Molybdenum nickel oxide (MoNiO4): Human health tier II assessment

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CAS Number: 14177-55-0

- Preface
- Chemical Identity
- Import, Manufacture and Use
- Restrictions
- Existing Work Health and Safety Controls
- Health Hazard Information
- Risk Characterisation
- NICNAS Recommendation
- References

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



27/04/2020

IMAP Single Assessment Report

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

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

Acronyms & Abbreviations

Chemical Identity

Synonyms	Molybdic acid (H2MoO4), nickel(2+) salt (1:1) Nickel molybdate (NiMoO4) Nickel molybdate(VI) (NiMoO4) Molybdenum nickel oxide (MoNiO4) Nickelous molybdate	
Structural Formula	Mo Mo Ni ²⁺	
Molecular Formula	Mo.Ni.O	
Molecular Weight (g/mol)	218.6	
Appearance and Odour (where available)	Green/yellow odourless powder.	
SMILES	O([Ni])[Mo](=O)(=O)O	

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (REACH) dossiers; Galleria Chemica and the Substances and Preparations in the Nordic countries (SPIN) database.

The chemical has reported site-limited use as an intermediate for refining catalysts.

Restrictions

Australian

Nickel and its compounds are listed in Schedule 10 (prohibited carcinogens, restricted carcinogens and restricted hazardous chemicals) of the Work Health and Safety Regulations for restricted use in abrasive blasting at a concentration of greater than 0.1 % of nickel (WHS, 2011).

International

REACH Regulations Annex XVII Section 27 on nickel and its compounds states:

'1. Shall not be used:

(a) in all post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0.2 μ g/cm²/week (migration limit);

(b) in articles intended to come into direct and prolonged contact with the skin such as:

- earrings,
- necklaces, bracelets and chains, anklets, finger rings,
- wrist-watch cases, watch straps and tighteners,
- rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,
- if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0.5 μg/cm²/week;

(c) in articles such as those listed in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel released from those parts of such articles coming into direct and prolonged contact with the skin will not exceed $0.5 \,\mu$ g/cm²/week for a period of at least two years of normal use of the article.

2. Articles which are the subject of paragraph 1, shall not be placed on the market unless they conform to the requirements set out in those points.

3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2' (REACH Annex XVII, 2009).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

'Nickel, soluble compounds (as Ni)' and 'molybdenum, soluble compounds (as Mo)' have an exposure standard of 0.1 and 5 mg/m³ time weighted average (TWA), respectively (Safe Work Australia).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 0.05–1 mg/m³ in different countries such as the United Kingdom, Canada (Yukon) and Norway (0.05 mg/m³) for nickel compounds and an exposure limit (TWA) of 5 mg/m³ in Canada (Yukon) for 'Molybdenum (as Mo) - Soluble compounds' (Galleria Chemica).

Health Hazard Information

Limited data are available for molybdenum nickel oxide (CAS No. 14177-55-0). Data are available for acute oral toxicity, skin irritation and in vitro genotoxicity. In the absence of further toxicological data for this chemical, it is expected that the chemical will dissociate into the molybdate and the Ni²⁺ ion in solution and have a similar hazard profile to soluble nickel compounds due to the high water solubility (4652 g/L) (REACH) of the chemical.

A range of molybdenum chemicals were assessed under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. The molybdate ion was assessed to be of low systemic hazard for human health (NICNASa).

The soluble nickel compounds (nickel chloride and nickel sulfate) assessed under the IMAP Framework are currently classified for carcinogenicity, genotoxicity and developmental toxicity. In addition, soluble nickel compounds are classified for acute toxicity from oral and inhalation exposure, skin and respiratory sensitisation and skin irritation. Also, soluble nickel compounds are classified for repeated dose toxicity via inhalation (NICNASc). The molybdate anion is isostructural with sulfate; therefore, where data are unavailable for molybdenum nickel oxide, nickel sulfate is used as an analogue. The available data for nickel sulfate (NICNASb) support an amendment to the classification for this chemical (refer to **Recommendation** section).

Acute Toxicity

Oral

27/04/2020

IMAP Single Assessment Report

The chemical had moderate acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in rats is greater than 300 mg/kg bw, but less than 2000 mg/kg bw. The available data warrant classification (refer to **Recommendation** section).

