



# Rosin, hydrogenated rosin and salts: Human health tier II assessment

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## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
<b>Rosin</b>	8050-09-7
<b>Resin acids and rosin acids, calcium salts</b>	9007-13-0
<b>Resin acids and rosin acids, potassium salts</b>	61790-50-9
<b>Resin acids and rosin acids, sodium salts</b>	61790-51-0
<b>Rosin, polymerized</b>	65997-05-9
<b>Rosin, hydrogenated</b>	65997-06-0

## Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: [www.nicnas.gov.au](http://www.nicnas.gov.au)

#### Disclaimer

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#### ACRONYMS & ABBREVIATIONS

## Grouping Rationale

The chemicals of this group are structurally related rosin compounds and have been reported as a chemical category under REACH. Rosin is a complex combination of chemicals derived from wood, especially pine wood. It is composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids. The major component of rosin is abietic acid (CAS No. 514-10-3) typically comprising over 25–45 %. The composition of rosin chemicals varies according to the origin of the source and production method.

The composition of hydrogenated rosin is similar to rosin except that some of the double bonds in the resin acids have been removed. The rosin salts are the simple metal salts of unmodified rosin and are made by treating rosin with the appropriate base. Polymerised rosin is effectively a dimer formed by the reaction of the double bonds of the rosin acid. It is not possible for complete dimerisation to occur in manufacture and the chemical will contain a mixture of rosin acid and rosin dimer.

Toxicological data are not available for all the chemicals in the group and available data have also been sourced from other structurally related rosins not included on the Australian Inventory of Chemicals Substances. These supporting chemicals include:

- rosin, reaction products with formaldehyde (CAS No. 91081-53-7);
- resin acids and rosin acids, hydrogenated, potassium salts (CAS No. 68990-01-2);

- resin acids and rosin acids, calcium zinc salts (CAS No. 68334-35-0); and
- resin acids and rosin acids, magnesium salts (CAS No. 68440-56-2).

## Import, Manufacture and Use

### Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information:

Rosin (CAS No. 8050-09-7) has reported domestic use as an adhesive and binder.

Calcium rosinates (CAS No. 9007-13-0) and polymerised rosin (CAS No. 65997-05-9) have reported domestic use as a colouring agent.

### International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program—OECD HPV, the US Environmental Protection Agency's Aggregated Computer Toxicology Resource—ACToR, and the US National Library of Medicine's Hazardous Substances Data Bank—HSDB.

The chemicals rosin (CAS No. 8050-09-7), hydrogenated rosin (CAS No. 65997-06-0), sodium rosinates (CAS No. 61790-51-0) and polymerised rosin (CAS No. 65997-05-9) are included in the CosIng database and US Personal Care Products Council INCI directory with the identified functions of binding, cleansing, film forming, depilatory, perfuming and viscosity controlling. However, there is currently no documented use of sodium rosinates (CAS No. 61790-51-0) and polymerised rosin (CAS No. 65997-05-9) in cosmetic products in the United States, and rosin (8050-09-7) and hydrogenated rosin (CAS No. 65997-06-0) had a low reported frequency of use (less than 15 products) (CIUCUS, 2011).

Most of the chemicals have reported domestic use including in:

- adhesives and binding agents;
- colouring agents;
- electronics solder,
- fillers;
- paints, lacquers and varnishes; and
- dancers' and violinists' resins.

Rosin (CAS No. 8050-09-7), sodium rosinates (CAS No. 61790-51-0) and polymerised rosin (CAS No. 65997-05-9) are reported to be present in a range of domestic products including home maintenance products, such as fillers, adhesives and solders up to a concentration of 30 %. Rosin (CAS No. 8050-09-7) is also reported to be present in an auto product up to a concentration of 60 % (Household Products Database, US Department of Health and Human Services; HSDB).

Rosin (CAS No. 8050-09-7), polymerised rosin (CAS No. 65997-05-9) and hydrogenated rosin (CAS No. 65997-06-0) have reported commercial use including as:

- construction materials;

- flux, welding and soldering agents;
- process regulators; and
- reprographic agents.

