.1 – 100	0 – 20	-	0 – 100
Pimarane and isopimarane types	0 – 80	0 – 80	0 – 80	0 – 80	0 – 30	-	0 – 80
Labdane type	0 – 80	0 – 80	0 – 80	0 – 80	0 – 15	-	0 – 80
Fatty acids	0 – 10	0 – 10	0 – 10	0 – 10	-	-	0 – 10
Dihydro (combined)	0 – 45	0 – 45	0 – 45	0 – 45	10 – 85	-	0 – 85
Tetrahydro (combined)	0 – 25	0 – 25	0 – 25	0 – 25	0 – 60	-	0 – 60
Dehydroabietic acid	0 – 70	0 – 70	0 – 70	0 – 70	0 – 30	-	0 – 70
Neutral fraction (including decarboxylated rosin)	0 – 10	0 – 10	0 – 10	0 – 10	0 – 10	0 – 20	0 – 20
Dimers	0 – 20	0 – 20	0 – 20	0 – 20	0 – 20	5 – 70	0 – 70
Trimers and Higher Oligomers	0 – 15	0 – 15	0 – 15	0 – 15	-	0 – 40	0 – 40
Magnesium (Mg) Content	0.5 – 20	-	-	-	-	-	0 – 20
Calcium (Ca) Content	-	1.5 – 6.2	-	-	4.9 – 6.2	-	0 – 6.2
Manganese (Mn) Content	-	-	-	6.6 - 8.3	-	-	0 – 8.3
Zinc (Zn) + Calcium (Ca) Content	-	-	-	-	-	>0 - 10	0 – 10

Table 5 Category Constituents – Subcategory: Trivalent Salts of Rosin

Constituent Types	Resin acids and Rosin acids, Aluminum salts	Subcategory Boundary Conditions
Abietane type	0.1 – 100	0.1 – 100
Pimarane and isopimarane types	0 – 80	0 – 80
Labdane type	0 – 80	0 – 80
Fatty acids	0 – 10	0 – 10
Dihydro (combined)	0 – 45	0 – 45
Tetrahydro (combined)	0 – 25	0 – 25
Dehydroabietic acid	0 – 70	0 – 70
Neutral fraction (including decarboxylated rosin)	0 – 10	0 – 10
Dimers	0 – 20	0 – 20
Trimers and Higher Oligomers	0 – 15	0 – 15
Aluminum (Al) Content	2.3 – 2.9	2.3 – 2.9

Table 6 Category Constituents – Subcategory: Rosin, reaction products with Formaldehyde (and salts)

Constituent Types	Rosin, reaction products with formaldehyde	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	Resin acids and Rosin acids, reaction products with formaldehyde, sodium salts	Subcategory Boundary Conditions
Abietane type	0 – 55	0 – 65	0 – 55	0 – 65
Pimarane and isopimarane types	0 – 35	0 – 35	0 – 35	0 – 35
Labdane type	0 – 30	0 – 30	0 – 30	0 – 30
Fatty acids	0 – 10	0 – 10	0 – 10	0 – 10
Dihydro (combined)	0 – 30	0 – 30	0 – 30	0 – 30
Tetrahydro (combined)	0 – 10	0 – 10	0 – 10	0 – 10
Dehydroabietic acid	0 – 40	0 – 40	0 – 40	0 – 40
Neutral Fraction (including decarboxylated rosin)	0 – 20	0 – 20	0 – 20	0 – 20
Dimers	0 – 25	0 – 25	0 – 25	0 – 25
Trimers and Higher Oligomers	0 – 40	0 – 40	0 – 40	0 – 40
Methyldehydroabietic acid	5 – 40	5 – 40	5 – 40	5 – 40
Potassium (K) Content	-	2 – 10	-	0 – 10
Sodium (Na) Content	-	-	1.5 – 4	0 – 4

1.2 Purity / Impurities

The substances in this category are UVCBs and as such are considered to be 100% pure. The term impurity is not relevant for UVCBs. Often, substances will be described by known constituents present at 10% or greater identified by IUPAC name and EC number/CAS number, indicating typical concentrations and/or concentration ranges. There are no other constituents present at > 10%, and there are no additional constituents present that would change the classification and labelling or the PBT/vPvB status of the substance.

1.2.1 Substances with CLP Implications

Gum Rosin (CAS # 8050-09-7) is classified according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 as "Skin Sensitiser Category 1" and assigns the hazard statement *H317: May cause an allergic skin reaction*. Gum Rosin is also classified *R43: May cause sensitization by skin contact*, according to Annex I to Directive 67/548/EEC.