In a study performed according to OECD TG 423, six Sprague Dawley (SD) rats were administered a single oral dose of either 300 or 2000 mg/kg bw of the chemical and monitored for 14 days. Mortality occurred in 5/6 rats dosed in the 2000 mg/kg bw. No mortality was observed in animals administered 300 mg/kg bw. Clinical effects observed in the animals prior to mortality (5/6 animals in the 2000 mg/kg bw group) included decreased spontaneous activity, decreased body temperature, piloerection, decreased body weight, a swollen stomach, and a thickened body with white spots or dark colouration. At necropsy, observations included forestomach thinning, intestines coloured dark brown, lungs coloured red, and signs indicative of rigor mortis (REACH).

Dermal

No data are available for molybdenum nickel oxide. Data available for nickel sulfate hexahydrate (ATSDR, 2005; EU RAR, 2008) indicate that dermal absorption is expected to be very limited (ATSDR, 2005) and, therefore, acute dermal toxicity has not been evaluated using OECD TGs.

Inhalation

No data are available for the chemical. Data available for nickel sulfate indicate that this chemical has moderate acute inhalation toxicity. Nickel sulfate is classified as hazardous with the risk phrase 'Harmful by inhalation' (Xn; R20) in HSIS (Safe Work Australia) and the same classification is recommended for molybdenum nickel oxide.

In a study carried out according to OECD TG 403, nickel sulfate hexahydrate (CAS No. 10101-97-0) was administered as an aerosolised dust (0.063–5.08 mg/L of nickel sulfate hexahydrate) to male and female SD rats. The median lethal concentration (LC50) value was calculated as 2.48 mg/L in male and female rats exposed to nickel sulfate hexahydrate (REACHb). At the highest dose (5.08 mg/L) 100 % mortality was observed within three days of administration. Gross pathological necropsy conducted 14 days after administration showed discoloured lungs and liver, and rigor mortis at 2.12 mg/L. At the highest dose (5.08 mg/L), discoloured lungs, liver and/or intestines, distended stomach and/or intestines, and/or rigor mortis were observed (REACHb).

Corrosion / Irritation

Skin Irritation

In an in vitro test conducted according to OECD TG 439 (human skin model test), the chemical was considered to be a nonirritant (REACH). Based on human data for nickel sulfate, a recommendation for classification is warranted for molybdenum nickel oxide (refer to **Recommendation** section).

In animal tests, nickel sulfate was mildly irritating according to OECD TG 404. However, human data demonstrated nickel sulfate to be a 'marginal' irritant at 0.13 % and a 'ferocious' one at 1 % on scarified skin. Based on these data, a classification for skin irritation is warranted (EU RAR, 2008).

Eye Irritation

Using methodology (Hen's Egg Test Chorioallantoic Membrane—HET-CAM) evaluated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the chemical was determined to be non-irritating to the eyes (REACH).

In animal tests, nickel sulfate was negative for eye irritation.

Sensitisation

Respiratory Sensitisation

No data are available for this chemical. Human data available (refer to **Observation in Humans**) for nickel sulfate indicate that nickel sulfate is a respiratory sensitiser. Nickel sulfate is classified as hazardous with the risk phrase 'May cause sensitisation by inhalation' (R42) in HSIS (Safe Work Australia) and the same classification is recommended for molybdenum nickel oxide.

Skin Sensitisation

No data are available for the chemical. Data available for nickel sulfate (NICNASb) indicate that the chemical is a skin sensitiser and is classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in HSIS (Safe Work Australia) and the same classification is recommended for molybdenum nickel oxide.

All six studies reported by the European Union Risk Assessment Report (EU RAR) for skin sensitisation in guinea pigs found a positive response to nickel sulfate hexahydrate (CAS No. 10101-97-0). Methods included the guinea pig maximisation test (GPMT), open epicutaneous testing and skin painting studies (REACHb).

Observation in humans

Skin

Allergic contact dermatitis was found to occur in 15.5 % of approximately 75000 people undergoing patch-testing with the analogue nickel sulfate (ATSDR, 2005). Further skin-patch studies show a similar incidence of allergic contact dermatitis to nickel patch tests (11–21%) (ATSDR, 2005; EU RAR, 2008). The prevalence of nickel sensitivity is reported to be higher in younger females than in males or older individuals (ATSDR, 2005). This is related to nickel exposure through jewellery rather than biochemical susceptibility (ATSDR, 2005).

