

# Is Rosin Classifiable as a Skin Sensitiser?

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With respect to the ELoC (equivalent level of concern) substances, these can be identified on a case-by-case basis as substances of very high concern (SVHCs), where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to CMR substances (under Article 57(f) of REACH Regulation). To date the focus has been on substances with sensitising properties and those with specific target organ toxicity – repeated exposure (STOT RE) properties.  
(ECHA website 2016)

The initial autoscreen identified that rosin should be one of the selected substances for evaluation by a Member State Competent Authority on the basis of uses and tonnage.

# CLASSIFICATION IN EU UNDER REACH AND PREDECESSORS

- Rosin (gum rosin) is classified as “**Skin Sensitizer Category 1**” and assigned the hazard statement **H317: May cause an allergic skin reaction** according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.
- This is translated from a list of harmonized classifications and labelling of hazardous substances in Annex I to Directive 67/548/EEC where Gum Rosin is assigned **R43: May cause sensitization by skin contact**.

- With naturally occurring complex mixtures such as colophony [rosin], which *inevitably* contain sensitising oxidation products , these should then (on the basis of sufficient evidence) be classified with **R43 [i.e. as a skin sensitiser]**

Karlberg et al., 1999 (ESCD Working Party on the chemical basis of allergic contact dermatitis)

[if the presence of sensitising oxidation products is inevitable, it will be present in both animal tests and human studies]

*For classification of a substance as a skin sensitiser, evidence shall include any or all of the following:*

- positive data from **patch testing [presumably with uncontaminated test substance]**, normally obtained in more than one dermatology clinic;
- epidemiological studies showing allergic contact dermatitis caused **by the substance**; Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;
- positive data from **appropriate animal studies**;
- positive data from **experimental studies on humans**;
- well documented **episodes** of allergic contact dermatitis, normally obtained in more than one dermatology clinic.

# Rosin

A complex combination derived from wood, especially pine wood.

Composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids.

Includes rosin stabilized by catalytic disproportionation.

[Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB)]

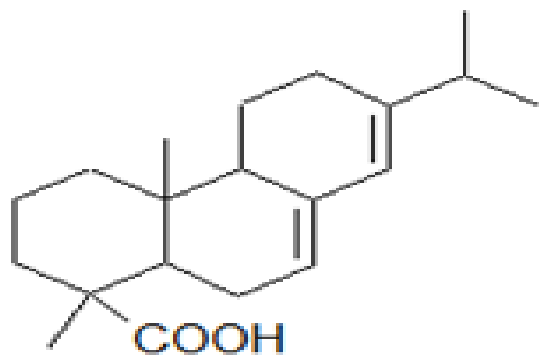
# Rosin

Now agreed by the US EPA under the HPV program and the EU REACH Authority that rosin includes

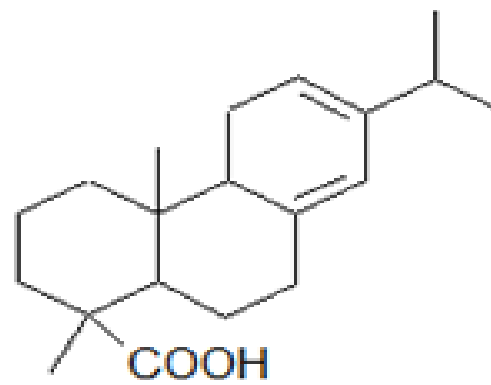
- Gum rosin (CAS 8050-09-7)
- Tall oil rosin (CAS 8052-10-6)
- Rosin acids and resin acids (CAS 73138-82-6)
- Rosin acids and resin acids, tall oil (CAS 94114-23-5)

These different names refer to manufacturing processes, not to chemical/toxicological differences.