The monovalent salts are irritating to the eye, whereas the divalent and trivalent salts are not. Results of *in vitro* genotoxicity testing reveal no activity toward microbial or mammalian cells both in the absence and presence of exogenous metabolic activation.

1.2.2 Toxicity Classification Overview

The sensitisation potential of the substances included in this category is well understood and comprises results from three local lymph node assays, twelve Guinea Pig Maximisation Tests and a Buehler test. The results consistently show no evidence of a potential to induce skin sensitisation using methods equivalent or similar to current regulatory guidelines. However, Gum Rosin is currently classified *R43: May cause sensitization by skin contact* according to Annex I to Directive 67/548/EEC. Gum Rosin is also classified according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 as "Skin Sensitiser Category 1" and assigns the hazard statement *H317: May cause an allergic skin reaction*. Subsequent evaluation determined that the single positive study for Gum Rosin was conducted with an oxidized form of the test material. Several esters of Rosin have been tested using similar protocols with similar results. When the Rosin esters were heated beyond specified protocol, the oxidized material caused a positive sensitization response. When the same un-oxidized Rosin esters were re-tested no sensitisation responses were observed. Consequently, the oxidized form of Gum Rosin should be considered a skin Sensitiser. However, the H4R Consortium made a recommendation to declassify non-oxidized Gum Rosin (CAS # 8050-09-7) based on the available evidence. In addition, repeated dose toxicity studies have been conducted on UVCB Rosins and their salts. The data show no evidence of adverse effects on the immune system.

The monovalent salts have been self-classified as irritating to the eye, whereas the divalent and trivalent salts are not ocular irritants.

2 CATEGORY JUSTIFICATION

2.1 Composition

See Table 2 to

Table 6.

2.2 Physico-Chemical

The molecular weight and salt cations of these compounds differ and, therefore, some differences in physico-chemical properties are expected. Available data are summarized in Table 7. All the substances in this category are solids at ambient temperature, with similar densities and vapour pressures. The melting points are lower for the rosins than the salts, but all category members decompose before boiling. The major variation in physicochemical properties between category members is the water solubility. The rosins and divalent salts have low solubility, whilst the monovalent salts are highly soluble in water.

Table 7 Phys-chem data for Category Members of Rosin, hydrogenated rosin, and their salts

	Substance Type / Substance	Physical state	Melting point (°C)	Boiling point (°C)	Density (kg/m³)	Vapour pressure (mbar at 25 °C)	$logK_{ow}$ (unbuffered)	Water solubility (mg/L)
Rosin	Rosin	Solid	66.5 - 93.4	Not available	1034	0.6	3.0 – >6	0.9
	Rosin, hydrogenated	Solid	55.2 - 72.1	Decomposes before boiling	1049	<1.41	2.3 – >6	1.18
	Rosin, oligomers	Solid	90 - 103	360 - >450	1070	2.1×10^{-7}	>6.5	≥2.2
Monovalent salt	Resin acids and Rosin acids, sodium salts	Solid	>255	Decomposes before boiling	1006	0.85	3.0 - 5.8	Miscible
	Resin acids and Rosin acids, potassium salts	Solid	>250 (decomposition temperature)	Decomposes before boiling	1054	0.42	3.1 - 5.9	Miscible
	Resin acids and Rosin acids, hydrogenated, sodium salts	Solid	42	>300	1050	Not available	6.89	7.56
Diva	Resin acids and Rosin acids, calcium salts	Solid	>300	>300	1115	Data waiver – Melting point >300 ºC	3.01	42.6

lentSalts	Resin acids and Rosin acids, magnesium salts	Solid	>265 (decomposition temperature)	Decomposes before boiling	1129	0.071	0.74	65
	Resin acids and Rosin acids, calcium zinc salts	Solid	>223 (decomposition temperature)	Decomposes before boiling	1111	<1.41	1.84	18.2
	Resin acids and rosin acids, hydrogenated, calcium salts	Solid	>165 (decomposition temperature)	Decomposes before boiling	1190	Decomposes without melting	3.7	7.5
	Resin acids and Rosin acids, manganese salts	Solid	>75 (decomposition temperature)	Decomposes before boiling	1430	Decomposes without melting	2.92	1.1
	Resin acids and Rosin acids, dimers, calcium zinc salts	Solid	>165	>300	1088	Not available	3.38	$<1.0 \times 10^{-1}$
TrivalentSalts	Resin acids and Rosin acids, aluminum salts	Solid	>65 (decomposition temperature)	Decomposes before boiling	1180	Decomposes without melting	1.4	6.7
React	Rosin, reaction products with formaldehyde	Solid	31.9 – 66.5	>275	1008	0.282	5.36	8.1

ionproductswithformaldehyde	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	Solid	31 ± 3	>171	1160	4.8×10^{-8}	5.37 – >6.5	≤438
	Resin acids and Rosin acids, reaction products with formaldehyde, sodium salt	Solid	Not available	Not available	Not available	Not available	Not available	Not available

