Resin acids and rosin acids, calcium lead salts: Human health tier II assessment

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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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	lead calcium resinate gum rosin, litharge polymer
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight (g/mol)	Unspecified
SMILES	C(=O)(O)C1(C)C2C(C)(C3C(C=C(C(C)C)CC3)=CC2)CCC1

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

No specific international use, importation, or manufacturing information has been identified for the chemical.

However, the following uses were reported for lead salts of fatty acids (NICNASa), which may be relevant to the chemical:

- domestic—in pigments, paints, lacquers and varnishes;
- commercial—in corrosion inhibitors, lubricants, additives and process regulators; and
- site-limited—in the metallurgy sector.

Restrictions

Australian

This chemical is not individually listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). However, it is covered by the generic entry 'LEAD COMPOUNDS' in Schedules 5, 6 and 10, and by the entry 'LEAD' in Schedule 4 (SUSMP, 2018). It is also covered by the entry 'ROSIN' in Schedule 5 (SUSMP, 2018).

Schedule 4 — Prescription Only Medicine

LEAD for human therapeutic use.

Schedule 4 chemicals are 'substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription' (SUSMP, 2018).

Schedule 5 — **Caution**

LEAD COMPOUNDS in preparations for use as hair cosmetics.

ROSIN when packaged for use as a soldering flux or in flux-cored solder.

Schedule 5 chemicals are 'substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label' (SUSMP, 2018).

Schedule 6 — Poison

LEAD COMPOUNDS **except**:

a) when included in Schedule 4 or 5;

b) in paints, tinters, inks or ink additives;

c) in preparations for cosmetic use containing 100 mg/kg or less of lead;

d) in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or

e) in ceramic glazes when labelled with the warning statement: CAUTION – Harmful if swallowed. Do not use on surfaces which contact food or drink. Written in letters not less than 1.5 mm in height.

Schedule 6 chemicals are 'substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label' (SUSMP, 2018).

Schedule 10 (previously Appendix C) — Substances of such danger to health as to warrant prohibition of sale, supply and use

LEAD COMPOUNDS in paints, tinters, inks or ink additives **except** in preparations containing 0.1 per cent or less of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Schedule 10 chemicals are 'substances which are prohibited for the purpose or purposes listed for each poison' (SUSMP, 2018).

International

The chemical is not individually listed but is covered by the entry 'Lead and its compounds' on the following (Galleria Chemica):

- ASEAN Cosmetic Directive Annex II Part 1—List of substances which must not form part of the composition of cosmetic products;
- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain; and
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient ‘Hotlist’).

Lead compounds are also restricted as stipulated in Annex XVII to the REACH Regulation. They cannot be used in substances and preparations placed on the market for sale to the general public in individual concentrations ≥0.05 % (ECHA).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not individually listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia). However, the chemical is covered by the entry 'lead compounds with the exception of those specified elsewhere in this database' in HCIS (Safe Work Australia), with the following hazard categories and hazard statements for human health:

- Acute toxicity–Category 4; H302 (Harmful if swallowed)
- Acute toxicity–Category 4; H332 (Harmful if inhaled)
- Reproductive toxicity–Category 1A; H360Df (May damage the unborn child. Suspected of damaging fertility)
- Specific target organ toxicity (repeated exposure)–Category 2; H373 (May cause damage to organs through prolonged or repeated exposure)

Exposure Standards

Australian

No specific exposure standards are available for the chemical.

Lead, inorganic dusts and fumes (as lead) have the following exposure standards reported (Safe Work Australia):

- Time Weighted Average (TWA)—0.15 mg/m^3 for lead compounds (as lead).
- Short-Term Exposure Limits (STEL)—No specific exposure standards are available.

International

No specific exposure standards are available for the chemical.

For lead and its inorganic compounds in general, the following exposure limits were identified (Galleria Chemica):

- TWA = 0.05 mg/m^3 [Bulgaria, Canada, China, Denmark, Iceland, Malaysia, Norway, Poland, Russia, Taiwan, USA]
- TWA = 0.10 mg/m^3 [Austria, Estonia, France, Japan, South Africa, Sweden, Switzerland]
- TWA = 0.15 mg/m^3 [Argentina, Egypt, EU (Directive 98/24/EC), Hungary, India, Ireland, Mexico, Malta, Netherlands, Philippines, Singapore, Spain]
- TWA = 0.20 mg/m^3 [Thailand]
- STEL = 0.10 mg/m^3 [Austria]
- STEL = 0.15 mg/m^3 [Canada]
- STEL = 0.45 mg/m^3 [Argentina, Egypt]
- STEL = 0.8 mg/m^3 [Switzerland]

Health Hazard Information

The chemical is closely related to a group of chemicals consisting predominantly of lead salts of naturally occurring fatty acids, 'Lead salts of selected fatty acids', previously assessed under the NICNAS IMAP program (NICNASa). The toxicity of these lead compounds, including the chemical in this assessment, is considered due to the presence of the lead component (cation). In the absence of data for the chemical, the health hazard information of the previously assessed lead salts was used in this assessment as a read across. Therefore, this report should be read in conjunction with the Tier II assessment report of ‘Lead salts of selected fatty acids’ (NICNASa).

The Tier II human health assessment report for the previously assessed 'Lead salts of selected fatty acids' is available at:

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=114.

The toxicity information for ‘Lead salts of selected fatty acids’ is summarised below. This information is considered applicable to the chemical, resin acids and rosin acids, calcium lead salts.

Due to the lack of information for each of these lead salts, the generic HCIS classification for lead compounds was recommended for the following endpoints: acute toxicity via oral and inhalation routes, repeat dose toxicity and reproductive toxicity. These lead salts and lead compounds in general are not considered to be irritating to the skin or eyes, or sensitising to the skin.