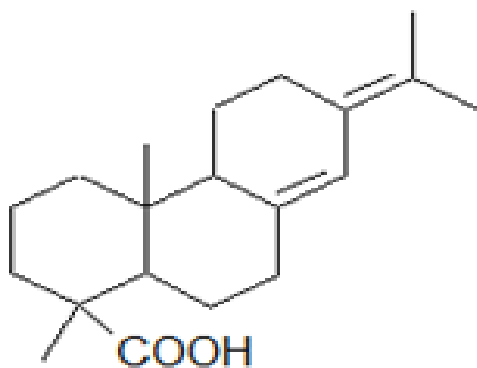
Also rosin includes catalytically disproportionated rosin.  
Wood rosin was not registered.



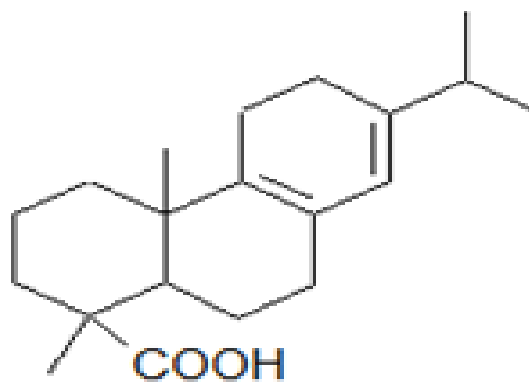
Abietic acid



Levopimaric acid

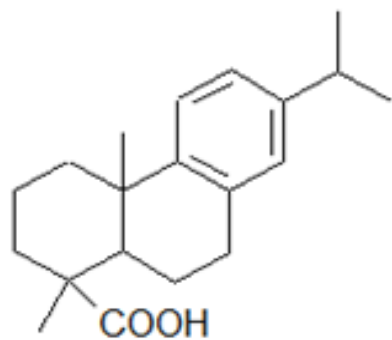


Neoabietic acid

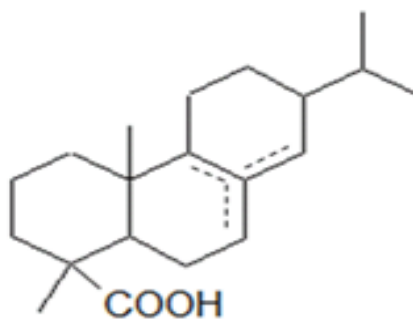


Palustric acid

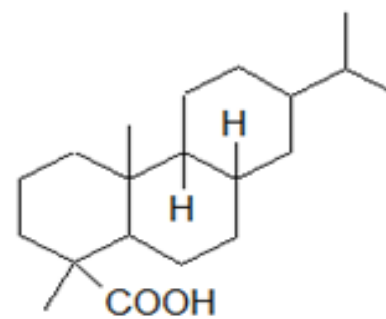




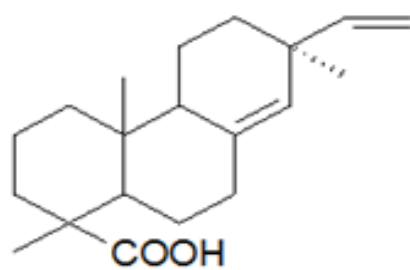
Dehydroabietic acid



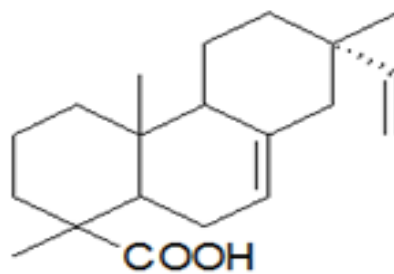
Dihydroabietic acid



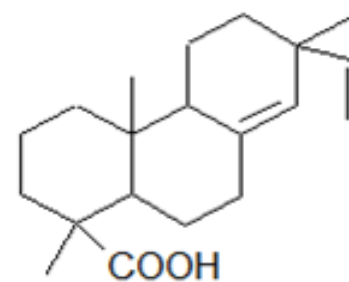
Tetrahydroabietic acid



pimaric acid



isopimaric acid



Sandaraco pimaric acid

- Related substances have been grouped with rosin in both EPA HPV and EU REACH, and therefore tests on these substances are also relevant to the classification of rosin (by 'read across'):