Rosin (CAS No. 8050-09-7) also has reported commercial use including as a solvent, anti-adhesive agent and viscosity adjustor.

Salts of rosin are widely used in the paper industry as sizing agents.

Rosin (CAS No. 8050-09-7) has reported site-limited use as an intermediate.

Some of the chemicals have reported non-industrial use as non-agricultural pesticides and preservatives.

## Restrictions

### Australian

No known restrictions have been identified.

Rosin (CAS No. 8050-09-7) is listed, under the synonym colophony, in the SUSMP in Appendix B – Substances considered not to require control by scheduling (Feb 1997). The reason for listing was that the use pattern restricts hazard. The identified use was as flux.

### International

No known restrictions have been identified.

## Existing Worker Health and Safety Controls

### Hazard Classification

The following chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Rosin (CAS No. 8050-09-7): R43 – May cause sensitisation by skin contact

### Exposure Standards

#### Australian

Rosin core solder pyrolysis products (as formaldehyde) have an exposure standard of 0.1 mg/m<sup>3</sup> time weighted average (TWA).

#### International

The following exposure standards are identified (Galleria Chemica):

For rosin (CAS No. 8050-09-7) an exposure limit of 0.05–4 mg/m<sup>3</sup> (TWA) and 0.15–3 mg/m<sup>3</sup> short-term exposure limit (STEL) in different countries such as USA (Washington, Hawaii), Canada (Quebec), United Kingdom, Germany, Latvia and Mexico.

For calcium rosinate (CAS No. 9007-13-0) an exposure limit of 0.15–10 mg/m<sup>3</sup> (TWA) and 10–20 mg/m<sup>3</sup> (STEL) in different countries such as USA (Washington, Hawaii), Canada (Quebec), Norway, Germany, Ireland and Spain.

For polymerised rosin (CAS No. 65997-05-9) an exposure limit of 2–10 mg/m<sup>3</sup> (TWA, respirable fraction) and 15 mg/m<sup>3</sup> (TWA, total dust) in different countries such as USA (Washington, Hawaii), Iceland, France and Hungary.

For hydrogenated rosin (CAS No. 65997-06-0) an exposure limit of 10 mg/m<sup>3</sup> (TWA, respirable fraction) in different countries such as Iceland and Japan.

For rosin core solder thermal decomposition products a numerical threshold level value (TLV) is not recommended by ACGIH in the USA. TLV: None—control exposure to resin acids colophony to the lowest achievable concentration (ACGIH, 2011).

## Health Hazard Information

Toxicological data are not available for all the chemicals in the group and available data have been sourced from other structurally related rosins not included on the Australian Inventory of Chemicals Substances. These supporting chemicals include: rosin, reaction products with formaldehyde (CAS No. 91081-53-7), resin acids and rosin acids, hydrogenated, potassium salts (CAS No. 68990-01-2), resin acids and rosin acids, calcium zinc salts (CAS No. 68334-35-0) and resin acids and rosin acids, magnesium salts (CAS No. 68440-56-2). Data from the main component abietic acid (CAS No. 514-10-3) have also been used.

## Toxicokinetics

Rosin undergoes oxidation on contact with air. Hydrogenation, polymerisation and disproportionation of rosin results in increased oxidative stability, presumably due to the decrease in conjugated double-bond structures typical of abietic acid-type molecules (Minn, 1985).

Powdered rosins undergo extensive oxidation when compared to pelleted rosin (Botham et al, 2008).

## Acute Toxicity

### Oral

Based on the information available, the chemicals in this group are considered to have low acute oral toxicity. For a number of chemicals (CAS Nos 8050-09-7, 9007-13-0, 65997-05-9), and supporting chemicals (CAS Nos 91081-53-7, 68990-01-2, 68334-35-0 and 68440-56-2) the median lethal dose (LD50) in rats is greater than 2000 mg/kg bw. No adverse effects were reported (REACH; IUCLID, 2000a; IUCLID, 2000b).