These lead salts are considered to be genotoxic based on positive results observed in in vitro and in vivo genotoxic studies with lead. Classification was recommended.

These lead salts are also considered to be potential carcinogens based on the evidence that soluble lead compounds are carcinogenic in animals. Classification was recommended. In addition, inorganic lead compounds are classified by the IARC as probably carcinogenic to humans (Group 2A).

Lead has multiple modes of action, which can result in multiple effects in the body. The most sensitive target organs are listed below (NICNASa):

- the central nervous system—lead encephalopathy is the most severe neurological effect of lead exposure observed in humans;
- the haematological system—lead can cause anaemia; and
- the renal system—lead can cause proximal tubular nephropathy, glomerular sclerosis and interstitial fibrosis.

The chemical is also related to a group of chemicals, 'Rosin, hydrogenated rosin and salts', previously assessed under the NICNAS IMAP Program (NICNASb). These chemicals are sensitising to the skin, after contact with oxidation products. Equivocal evidence suggests that inhalation of vapours generated on heating during soldering may cause respiratory sensitisation. Products containing rosin acid and resin acid salts formulated as dusts may have nuisance dust related respiratory effects. The chemical is expected to have similar properties regarding skin sensitisation; however, the critical toxic effects are expected to be driven predominantly by the lead component.

The Tier II human health assessment report for the previously assessed 'Rosin, hydrogenated rosin and salts' is available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=872 .

Risk Characterisation

Critical Health Effects

Based on the assessment of lead salts of selected fatty acids, and rosin, hydrogenated rosin and salts, the main critical effects of the chemical to human health are expected to be:

- reproductive and developmental toxicity;
- potential genotoxicity;
- potential carcinogenicity; and
- skin sensitisation when oxidised.

Lead compounds are also expected to have acute and repeated dose toxicity. Due to the existing mandatory restrictions on lead, local exposure leading to skin sensitisation is very unlikely to occur.

Lead systemic toxicity is associated with average blood lead levels of >20 µg/dL in humans (Safe Work Australia, 2016).

Public Risk Characterisation

The chemical is currently covered by restrictions on lead and lead compounds in the Poisons Standard (SUSMP, 2018). These restrictions should prevent any associated risks from the use of domestic and cosmetic products containing lead compounds, including the chemical. Given these restrictions, domestic use in paints identified from international sources can be considered as not relevant to Australia.

Historical uses of lead compounds in surface coatings indicates that the potential for the public to be exposed, through flaking paint and during home renovation, still exists. While it is possible that the public will be exposed to lead or lead compounds, the risk can be managed by following appropriate guidelines (NHMRC, 2009; DoEE, 2014).

Therefore, based on the current restrictions of this chemical in Australia and the NHMRC guidelines, the chemical is not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation, oral, dermal, ocular and inhalation exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could 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.

In addition, the current regulatory thresholds for workplace lead exposure are higher in Australia compared with many other countries. The thresholds for blood lead removal levels an return to lead risk work blood levels, and workplace exposure

standard for dusts and fumes of inorganic lead are considered insufficient to 'adequately protect worker health', and are under review by Safe Work Australia (Safe Work Australia, 2016).

Given the critical health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal, ocular and inhalation exposure are implemented. The chemical 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

Current restrictions control the use of lead and lead compounds in cosmetics, paint, tinters, inks or ink additives, which effectively reduces the risk of public exposure. Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2018).

The availability and permissible lead content in products, such as paint, are regulated in terms of availability and concentration (SUSMP, 2018). Products that historically contained lead or lead compounds still pose an exposure risk to the public due to their existence in the public domain.

The National Health and Medical Research Council (NHMRC) of Australia has published recommendations regarding how the public can manage exposure to lead by mitigating the risk (NHMRC, 2009). Methods for the safe approach to painting a house (when there is a likelihood of lead paint having been used previously) have been published by the Department of the Environment and Energy (DoEE) (DoEE, 2014).

Work Health and Safety

In August 2016, Safe Work Australia published a decision in relation to a regulation impact statement (RIS) proposing to reduce the current regulatory thresholds for blood lead removal levels for lead risk workers and reduce the workplace exposure standards for dusts and fumes of inorganic lead from 0.15 mg/m^3 to 0.05 mg/m^3. Should the RIS proposal be adopted, the *Model Work Health Safety Regulations* will be amended and the transition period for compliance with the regulatory requirements is recommended to be 2 years from adoption (Safe Work Australia, 2016).

Currently, the health risk to workers from these chemicals is controlled when correct classification and labelling are considered, and adequate control measures to minimise occupational exposure and protective clothing are implemented. Safe Work Australia (SWA) encourages working safely with lead and promotes the *National Code of Practice for the Control and Safe Use of Inorganic Lead at Work* [NOHSC: 2015 (1994)] and the *National Standard for the Control of Inorganic Lead at Work* [NOHSC:1012 (1994)]. These codes of practice, in addition to the *Model Work Health Safety Regulations (2016)* are available from the SWA website.

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

If empirical data become available for the chemical indicating that a lower (or higher) classification is appropriate, this may be used to amend the default classification.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)* Harmful if inhaled - Cat. 4 (H332)*
Repeat Dose Toxicity	Not Applicable	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)*
Genotoxicity	Not Applicable	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Not Applicable	Suspected of causing cancer - Cat. 2 (H351)
Reproductive and Developmental Toxicity	Not Applicable	May damage the unborn child. Suspected of damaging fertility - Cat. 1A (H360Df)*

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

[b] 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 chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from exposure to the chemical 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 that could 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;
- air monitoring to ensure control measures in place are working effectively and continue to do so;

- 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 help meet 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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