2.3 Environmental

Ready biodegradation studies are available for a number of different category members, covering rosin, monovalent and divalent salts of rosin and hydrogenated variants. Although there is some variation in the amount of degradation demonstrated in these studies, likely to be due to the low solubility of the test items and difficulties with ensuring bioavailability of the test item, the weight of evidence demonstrates that substances in this category are readily biodegradable. An enhanced ready biodegradation study and an inherent biodegradation study are also available for category members, and also indicate that these substances are unlikely to be persistent.

Measured BCF values obtained from a bioaccumulation study with *Oncorhynchus mykiss* are available for nine resin acids (abietic, dehydroabietic, chlorodehydroabietic, dichlorodehydroabietic, neoabietic, pimaric, isopimaric, sandaracopimaric and palustric acids) and these show a range of BCFs between 23 and 129. BCF values in mussels (*Hyridella menziesi*) for the individual resin acids ranged from 110 to 330 L/kg. Resin acids are the main constituents in rosin and rosin salts, and these BCF values are far below the bioaccumulation threshold, therefore rosin and rosin salts are not considered to be bioaccumulative. In addition, QSAR predictions have been conducted for a representative structure of rosin dimers and based on the predictions these constituents are considered to have a low potential for bioaccumulation due to their large molecular size and very high log K_{ow} (log K_{ow} >10), meaning that they are unlikely to be taken up by organisms. Overall, members of the category rosin and rosin salts are not considered to be bioaccumulative.

Acute ecotoxicity results are available for members of the rosin and rosin salts category, covering rosin, monovalent and divalent salts of rosin and hydrogenated variants. There are differences in solubility between category members, with monovalent salts being highly soluble and divalent salts and acids being insoluble. There may therefore be differences in environmental toxicity between category members, as monovalent salts will be more bioavailable. However, the lowest ecotoxicity value for any category member is used to derive the PNECs for all category members as a worst case approach. The lowest LC_{50} value is 1.6 mg/L for *Daphnia magna*, for category member resin acids and rosin acids, hydrogenated, potassium salts.

In addition to the rosin component of the substances, for the salts within the category environmental toxicity may also be affected by the cation (Na, K, Ca, Mg, Zn, Mn or Al). The cations that do not have environmental classifications (Na, K, Ca, Mg and Al) are not considered to contribute to the toxicity of the substances. Some soluble zinc and manganese substances are classified for the environment, therefore these need to be considered in the environmental assessment. There are ecotoxicity data available for resin acids and rosin acids, calcium zinc salts, which indicates that this substance is not toxic at the limit of solubility in an acute study (EL_{50} >100 mg/L for *Daphnia magna*). Based on data for the substance itself, it does not therefore require classification for environmental endpoints.

2.4 Mammalian Toxicology

Based on the molecular weights, chemical structures, and K_{ow} values for Rosins and Rosin salts, this category of substances is expected to be poorly absorbed and minimally toxic. This is confirmed by toxicokinetic information which demonstrates negligible uptake from the gastrointestinal tract. In addition, Rosins and Rosin salts are not acutely toxic, not irritating to skin, and do not induce or elicit allergic skin conditions. The monovalent salts are irritating to the eye, whereas the divalent and trivalent salts are not. Results of *in vitro* genotoxicity testing reveal no activity toward microbial or mammalian cells both in the absence and presence of exogenous metabolic activation.

Several key guideline (OECD 408, 414, 421, & 422) studies that investigated the oral (dietary) repeated dose toxicity potential in rats of Rosin; Rosin, hydrogenated; Rosin, oligomers; and Rosin, reaction products with formaldehyde are available. The results of these studies showed that none satisfy the CLP hazard classification criteria for specific target organ toxicity following repeated oral exposure (STOT RE).

OECD 408:

Three OECD 408 (90 day) studies are available for Cat 1 members; the NOAELs from each are summarized below:

1. Rosin (CAS# 8050-09-7): The systemic toxicity NOAEL was determined to be 5000 ppm (equivalent to a mean achieved dosage of 335.2 mg/kg bw/day for males and 401.2 mg/kg bw/day for females) based on reduced body weight gains in animals of either sex exposed to 7500 ppm.

2. Rosin, reaction products with formaldehyde (CAS# 91081 -53 -7):The NOAEL for systemic toxicity of Rosin, reaction products with formaldehyde was considered to be 3000 ppm (equivalent to mean achieved dosages of approximately 213.1 mg/kg bw/day or 255.2 mg/kg bw/day for males and females, respectively), based on the effects on body weight, body weight gain and, to a lesser extent, food consumption, observed among females exposed to diets containing 7500 ppm of the test material for ninety days.