### Dermal

Based on the limited information available, the chemicals in this group are considered to have low acute dermal toxicity. For rosin (CAS No. 8050-09-7) and supporting chemical rosin acids, hydrogenated, potassium salts (CAS No. 68990-01-2), the median lethal dose (LD50) in rats is greater than 2000 mg/kg bw. Observed sub-lethal effects included skin dryness (CAS No. 8050-09-7), and discolouration and desquamation (CAS No. 68990-01-2) (REACH).

### Inhalation

No reliable data are available.

A median lethal concentration (LC50) of 2480 ppm in rats was identified for hydrogenated rosin (CAS No. 65997-06-0) indicating low acute inhalation toxicity. However, no study details relating to this value were provided (IUCLID, 2000c).

## Observation in humans

Exposure to vapours of the chemicals have been reported, typically in solder fluxes. Although respiratory sensitisation has been reported (see **Sensitisation**), there have been no reports to support acute toxicity by inhalation.

## Corrosion / Irritation

### Skin Irritation

Based on the data available, the chemicals in this group may cause slight skin irritation. The effects were not sufficient to warrant a hazard classification.

The chemicals rosin (CAS No. 8050-09-7), calcium rosinate (CAS No. 9007-13-0) hydrogenated rosin (CAS No. 65997-06-0) and supporting chemicals (CAS Nos, 68990-01-2 and 91081-53-7) produced slight skin irritation (slight erythema) in studies which were performed in accordance with OECD Test Guideline (TG) 404. The effects were not sufficient to warrant a hazard classification (REACH; IUCLID, 2000a).

### Eye Irritation

Based on the data available the chemicals in this group may cause slight eye irritation. The effects were not sufficient to warrant a hazard classification in Australia and were reversible within 7 days. Test results are available for rosin and one of its salts.

Rosin (CAS No. 8050-09-7) was reported to slightly irritate the eyes when tested similarly to OECD TG 405. The average scores for cornea/iris/conjunctivae (redness)/conjunctivae (chemosis) were given as 0.6/0.9/0/0. The effects were reversible within 72 hours (REACH).

The structurally related chemical rosin, reaction products with formaldehyde (CAS No. 91081-53-7), was reported to slightly irritate the eyes of rabbits. Slight signs of irritation were seen for the cornea, iris, and conjunctiva. The overall mean eye irritation scores (Draize) were 5.7 at 24 hours, 3.0 at 48 hours, and 0 at 72 hours. The effects were reversible within 72 hours (REACH).

The structurally related chemical rosin acids, hydrogenated, potassium salts (CAS No. 68990-01-2), was reported to irritate the eyes when tested according to OECD TG 405. Signs of irritation in unwashed eyes included slight to severe chemosis and slight to moderate redness of the conjunctivae. In washed eyes, signs of irritation were limited to slight redness of the conjunctivae. The effects were reversible in the unwashed eyes by 7 days and in washed eyes by 72 hours (REACH).

## Sensitisation

### Respiratory Sensitisation

There are equivocal data to show that fumes from heated compounds containing rosin chemicals may cause occupational asthma (see **Observation in humans** below).

### Skin Sensitisation

The chemical rosin (CAS No. 8050-09-7) is classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in HSIS (Safe Work Australia). There is sufficient evidence to show that the skin sensitisation potential can be

attributed to the oxidation products of the chemicals and that the rosin chemicals in this group are not skin sensitisers unless oxidised.

In 2005, NICNAS published an assessment of the sensitisation potential of abietic acid (CAS No. 514-10-3), the main component of rosin (NICNAS, 2005). In this report, the results from multiple guinea pig maximisation tests (GPMT) were summarised. Abietic acid was a weak to moderate sensitiser in tests. However, after purification of the abietic acid, no sensitisation was observed. Oxidised abietic acid compounds were prepared and showed weak to moderate sensitising potential.

In a GPMT conducted in accordance with OECD TG 406, rosin (CAS No. 8050-09-7) was a sensitiser in animals challenged with a 40 % solution of the chemical. However, it was determined that the sample was oxidised and degraded and the result was unreliable. Rosin (CAS No. 8050-09-7) was not a sensitiser in nine other GPMTs, four conducted according to OECD TG 406, and five conducted similarly to OECD TG 406.