- 001740-19-8 Abietic acid
- 008050-09-7\* Rosin.
- 008052-10-6 Tall oil rosin (now included in CAS 8050-09-7).
- 009007-13-0 Resin acids and Rosin acids, calcium salts
- 009010-69-9 Resin acids and Rosin acids, zinc salts
- 061790-50-9\* Resin acids and Rosin acids, potassium salts
- 061790-51-0\* Resin acids and Rosin acids, sodium salts
- 065997-05-9 Rosin, oligomers
- 065997-06-0\* Rosin, hydrogenated
- 068334-35-0 Resin acids and Rosin acids, calcium zinc salts
- 068648-50-0 Rosin, dimers, calcium salts
- 068990-01-2 Resin acids and Rosin acids, hydrogenated, potassium salts
- 068990-02-3 Resin acids and Rosin acids, hydrogenated, sodium salts
- 070879-76-4 Resin acids and rosin acids, calcium magnesium zinc salts
- 084776-85-2 Resin acids and Rosin acids, tall-oil, potassium salts (now included in CAS 61790-50-9)
- 085409-26-3 Resin acids and Rosin acids, tall-oil, sodium salts (now included in CAS 61790-51-0)

\*These substances were also included in this family in the US HPV program test plan.

- Friends complete adjuvant test
- Cumulative Contact Enhancement Test
- Guinea pig maximisation test
- Mouse local lymph node assay
- Buehler assay

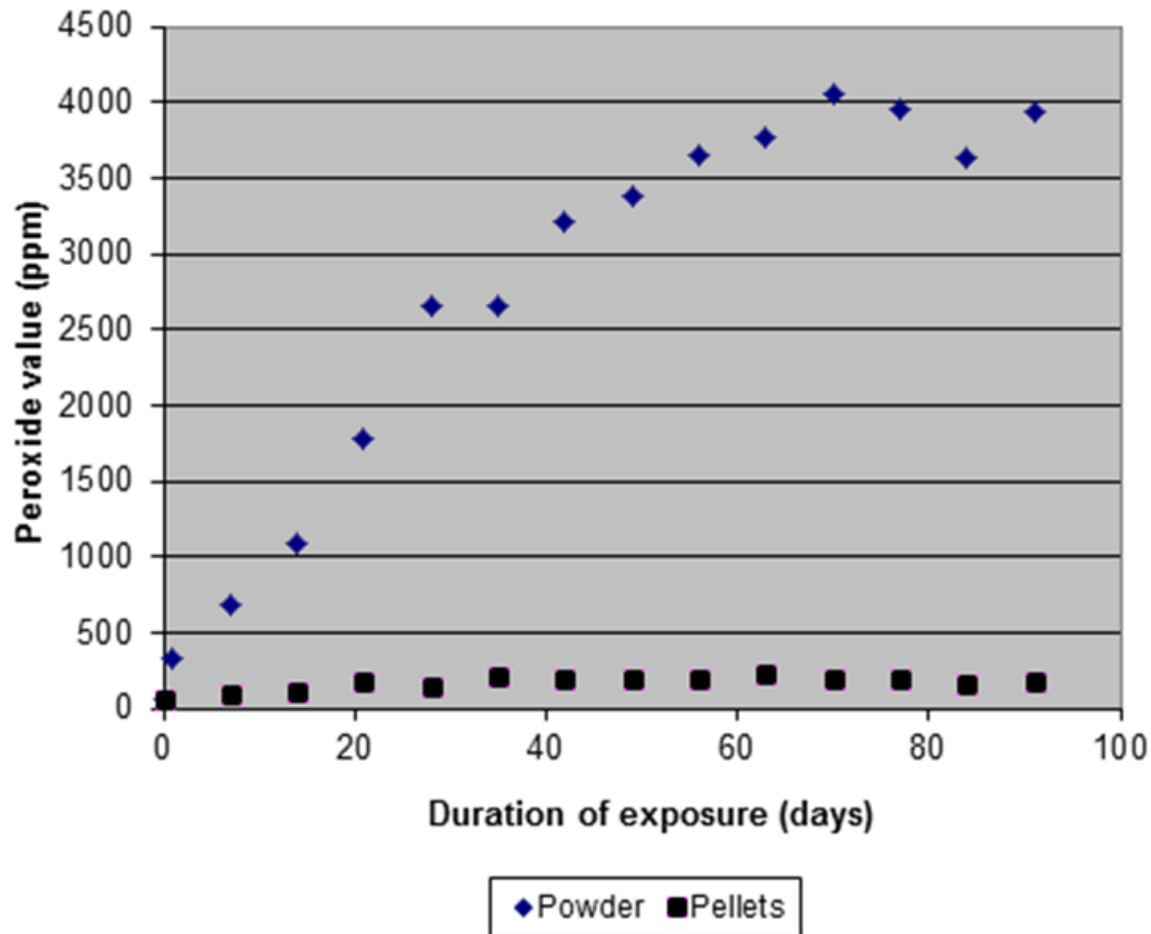
**Table 9: Summary of test results – Rosin, oxidised rosin, disproportionated rosin, hydrogenated rosin and rosin adduct with formaldehyde.**

