Silica-modified lead chromates: Human health tier II assessment

10 March 2017

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Chromium lead molybdenum oxide sulfate, silica modified	116565-73-2
Chromium lead oxide sulfate, silica modified	116565-74-3

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

Grouping Rationale

The chemicals in this group are silica modified lead chromate pigments. These compounds consist of insoluble lead chromates (chromium in the hexavalent (VI) oxidation state) partly or completely encapsulated in completely water insoluble silica. Considering the hazardous nature of lead and chromate, it is expected that both species will drive the toxicological profile of this group while the molybdenium is at comparatively low toxicity. The silica encapsulation and/or modification reduces the solubility and gastrointestinal bioavailability of lead and chromium from lead chromate pigments (Government of Canada, 2008). The chemicals in this group have similar end uses, typically in the paint and pigment industries.

The toxic properties of lead chromates, including the unencapsulated forms of these chemicals, have been assessed applying Inventory Multi-tiered Assessment and Priorisation (IMAP) Tier II framework (NICNASa).

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; European Chemicals Agency (ECHA) website; eChemPortal; Galleria Chemica; 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 have reported commercial uses including:

- as colour pigments in paint, plastics, hot melt traffic markers; and
- as catalysts.

Encapsulated pigments have improved properties, better resistance to harsh weather conditions and high temperatures and suitability for many industrial applications. Silica-encapsulated pigments can be used in plastics or coating applications at temperatures of up to approximately 300 °C, with the majority (> 90%) used for coatings (e.g. coil coatings and signage) (ECHA, 2010).

Restrictions

Australian

The following restrictions apply to the chemicals in this group based on restrictions for lead compounds and chromate compounds.

Lead and chromium compounds are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedules 5, 6 and 10 (SUSMP, 2017).

Schedule 6:

'LEAD COMPOUNDS **except:**

(a) when included in Schedules 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 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 and drink.* Written in letters not less than 1.5 mm in height.'

and

'CHROMATES (including dichromates) except in paints or tinters containing 5 per cent or less of chromium as the ammonium, barium, potassium, sodium, strontium or zinc chromate calculated on the non-volatile content of the paint or tinter.'

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label.

Schedule 5:

LEAD COMPOUNDS in preparations for use as hair cosmetics.

Schedule 5 substances are considered to have 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.

The chemicals in this group are also subject to additional restrictions as described in the appendices of the above standard:

Schedule 10

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

Schedule 10 substances are considered of such danger to health as to warrant prohibition of sale, supply and use. These substances are poisons prohibited from sale, supply or use because of their known potential for harm to human and/or animal health.

Customs Prohibitions

Under the Customs (Prohibited Imports) Regulations 1956, "The importation of cosmetic products containing more than 250 mg/kg (0.025 % w/w) of lead or lead compounds (calculated as lead), except products containing more than 250 mg/kg of lead acetate designed for use in hair treatments, is prohibited unless written permission is granted by the Minister or an authorised person has been granted." (Australian Government, 2013).

International

The following restrictions apply to the chemicals in this group based on restrictions for lead compounds and chromate compounds (Galleria Chemica):

• EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;

• EU Cosmetic Regulation 76/768/EEC Annex II—List of substances which must not form part of the composition of cosmetic products;

• New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain;

• Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist"); and

• Association of Southeast Asian Nations (ASEAN): Cosmetic Directive Annex II, Part 1: List of substances which must not form a part of the composition of cosmetic products.

Lead and lead compounds are also restricted in Annex XVII to the REACH Regulations, 'The chemicals cannot be used in substances and preparations placed on the market or used in any individual part of jewellery articles if the concentration of lead is equal to or greater than 0.05 % by weight'.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

• an exposure limit (TWA) of 0.012–0.1 mg/m^3 in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Spain, Germany, Norway and Switzerland.

Health Hazard Information

No specific toxicity data are available for the chemicals. In the absence of toxicological data for the chemicals in this group, data from the following has been used to infer the toxicity:

- non-encapsulated lead chromates (NICNASa);
- insoluble chromates and dichromates (NICNASb);
- lead oxides (NICNASc); and
- the impact of silica encapsulation on bioavailability and toxicity.

Lead chromates are classified as hazardous on the HCIS (Safe Work Australia) for acute toxicity (toxic by inhalation), sensitisation, repeated dose toxicity (harmful), genotoxicity, carcinogenicity and reproductive and developmental toxicity. The Tier II assessment report for lead chromates is available at: **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=843**. The report should be read in conjunction with this Tier II assessment.