In GPMTs conducted according to or similar to OECD TG 406, hydrogenated rosin (CAS No. 65997-06-0) (three tests) and polymerised rosin (CAS No. 65997-06-0) (one test) were not sensitisers. Slight erythema was observed in some animals in some tests and was attributed to the irritant potential of the chemical.

Sodium rosinate (CAS No. 61790-50-9), calcium rosinate (CAS No. 9007-13-0) and polymerised rosin (CAS No. 65997-05-9) were not skin sensitisers in local lymph node assays (LLNA). Although the structurally related chemical, hydrogenated calcium rosinate (CAS No. 68990-01-2) was positive in an LLNA test, the reliability of this result was questioned given the negative result for calcium rosinate.

Different oxidised rosins (CAS No. not reported) were positive in three separate GPMTs but negative in a Buehler test (Botham et al, 2008). However, the Buehler test is generally considered to be not as sensitive as the GPMT. In a LLNA study, oxidised rosin (CAS No. not reported) when tested up to a concentration of 25%, was not a potent sensitiser. The estimated concentration three (EC3) value was extrapolated to be just greater than 25 %, and a stimulation index of 2.87 was recorded at 25 %.

## Observation in humans

Sensitisation to rosin chemicals has been reported following human exposure.

In the above mentioned assessment report (NICNAS, 2005) human evidence was summarised for ten studies which showed that preparations of abietic acid or rosin (CAS No. 8050-09-7) could elicit a skin sensitisation response in humans but that oxidised resin acids are stronger sensitisers than the resin acids themselves. In one study, no subjects were sensitised to abietic acid that was purified immediately before application. More recent publications also provide evidence that rosin is a contact allergen, with positive response rates up to 12 % reported in clinics (Botham et al, 2008; Siegel et al, 2010; Landeck et al, 2010). The prevalence of allergy to rosin in the general population has been reported to be approximately 1 % (Botham et al, 2008; Siegel et al, 2010).

Samples of rosin material used in human testing (including commercial preparations for patch testing) have been shown to contain oxidised rosin products that increase in concentration upon storage (Botham et al, 2008).

There are equivocal data to show that fumes from heated compounds containing rosin chemicals may cause occupational asthma. Respiratory symptoms including breathlessness, wheezing and tightness of the chest have been reported in individuals exposed to fluxes or core solders containing rosins or rosin components (Moore & Burge, 2010, Burge et al, 1986; Burge et al, 1981). In some cases, exposed workers showed short-term reversible airway obstruction but in other cases, workers were symptom free for on average six years before developing chronic asthma (ACGIH, 2011). In hobbyist situations, flux is heated with soldering irons with operating temperatures between 200 and 450 °C (Worksafe WA, 2000). This heating causes fluxes to produce fumes containing a mixture of chemicals including rosin oxidation products.

While rosin (CAS No. not stated) and rosin components were shown to have the potential to act as haptens, the mechanism for respiratory effects is unknown and may be non-immunological (Cullen et al, 1992).

## Repeated Dose Toxicity

## Oral

Based on the limited information available, the chemicals in this group are considered to have low toxicity following repeated oral exposure (REACH, US EPA 2004).

While there are several repeated dose toxicity studies available, the majority of these were performed by a laboratory which was reported in the REACH dossier to have conducted fraudulent work during a period after the above studies were conducted and therefore the reliability of the data is questionable (REACH). However it is considered that the data can be taken as weak evidence of the effects of the chemicals, as effects were consistent with studies conducted later in another laboratory (US EPA, 2004).