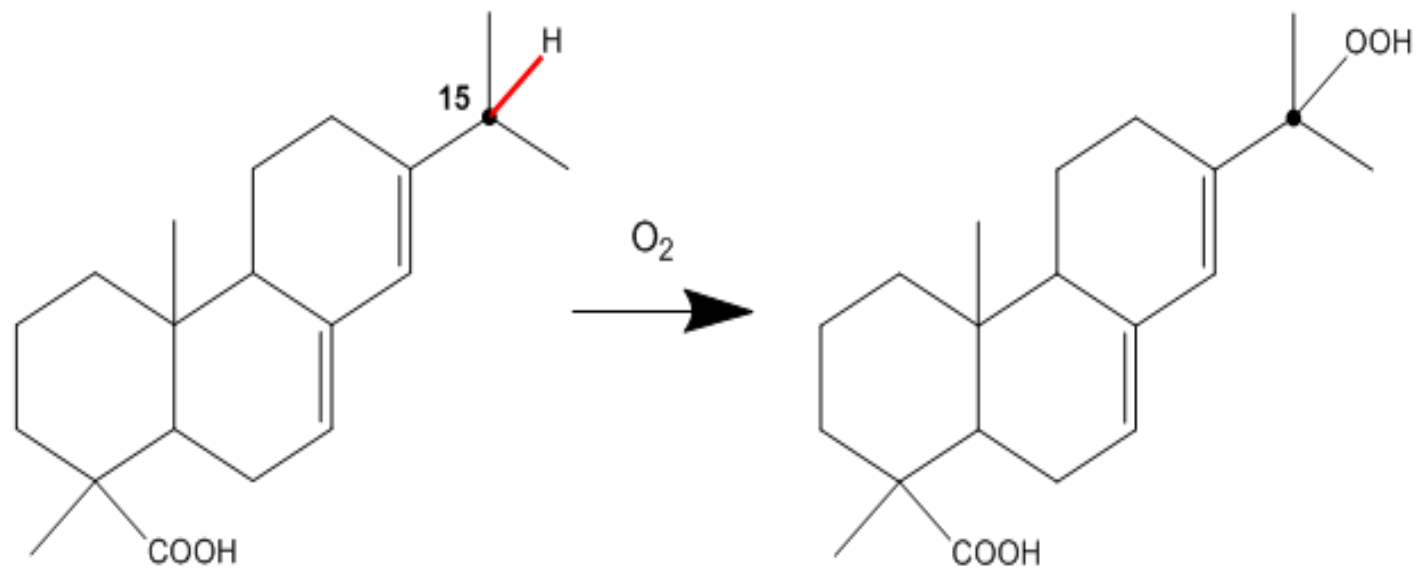
Name	Adjuvant based (*GPMT )	LLNA	Buehler
Rosin	*Negative (9)	Negative	Negative (2)
Naturally oxidised rosin	*Positive (4)	Negative	Negative
Disproportionated rosin	*Negative (3)+	ND	ND
'Superoxidised' rosin	*Negative (1)	ND	ND
Hydrogenated gum rosin	*Negative (1) Negative (2)	ND	ND
Resin acids and rosin acids, potassium salt	ND	Negative	ND
Resin acids and rosin acids, calcium salt	ND	Negative	ND
Rosin, reaction product with formaldehyde	*Negative	ND	Negative