Toxicokinetics

Silica encapsulation reduces the solubility and reduces the gastrointestinal bioavailability of lead and chromium from lead chromate pigments (Connor and Pier, 1990; ECHA SVHV, 2005; Government of Canada, 2008; Pier et al, 1991).

In a study, oral administration (gavage) of 150 mg/kg bw/day of silica-encapsulated chrome yellow or non-encapsulated lead chromate to rats, five days per week for four weeks, resulted in increased levels of lead, compared to control groups being detected in the blood and kidney for both silica-encapsulated and non-encapsulated lead chromate. However, levels were 3.5–13 times greater for the non-encapsulated chemical in the blood and 8.5 times greater in the kidney.

No chromium was detected in blood from all treated rats. Significantly increased levels of chromium in kidneys were reported in rats treated with non-encapsulated lead chromate.

Acute Toxicity

Oral

Based on data for lead chromates (NICNASa) the chemicals are expected to have low acute toxicity following oral exposure.

Dermal

Based on data for lead chromates (NICNASa) the chemicals are expected to have low acute toxicity following dermal exposure.

Inhalation

Lead chromates are classified as toxic if inhaled based on data for chromate compounds (NICNASa; NICNASb). However given that silica-encapsulation reduces the bioavailability of the chromium, reduced acute inhalation toxicity is expected.

Corrosion / Irritation

Skin Irritation

Based on data for lead chromates (NICNASa) the chemicals are not expected to be skin irritants.

Eye Irritation

Based on data for lead chromates (NICNASa) the chemicals are not expected to be eye irritants.

Sensitisation

Skin Sensitisation

Evidence from human studies indicates that chromium(VI) is a skin sensitiser (NICNASb). However given that silica-encapsulation reduces the bioavailability of the chromium, sensitisation effects are not expected for these chemicals.

Repeated Dose Toxicity

Oral

Lead chromates are classified as hazardous with the hazard category 'Specific target organ toxicity (repeated exposure) – category 2' and hazard statement 'H373 (May cause damage to organs through prolonged or repeated exposure)' in HCIS (Safe Work Australia). This classification is based on toxicokinetic data on the accumulation of lead, studies on lead chromate and using data from selected lead-based pigments (NICNASb).

Although data indicates that silica encapsulation reduces the bioavailability of lead (following oral exposure), given that small amounts may still be absorbed, this may be sufficient to result in chronic effects. There are also a number of uncertainties on this issue including the degree to which encapsulation moderates absorption by the organism (for each route of exposure) and the dependence of bioavailability on the degree of encapsulation (ECHA, 2010).

Therefore in the absence of further data, classification is considered warranted (refer **Recommendation** section).

Dermal

Based on data for lead chromates (NICNASa) the chemicals are not expected to be harmful by repeated dermal exposure.

Inhalation

Lead chromates are classified as hazardous with the hazard category 'Specific target organ toxicity (repeated exposure) – category 2' and hazard statement 'H373 (May cause damage to organs through prolonged or repeated exposure)' in HCIS (Safe Work Australia). This was based on adverse effects observed in mice following exposure to soluble chromium (VI) compounds and that the risk of adverse effects from repeated exposure increase when a chemical accumulates in the organ (NICNASa; NICNASb).

Although data indicates that silica encapsulation reduces the bioavailability of chromium, small amounts may be available following inhalation exposure. Therefore adverse effects from repeated exposure cannot be ruled out. Classification is considered warranted (refer **Recommendation** section).

Genotoxicity

Lead chromates are classified as hazardous with the hazard category 'Germ cell mutagenicity – category 2' and hazard statement 'H341 (Suspected of causing genetic defects)' in HCIS (Safe Work Australia).

This is based on positive results in several in vitro assays (Ames test, chromosomal aberration test, sister chromatid exchange test) and an in vivo micronucleus study (NICNASa). The classification is also supported by data on insoluble chromates and lead oxides (NICNASb, NICNASc).

Silica encapsulated compounds with 10 % or more encapsulation were negative for genotoxicity when tested in *Salmonella typhimurium* TA100, with and without S9, in presence and absence of nitrilotriacetic acid (NTA) as a powerful chelating agent. Compounds with 2 and 5 % encapsulation were positive for mutagenicity similar to the non-encapsulated pigments, in the presence of a chelating agent (Connor and Pier, 1990; Pier et al, 1991).

Whilst this data indicates that silica encapsulation reduces the mutagenicity of lead chromates, positive results were reported at lower levels of encapsulation (The other mutagenicity tests would also be expected to be positive as they are known effects of the constituents). Therefore in the absence of further data, classification is considered warranted (refer **Recommendation** section).