Furthermore, contact dermatitis resulting from nickel exposure is reported to occur through an immunologic response. A relationship between the human lymphocyte antigen (HLA) and patients with nickel sensitisation has been reported (ATSDR, 2005).

Respiratory

Clinical assessment of five individual cases of occupational exposure to the analogue nickel sulfate through electro- or metalplating was reported as clinical asthma based on evaluation with specific tests such as the bronchial inhalation provocation test or testing for specific immunoglobulin E (IgE) antibodies (EU RAR, 2008).

Repeated Dose Toxicity

Oral

No data are available for this chemical. Data available for nickel sulfate show that the chemical does not cause serious damage to health by prolonged exposure if swallowed. While the lowest observed adverse effect levels (LOAELs) available from twoyear rat studies were 6.7–11 mg Ni/kg bw/day for nickel sulfate hexahydrate (EU RAR, 2008), the severity of effects seen in these studies do not meet the criteria for hazard classification.

Dermal

IMAP Single Assessment Report

No data are available for this chemical. Similarly, there are no reliable studies to assess dermal repeated dose toxicity for nickel sulfate. However, considering the ionic nature of nickel salts, dermal absorption is expected to be poor. Therefore, hazard classification is not warranted for either nickel sulfate or molybdenum nickel oxide.

Inhalation

No data are available for this chemical. Reading across from nickel sulfate, the chemical is classified as hazardous with the risk phrase, 'Toxic: danger of serious damage to health by prolonged exposure through inhalation' (T; R48/23) in HSIS (Safe Work Australia). Lung fibrosis was seen in a two-year rat study at a concentration of 0.25 mg/m³ (NTP, 1996; NICNASb) nickel sulfate hexahydrate (CAS No. 10101-97-0) (equivalent to 0.06 mg Ni/m³). This classification is recommended for molybdenum nickel oxide.

The National Toxicology Program (NTP) has conducted two-year studies in male and female Fischer 344 (F344) rats (NTP, 1996). In the two-year study in F344 rats, based on chronic active lung inflammation, fibrosis, and macrophage hyperplasia observed in males and females at 0.25 mg/m³ nickel sulfate hexahydrate (CAS No. 10101-97- 0) at the end of the two-year evaluation, a no observed adverse effect concentration (NOAEC) of 0.12 mg/m³ was determined (NTP, 1996; EU RAR 2008; NICNASb).

In the two-year study in mice, all levels of exposure were reported to induce chronic lung inflammation in female mice; a lowest observed adverse effect concentration (LOAEC) of 0.25 mg/m³ nickel sulfate hexahydrate was assigned for females and a LOAEC of 0.5 mg/m³ nickel sulfate hexahydrate was assigned for males (NTP, 1996; EU RAR, 2008; NICNASb).

Genotoxicity

Limited in vitro genotoxicity data are available for this chemical. In the absence of in vivo study data and based on the high solubility of the chemical, genotoxicity data will be read-across from the NICNAS assessments of nickel sulfate (NICNASb). Based on analogue information for nickel sulfate, a recommendation for classification is warranted for molybdenum nickel oxide (refer to **Recommendation** section).

An in vitro study conducted according to OECD TG 471 reported that the chemical did not induce mutagenicity in several *Salmonella typhimurium* bacterial strains (TA 97a, TA 98, TA 100, TA 102 and TA 1535) with and without metabolic activation (REACH).

Nickel sulfate is classified as hazardous—a Category 3 mutagenic substance—with the risk phrase 'Possible risk of irreversible effects' (Xn; R68) in HSIS (Safe Work Australia). The positive results reported in several in vitro (nickel sulfate hexahydrateinduced sister chromatid exchanges and chromosomal aberrations) and in vivo genotoxicity (nickel sulfate hexahydrate induced DNA strand breaks and sex–linked recessive mutations in *Drosophila melanogaster*) studies support this classification.

Carcinogenicity

No data are available for this chemical. Data available for nickel sulfate indicate that the chemical is a carcinogen via inhalation. Nickel sulfate is classified as hazardous—a Category 1 carcinogenic substances—with the risk phrase 'May cause cancer by inhalation' (T; R49) in HSIS (Safe Work Australia). The International Agency for Research on Cancer (IARC) has classified soluble nickel compounds as 'Carcinogenic to humans' (Group 1) (IARC, 2012). The available epidemiological data for the analogue nickel sulfate support this classification for molybdenum nickel oxide.