***Table. Typical oxygen absorption of various types of rosin and rosin derivatives (source Kennedy et al., 1989)***

Unmodified rosin	9 %
Partially dimerised rosin	5 %
Polymerised rosin	1 %
Hydrogenated rosin	< 1 %
Pentaerythritol ester of rosin	< 1

# Oxidation rates of pelletised and powdered rosin



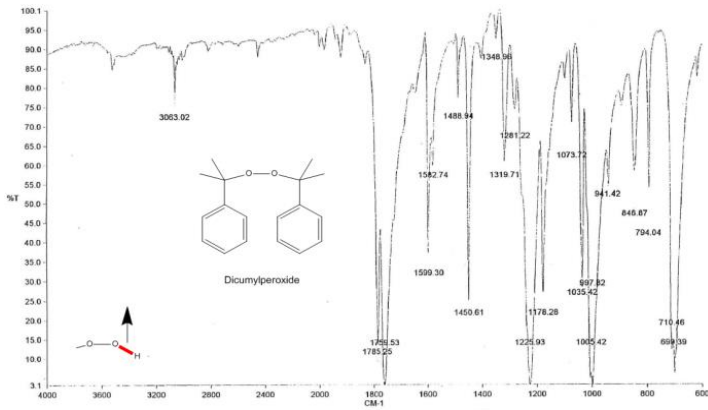
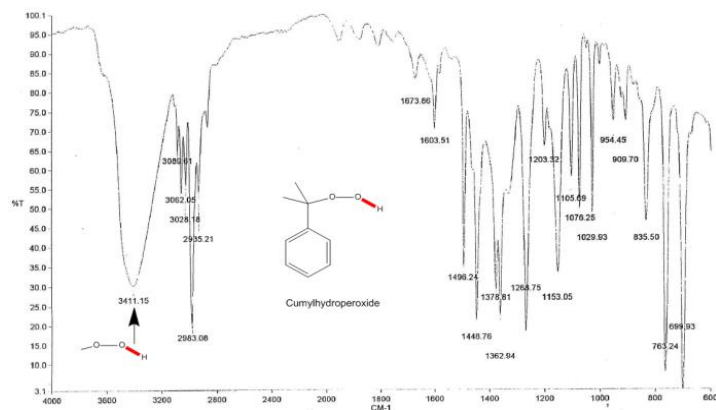