Five separate 90-day repeated dose toxicity studies in rats (one using gum rosin, two using wood rosin and two using rosin with no trade name given) have been conducted. In each test, Sprague Dawley rats (10/sex/treatment) were exposed to rosin in the diet at concentrations of 0, 0.01, 0.05, 0.2, 1.0 or 5.0 % (approximately corresponding to 0, 10, 50, 200, 1000 or 5000 mg/kg bw/day). Mortality was observed in the high dose groups (5 % dietary exposure) and statistically significantly decreased body weights were observed in the 1 % groups, with organ weight changes also observed. The authors concluded that the body weight and organ weight changes were related to palatability of the test material. Gross and histopathological examination findings were reported to not reveal any changes related to the chemical in four studies, although histological changes in kidneys of high dose animals were found in one study. The NOAEL was reported 0.2 % in the diet (approximately 200 mg/kg bw/day) (US EPA, 2004). Similar effects were observed in 90-day studies with hydrogenated rosin (CAS No. 65997-06-0) and polymerised rosin (CAS No. 65997-05-9). While these data are of limited reliability, similar systemic effects were observed in a reproductive/developmental screening study in rats (see **Reproductive and developmental toxicity**) and a non-guideline 90-day study for polymerised rosin conducted by another laboratory (described below).

In a subchronic dietary toxicity study, polymerised rosin (CAS No. 65997-06-0) was exposed to rats at a dietary concentration of 1.0 % for 90 days (approximate dose not available). Statistically significant changes included: a decrease in body weight in females only, an increase in thyroid organ weights in males only, increases in adrenal and thyroid-to-body weight ratios in females only, and higher organ-to-body weight ratios for liver, spleen and kidneys in both sexes. These changes were attributed to the slightly reduced body weights in test animals. There were no gross or microscopic findings observed at necropsy or effects on clinical chemistry parameters. The LOAEL was 1.0 % in the diet for both male and female rats.

## Dermal

No data are available.

## Inhalation

No data are available.

## Genotoxicity

Overall, the data indicate that the chemicals in the group have no mutagenic or genotoxic potential.

Rosin (CAS No. 8050-09-07), calcium rosinate (CAS No. 9007-13-0) and the structurally related chemical rosin, calcium and zinc salt (CAS No. 68334-35-0) tested negative in Ames tests in *Salmonella typhimurium* (strains TA 98, TA 100, TA 1535 and TA 1537) and *Escherichia coli* (WP2) with and without metabolic activations at all doses tested (62–5000 µg/plate) using the plate incorporation and pre-incubation methods (REACH).

The structurally related chemical, rosin acids, hydrogenated, potassium salts (CAS No. 68990-01-2), tested negative in an Ames test in *S. typhimurium* (strains TA 98, TA 100, TA 1535 and TA 1537) and *E. coli* (WP2 urv A) with and without metabolic activations at all doses tested (50–5000 µg/plate) using the plate incorporation method. A white film was observed at the highest dose but it did not affect scoring of the colonies (REACH).



The structurally related chemical, resin acids and rosin acids, magnesium salts (CAS No. 68440-56-2), was tested in an Ames test in *S. typhimurium* (strains TA 98, TA 100, TA 1535 and TA 1537) and *E. coli* (WP2) with and without metabolic activations at all doses tested (0.76–61 µg/plate) using the plate incorporation and pre-incubation methods. Cytotoxicity was observed at the highest dose for some strains (not identified). No dose response was observed for any of the tested strains (REACH).

Rosin (CAS No. 8050-09-7) was tested in a chromosome aberration test in accordance with OECD TG 473. There was not a statistically significant increase in the number of cells carrying structural chromosomal aberrations or an increase in polyploid metaphases. In the main experiment, in the absence of metabolic activation, cytotoxicity was observed at the highest evaluated concentration. With metabolic activation, no cytotoxicity was observed up to the highest applied concentration (REACH).

Rosin (CAS No. 8050-09-7) was tested in an in vitro mammalian cell gene mutation test (OECD TG 476). There were no significant dose-related increases in the mutant frequency at any dose level, either with or without metabolic activation (REACH).

## Carcinogenicity

No reliable data are available.

While there are 2-year dietary toxicity studies available for rosin (CAS No. 8050-09-7), hydrogenated rosin (CAS No. 65997-06-0) and polymerised rosin (CAS No. 65997-05-9) these were performed by a laboratory which was reported in the REACH dossier to have conducted fraudulent work during a period after the studies were conducted and therefore the reliability of the data is questionable (REACH).