Epidemiological study data from nickel refineries demonstrate a positive dose-dependent association between exposure to nickel sulfate and an increased risk of respiratory and nasal cancers (EU RAR, 2008). Data from key epidemiological studies are summarised in the NICNAS report on nickel sulfate (NICNASb).

Reproductive and Developmental Toxicity

No data are available for this chemical. Data available for nickel sulfate indicate that there is a concern for developmental toxicity. Nickel sulfate is classified as hazardous—a Category 2 substance toxic to reproduction—with the risk phrase 'May cause harm to the unborn child' (T; R61) in HSIS (Safe Work Australia). The available data for the analogue nickel sulfate support this classification for molybdenum nickel oxide.

Read-across data from the analogue chemical, nickel sulfate, indicate that the chemical administered orally to experimental animals can result in postimplantation/perinatal mortality (NICNASb).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (genotoxicity and developmental toxicity), local long-term effects (carcinogenicity), local and systemic acute effects (acute toxicity from oral and inhalation exposure) and local acute effects (skin and respiratory sensitisation). The chemical may also cause harmful effects on the respiratory tract following repeated exposure through inhalation and skin irritation.

Public Risk Characterisation

The chemical has no identified uses in Australia. Overseas, the chemical has site-limited uses. Therefore, it is unlikely that the public will be exposed to this chemical. The risk to the public is not considered to be unreasonable.

Occupational Risk Characterisation

Based on overseas use, it is possible that the chemical may be used as a chemical mediator and/or as a chemical intermediate. While using the chemical, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaing 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 systemic long-term, local long-term and systemic acute/local health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical 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 appropriate controls.

The data available support an amendment to the hazard classification in HSIS (refer to Recommendation section).

Based on the available data on nickel sulfate hexahydrate from animal studies, there is a concern that the current occupational exposure standard (0.1 mg Ni/m³—inhalable fraction) for 'Nickel, soluble compounds (as Ni)' in HSIS may not sufficiently protect worker's health. A concentration of 0.25 mg/m³ nickel sulfate hexahydrate (CAS No. 10101-97-0) (equivalent to 0.06 mg Ni/m³) was identified in the inhalation repeated dose toxicity studies as a level at which severe effects are observed. The Scientific Committee on Occupational Exposure Limits (SCOEL) in the EU proposed that the exposure standard be lowered to 0.01 mg Ni/m³ (TWA—inhalable fraction) for water soluble and poorly water soluble nickel compounds, excluding metallic nickel (SCOEL, 2011). The differences between rats and humans with respect to particle deposition in the alveolar region should be considered and quantified in considering an exposure standard (SCOEL, 2011).

NICNAS Recommendation

A Tier III assessment may be necessary to provide further information as to whether the current exposure controls offer adequate protection to workers.

All other risks are considered to have been sufficiently assessed at the Tier II level, subject to implementing any risk management recommendations, and provided that all 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 chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

In the absence of specific data on the chemical, data have been read-across (OECD, 2007) from the NICNAS assessment of nickel sulfate (NICNASb). Should empirical data become available indicating that a lower (or higher) classification is appropriate for the chemical, this may be used to amend the default classification.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Harmful if swallowed (Xn; R22) Harmful by inhalation (Xn; R20)	Harmful if swallowed - Cat. 4 (H302) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Irritating to skin (Xi; R38)	Causes skin irritation - Cat. 2 (H315)
Sensitisation	May cause sensitisation by inhalation (Xn, R42) May cause sensitisation by skin contact (Xi; R43)	May cause allergy or asthma symptoms or breathing difficulties if inhaled - Cat. 1 (H334) May cause an allergic skin reaction - Cat. 1 (H317)
Repeat Dose Toxicity	Toxic: danger of serious damage to health by prolonged exposure through inhalation (T; R48/23)	Causes damage to organs through prolonged or repeated exposure through inhalation - Cat. 1 (H372)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 1 - May cause cancer by inhalation (T; R49)	May cause cancer - Cat. 1A (H350i)
Reproductive and Developmental Toxicity	Repro. Cat 2 - May cause harm to the unborn child (T; R61)	May damage the unborn child - Cat. 1B (H360D)

^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 industry

Control measures

Control measures to minimise the risk from inhalation exposure to nickel chloride 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;
- 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 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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