abietic acid

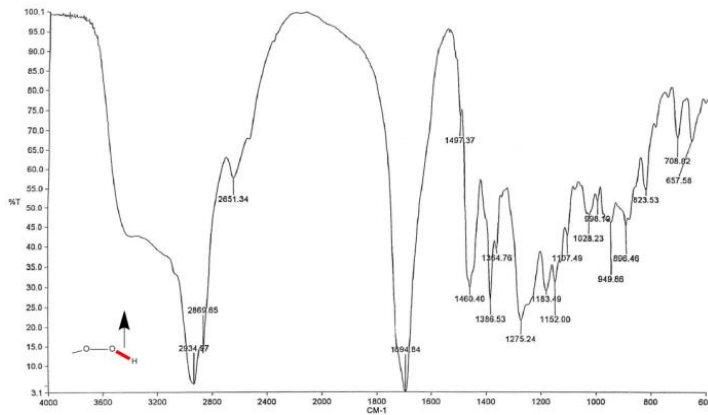
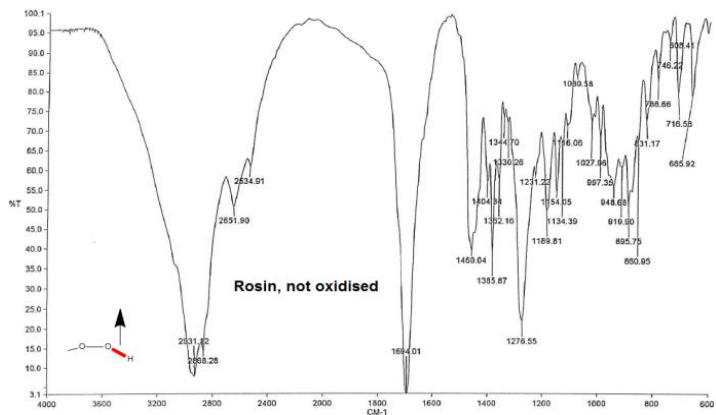
15-hydroperoxyabietic acid



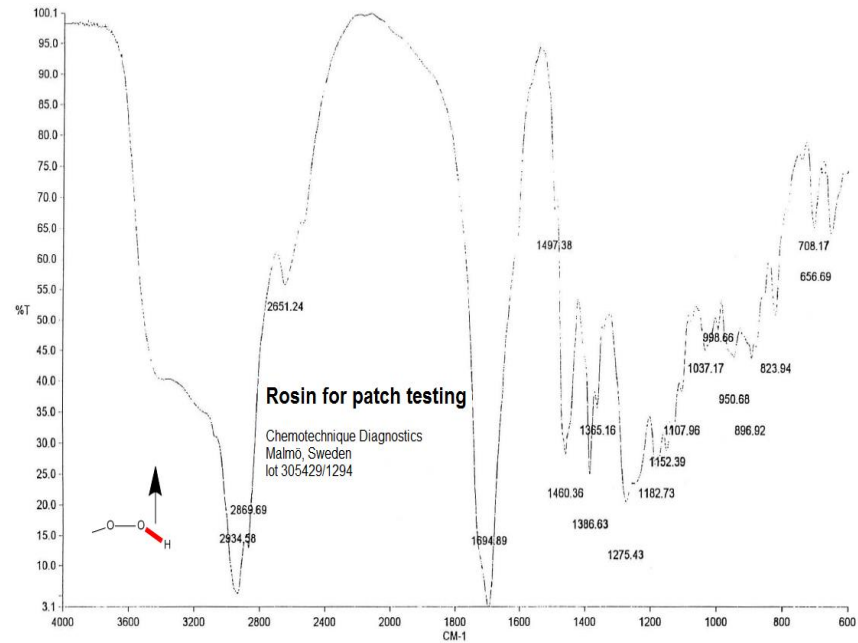
**Figure. Infrared spectra of cumylhydroperoxide and dicumylperoxide, reference spectra**



**Figure. Infrared spectra of rosin and powdered rosin after exposure to ambient air for 105 days**



**Figure Infrared spectrum of rosin solution as offered for sale to dermatological clinics**



- Animal tests (GPMT) with two different patch test samples of challenge material as eliciting agent confirmed cross reactivity when oxidised rosin was used as inducing agent

- Rosin is not a skin sensitiser in regulatory tests undertaken by CROs under Good Laboratory Practice conditions
- Naturally oxidised rosin is a skin sensitiser in adjuvant based tests
- The rate of natural oxidation depends on the physical form of the rosin (industrially rosin is in massive or hot liquid form and not readily oxidised)
- Patch testing with oxidised rosin is not relevant to the classification of rosin

# Acknowledgements

- Leon Rodenberg (Eastman) for the chemistry data
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- HARRPA and H4R (HARRPA for REACH - the Consortium undertaking registration of rosin and rosin related substances under REACH)