Carcinogenicity

Lead chromates are classified as hazardous with the hazard category 'Carcinogenicity – category 1B' and hazard statement 'H350 (May cause cancer)' in HCIS (Safe Work Australia). This is based on the available data from chromates and dichromates (insoluble) (NICNASb), selected lead-based pigments (NICNASc).

Data indicates that silica encapsulation reduces the bioavailability of lead (following oral exposure). As small amounts may still be absorbed, this may be sufficient to lead to chronic effects. There is uncertainty on the extent to which partial solubility in body fluids could lead to carcinogenic effects after long-term exposure to encapsulated lead chromate pigments (ECHA, 2010). Therefore in the absence of further data, classification is considered warranted (refer **Recommendation** section).

Reproductive and Developmental Toxicity

Lead chromates are classified as hazardous with the hazard category 'Reproductive toxicity – category 1A' and hazard statement 'H360Df (May damage the unborn child. Suspected of damaging fertility)' in HCIS (Safe Work Australia). This is based on the available data from lead-based pigments which are known to cause reproductive and developmental toxicity at very low levels (NICNASc).

Data indicates that silica encapsulation reduces the bioavailability of lead (following oral exposure). However as small amounts may still be absorbed, this may be sufficient to lead to chronic effects. There is uncertainty on the extent to which partial solubility in body fluids could lead to reproductive and developmental effects after long-term exposure to encapsulated lead chromate pigments (ECHA, 2010). Therefore in the absence of further data, classification is considered warranted (refer **Recommendation** section).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are the systemic long-term effects of carcinogenicity and developmental toxicity.

The toxicity may depend on the level of encapsulation. Data indicates that silica encapsulation reduces the biovailability of chromium and lead (following oral exposure). However, as small amounts may still be absorbed, particularly at lower levels of encapsulation, this may be sufficient to lead to chronic effects. There is uncertainty on the extent to which partial solubility in body fluids could lead to adverse effects after long-term exposure to encapuslated lead chromate pigments (ECHA, 2010).

Public Risk Characterisation

There are no reported cosmetic or domestic uses in Australia for chemicals in this group. Furthermore, the restrictions on the use of lead compounds in products available to the public in Australia are listed in the Poisons Standard (SUSMP, 2017).

These restrictions are sufficient to control risks from domestic use of these chemicals.

Historical use of lead compounds in surface coatings suggests 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 could be exposed to chemicals in this group, the risk can be managed by following the appropriate guidelines (Australian Standard 4361.2 Guide to Lead Paint Management; Part 2 Residential and Commercial Buildings, 1998).

Occupational Risk Characterisation

During product formulation, oral and inhalation exposure may 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 chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term effects the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure 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 the appropriate controls.

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

NICNAS Recommendation

Assessment of these chemical are 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

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. The classifications do not apply, if data are available to indicate that the lead and chromate ions are completely encapsulated with no bioavailability. 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.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
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	May cause cancer - Cat. 1B (H350)
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 chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from oral 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 chemicals are 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 chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemicals, 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 chemicals.

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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

References

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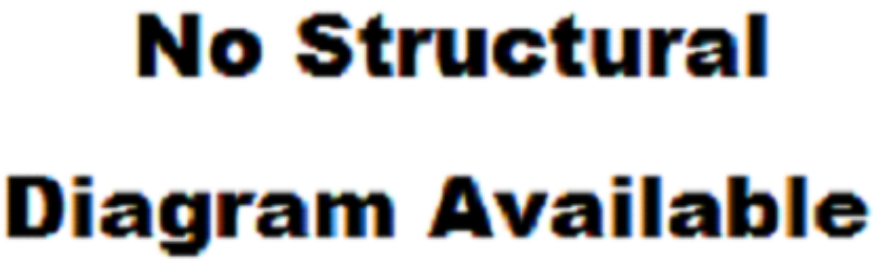
Safe Work Australia. Hazardous Chemicals Information System (HCIS). Accessed January 2017 at **http://hcis.safeworkaustralia.gov.au/HazardousChemical**

The Poisons Standard, February 2017. The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) No. 16. Accessed at **https://www.tga.gov.au/publication/poisons-standard-susmp**

The US Environmental Protection Agency (EPA) Aggregated Computer Toxicology Resource (ACToR) database. Accessed February 2017 at **http://actor.epa.gov/actor/faces/ACToRHome.jsp**

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Chromium lead molybdenum oxide sulfate, silica modified** silica encapsulated lead sulfomolybdochromate Krolor orange pigments Krolor red pigments
CAS Number	116565-73-2
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	NA

Chemical Name in the Inventory and Synonyms	**Chromium lead oxide sulfate, silica modified** Krolor yellow pigments Thermo yellow KS9259
CAS Number	116565-74-3
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	NA

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