3. Rosin, hydrogenated (CAS# 65997-06-0): Based on a lack of adverse treatment-related effects observed at the highest concentration tested, the systemic toxicity NOAEL for Rosin, hydrogenated was determined to be ≥6000 ppm for either sex (equivalent to a mean achieved dosage of 334.5 mg/kg bw/day for males and 399.8 mg/kg bw/day for females).

OECD 422:

Five key screening reproductive/developmental toxicity studies (OECD 422) were conducted with Rosin; Rosin, hydrogenated; Rosin oligomers; and Rosin, reaction products with formaldehyde. The NOAELs from each study are summarized below:

1. The reproductive toxicity NOAEL for Tall Oil Rosin was determined to be ≥10000 ppm, the highest concentration tested (Harlan Laboratories Ltd., 2015a).

2. The reproductive toxicity NOAEL for Rosin, hydrogenated was determined to be ≥10000 ppm, the highest concentration tested (Harlan Laboratories Ltd., 2015b).

3. The reproductive toxicity NOEL for Rosin, reaction products with formaldehyde was determined to be ≥10000 ppm, the highest concentration tested (Harlan Laboratories Ltd., 2015c).

4. The reproductive toxicity NOAEL for Gum Rosin was determined to be 5000 ppm, based on a reduction in corpora lutea count followed by a lower number of implantation sites and lower mean litter size observed at the 10000 ppm concentration (Harlan Laboratories Ltd., 2014a).

5. The reproductive toxicity NOAEL for Rosin, oligomers was determined to be 3000 ppm, based on effects on pup body weights observed at the 7500 ppm and 15000 ppm concentration levels (Harlan Laboratories Ltd., 2014b).

OECD 421:

Additionally, one key screening reproductive/developmental (OECD 421) study (Inveresk Research, 2003a) was identified conducted with Rosin. No reproductive effects were observed in this study although there was a slight reduction in litter size and slightly reduced pup weight in high dose animals (10,000 ppm in diet).

OECD 414:

A key pre-natal developmental toxicity study (OECD 414) was conducted with Rosin (Envigo Research Limited, 2017b). *In-utero* survival of the developing conceptus was unaffected by maternal exposure at 7500 ppm, although reduced foetal and placental weights indicated an adverse effect on foetal growth. The absence of any structural defects indicated that development per se was unaffected at this dietary exposure level. The 'No Observed Adverse Effect Level' (NOAEL) for foetal developmental toxicity was considered to be 5000 ppm (equivalent to a mean achieved dosage of 387.2 mg/kg bw/day).

In addition, no gross or microscopic changes in reproductive organs of male or female rats exposed to Rosin; Rosin, hydrogenated; or Rosin, reaction products with formaldehyde in OECD guideline 408 (90 day) repeat exposure studies.

3 CONCLUSIONS FOR CLASSIFICATION & LABELLING, PBT/vPvB

3.1 Classification & Labelling

3.1.1 Physico-chemical Hazard Assessment There are no hazardous properties.

3.1.2 Human Health Hazard Assessment

Rosin (CAS # 8050-09-7) is classified according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 as "Skin Sensitiser Category 1" and assigns the hazard statement H317: May cause an allergic skin reaction. As noted in 1.3.2 above, subsequent evaluation determined that the single positive study for Rosin was conducted with an oxidized form of the test material. When the same un-oxidized Rosin esters were re-tested no sensitisation responses were observed. Consequently, the oxidized form of Rosin should be considered a skin sensitiser. Based on the available evidence, the H4R Consortium made a recommendation to declassify non-oxidized Rosin (CAS # 8050-09-7).

The monovalent salts are irritating to the eye, whereas the divalent and trivalent salts are not. Results of in vitro genotoxicity testing reveal no activity toward microbial or mammalian cells both in the absence and presence of exogenous metabolic activation.

3.1.3 Environmental Hazard Assessment

There are no hazardous properties for classification for the environment.

3.2 Conclusion for PBT/vPVB

Members of the category rosin and rosin salts are not considered to be PBT or vPvB.

PACT assessments were conducted by the Finnish competent authority for category members rosin, rosin, hydrogenated and resin acids and rosin acids, sodium salts (Tukes 2015). The assessments state

that the conclusions can, in principle, be applied to all members of the category. Tukes based their assessment on the available measured data and EPISuite predictions conducted based on abietic, isopimaric and neoabietic acids, as representative structures. The assessments conclude that "…*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*."

Date:	**26th September 2022**
Revised by:	**Mike McMahon**