In these studies, the NOEL for carcinogenicity was determined to be 1.0 % of the diet (high dose group). No tumours were reported during the gross or microscopic examinations (REACH; US EPA 2004).

## Reproductive and Developmental Toxicity

Based on the limited information available, the chemicals in the group do not show specific reproductive or developmental toxicity. Developmental effects were only observed secondary to maternal toxicity.

In a reproductive/developmental toxicity screening study, SD rats were exposed to rosin at dose concentrations of 0, 1000, 3000, or 10000 ppm (approximately 105, 275 and 825 mg/kg bw/day) for 41–45 days (females) or 30 days (males) in the diet. The high dose group was associated with reduced weight gain/weight loss and reduced food consumption in the parental generation and a slight decrease in the mean number of implantation sites resulting in a slight reduction in litter size. Body weight gain reductions were observed in males in the 3000 ppm dose group. At 10000 ppm (825 mg/kg bw/day), the mean number of implantation sites per pregnancy was slightly decreased, resulting in a subsequent reduction in litter size. Mean litter and pup weights were also slightly reduced. Effects were considered secondary to reduced maternal food consumption and weight gain. The reported NOAEL for reproductive/developmental toxicity in rats was 3000 ppm (175 mg/kg bw/day). The NOAEL for subchronic toxicity was 1000 ppm in males (equivalent to 84 mg/kg bw/day) and 3000 ppm in females (equivalent to 309 mg/kg bw/day) based upon reduced feed consumption and lower weight gain (REACH).

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation include local effects (skin sensitisation), when contact with oxidation products of the chemicals occurs. There is equivocal evidence to suggest that inhalation of vapours generated on heating during soldering may cause respiratory sensitisation. Products containing the chemicals formulated as dusts may be a respiratory nuisance.

### Public Risk Characterisation

The chemicals have reported domestic use in Australia and one is reported to be used in domestic products overseas at concentrations up to 60%. Although use in cosmetic products in Australia is not known, international information indicates that the chemicals are not likely to be widely available for cosmetic use.

The main route of public exposure is expected to be by the skin. Inhalation of vapours could occur through heating of products containing the chemicals, i.e. soldering. Inhalation of dusts could occur if used in the powdered form.

Oxidation of the chemicals may occur in domestic products given potential for storage of these over long periods of time with repeated exposure to air, and therefore the potential for sensitisation effects cannot be ruled out.

In the absence of any regulatory controls, the characterised critical health effects (skin and respiratory sensitisation) have the potential to pose an unreasonable risk under the uses identified. The risks could be mitigated by implementing improved labelling with warning statements and safety directions relating to skin contact and breathing of fumes.

## Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemicals may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical local health effects, the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure to the chemicals are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

Given that reliable workplace air concentration data for the chemicals are not available, the levels of exposure that may result in respiratory problems in workers is uncertain. The levels of formaldehyde (referred to in the current Australian exposure standard) appear not to correlate with the level of exposure to resin acids, and therefore this exposure standard may not be adequate to protect workers (ACGIH, 2011). As such, exposure to rosin fumes should be maintained as low as possible.

Based on the available data, the hazard classification in HSIS is considered appropriate, where oxidation of the chemicals may occur.

## NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemicals in cosmetics and/or domestic products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through changes to classification and labelling.

Assessment of the chemicals are considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Safe Work Australia should consider whether current controls are adequate to minimise the risk to workers.

## Regulatory Control

### Public Health

Rosin (CAS No. 8050-09-7) is listed in Appendix B in the SUSMP as colophony for the use of flux.

Appropriate scheduling and labelling should be undertaken to mitigate risk for the chemicals in this group with uses in domestic and cosmetic products. Due to the toxicity profile at concentrations reported to be in use, this chemical should be considered for listing in Schedule 5 of the SUSMP, consistent with the Scheduling Policy Framework guidelines. Matters to be taken into consideration include:

- skin sensitisation may occur following oxidation of the chemicals after prolonged storage;
- respiratory sensitisation effects have been observed in humans following exposure to fumes of core solder or fluxes containing rosin chemicals;
- the domestic and cosmetic uses identified in Australia and internationally; and
- exemptions to scheduling may be applicable at low concentrations.

The chemicals should be referred to the ACCC to review whether current labelling of consumer products containing the chemicals is adequate.

## Work Health and Safety

The chemicals are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This is the existing classification for rosin (CAS No. 8050-09-7) and should apply to all members of the group in preparations where oxidation may occur based on storage and shelf life. This assessment does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

\* Existing Hazard Classification. No change recommended to this classification

## Advice for consumers

Products containing the chemicals should be used according to the instruction on the label.

## Advice for industry

### Control measures

Control measures to minimise the risk from ocular and inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;

- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

### **Obligations under workplace health and safety legislation**

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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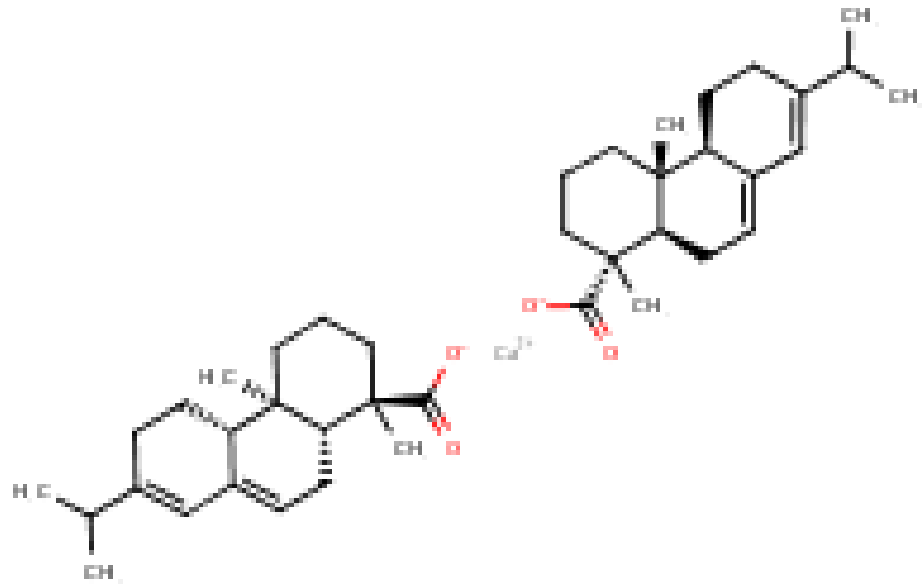
## Chemical Identities

Chemical Name in the Inventory and Synonyms	<b>Rosin</b> Colophony Disproportionated rosin Gum/wood/tall-oil rosin Colophonium
CAS Number	8050-09-7
Structural Formula	

# No Structural Diagram Available

Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Resin acids and rosin acids, calcium salts</b> Calcium rosinate Limed rosin Rosin acids, calcium salts Rosin, calcium salt Calcium resinate
CAS Number	9007-13-0
Structural Formula	



Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Resin acids and rosin acids, potassium salts</b> Disproportionated rosin, potassium salt Rosin, potassium salt Potassium rosinate Potassium soap of rosin Potassium resinate
CAS Number	61790-50-9
Structural Formula	

# No Structural Diagram Available

Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Resin acids and rosin acids, sodium salts</b> Disproportionated rosin acid, sodium salt Rosin acid, monosodium salt Wood rosin, sodium salt Sodium resinate Sodium rosinat
CAS Number	61790-51-0
Structural Formula	<h1 style="margin: 0;">No Structural Diagram Available</h1>
Molecular Formula	Unspecified
Molecular Weight	



Chemical Name in the Inventory and Synonyms	<b>Rosin, polymerized</b> Polymerized rosin Polypale resin Rosin, dimerized Dimer rosin Rosin, oligomers
CAS Number	65997-05-9
Structural Formula	<b>No Structural Diagram Available</b>
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Rosin, hydrogenated</b> Hydrogenated rosin Rosin, partially hydrogenated
CAS Number	65997-06-0
Structural Formula	

# No Structural Diagram Available

Molecular Formula	Unspecified
Molecular Weight	

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