Nickel hydroxide (Ni(OH)2): Human health tier II assessment

07 February 2014

CAS Number: 12054-48-7

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	Nickel dihydroxide Nickel (2+) hydroxide Nickelous hydroxide
Structural Formula	
Molecular Formula	H2NiO2
Molecular Weight (g/mol)	92.71
Appearance and Odour (where available)	Green powder.
SMILES	O{-}.[Ni]{2+}.O{-}

Import, Manufacture and Use

Australian

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was between 10000 and 100000 tonnes. Also, information provided indicates that the majority of the chemical is exported.

The following Australian industrial uses were reported by the National Pollutant Inventory (NPI):

The chemical has reported site-limited use including in:

- nickel-cadmium batteries; and
- the production of high yields of cellulose feeds.

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (REACH) dossiers; Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported site-limited use including:

- in the manufacture of nickel salts;
- in colouring agents;
- as corrosion inhibitors; and
- in process regulators.

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 (WHS, 2011) for restricted use in abrasive blasting at a concentration of greater than 0.1 % of nickel.

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 $\mu g/cm^2$/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 $\mu g/cm^2$/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 $\mu g/cm^2$/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 classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Carc. Cat. 3; R40 (Carcinogenicity)

Xn; R20/22 (Acute toxicity)

Xi; R43 (Skin sensitisation)

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 0.05 - 1 mg/m^3 time weighted average (TWA) in different countries such as USA (Washington, Hawaii - 1 mg/m^3), Canada (Yukon - 1 mg/m^3), Denmark (0.05 mg/m^3) and Sweden (0.1 mg/m^3).

Health Hazard Information

Limited data are available for nickel hydroxide (CAS No. 12054-48-7). To fill data gaps, data will be read across (OECD, 2007) from nickel oxide (NICNASa) and/or nickel subsulfide (NTP, 1996). This is possible as nickel oxide, nickel subsulfide and nickel

hydroxide have low water solubility. In addition, bioaccessibility studies have shown that nickel oxide, nickel subsulfide and nickel hydroxide release the Ni^{2+} ion into artificial biological fluids (gastric, alveolar, interstitial, lysosomal and sweat) at similar rates (REACH; Henderson et al, 2012b; Oller, 2013). Therefore, nickel oxide and nickel subsulfide can be considered close analogues, and relevant data can be used according to read-across principles (OECD, 2007) to assess the risks of nickel hydroxide.

Toxicokinetics

Nickel chemicals can be absorbed via inhalation, ingestion and to a limited extent following dermal exposure. The absorption of nickel chemicals and the release of the nickel ion are dependent on the solubility of the chemical in the specified physiological solutions (gastric or interstitial). Nickel is metabolised extracellularly through a series of ligand exchange reactions and binds albumin proteins in the blood, which is consistent across humans, rats and bovine species (ATSDR, 2005).

Specific toxicokinetic data for nickel hydroxide are not available; however, bioaccessibility studies have shown that the chemical has similar gastric bioaccessibility to nickel oxide in artificial gastric solution (oral exposure), in artificial sweat (dermal exposure) and in artificial alveolar and interstitial fluids (inhalation exposure) (Henderson et al, 2012b; Oller, 2013; REACH).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase ‘Harmful if swallowed’ (Xn; R22) in HSIS (Safe Work Australia). While there are some conflicting animal data, in the absence of more comprehensive information, there is insufficient evidence to support an amendment to this classification.

An acute oral toxicity study of the chemical (1000, 1495, 2236 or 5000 mg/kg bw nickel hydroxide) carried out similarly to OECD Test Guideline (TG) 401 in male and female Sprague Dawley (SD) rats reported an oral median lethal dose—LD50—1540 mg/kg bw. In addition to increased mortality, all animals exposed to a dose of $\geq$ 1495 mg/kg bw were reported to have a red fluid present in the intestines on necropsy. Further signs of toxicity reported were lethargy, diarrhoea, unsteady gait and presence of blood in the urine and faeces (REACH). A further study was conducted in female SD rats in accordance with OECD TG 401. This study utilised higher doses (3200, 4000, 5000 or 6300 mg/kg bw) and reported an oral LD50 of 5000 mg/kg bw. No further adverse effects were reported (Henderson et al, 2012a).

Dermal

No data are available.

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in HSIS (Safe Work Australia). The available animal data support this classification.

The Registry of Toxic Effects of Chemical Substances (RTECS) has reported the median lethal concentration—LC50— as 1200 mg/m^3 in rats (no strain details provided). Adverse effects reported included behavioural excitement and dyspnoea (REACH, RTECS). A further study investigated the pulmonary response to inhaled nanoparticles of nickel hydroxide (low (65.4 μg Ni/m^3), medium (358.2 μg Ni/m^3) or high dose (763.3 μg Ni/m^3)) in C57BL/6 mice for four hours. Analysis of bronchoalveolar lavage fluid (BALF) 24 hours after exposure showed that animals exposed to the mid and high doses had significantly increased polymorphonuclear leukocytes and total protein content, an indication of an inflammatory response in the lung (Gillespie et al, 2010).

The bioaccessibility data from studies conducted with artificial alveolar and interstitial fluids suggest that nickel hydroxide has a similar dissolution profile to that of nickel oxide (Oller, 2013; REACH). While the data indicate that nickel hydroxide should be classified for inhalation toxicity, it is of interest that nickel oxide has lower inhalation toxicity (NICNASa).

Corrosion / Irritation

Skin Irritation

The chemical is reported to slightly irritate skin in animal studies. The effects were not sufficient to warrant a hazard classification.

In a study conducted according to OECD TG 404, 0.63 g of a 80 % w/w mixture was applied under semiocclusive conditions to the trunks of three New Zealand White rabbits for four hours. Mild irritation in the form of slight erythema was observed within an hour of patch removal, which resolved within 24 hours (REACH).

Eye Irritation

The chemical was reported to slightly irritate the eyes when tested according to OECD TG 405. The effects were not sufficient to warrant a hazard classification.

In a study conducted according to OECD TG 405, 0.1 g of the chemical was instilled into one eye of each of the three New Zealand White rabbits. All treated eyes showed signs of iritis and conjunctivitis one hour after instillation. The severity of irritation decreased with time, and completely resolved at the end of the seven day study (REACH).

Sensitisation

Skin Sensitisation

The chemical is classified as hazardous with the risk phrase ‘May cause sensitisation by skin contact’ (R43) in HSIS (Safe Work Australia). No data are available for nickel hydroxide, although, reading across from nickel oxide (NICNASa), there is insufficient evidence to support a recommendation to amend this classification.

Repeated Dose Toxicity

Oral

No data are available. However, considering the anticipated low absorption of the chemical via the oral route, similar to nickel oxide (NICNASa), the chemical is not expected to cause serious damage to health by prolonged exposure if swallowed. Furthermore, data from nickel sulfate (NICNASb), which is more bioavailable than nickel oxide through the oral route, but not classified for this endpoint, suggest that classification is not warranted.

Dermal

No data are available. However, considering the ionic nature of nickel salts and low water solubility of the chemical, dermal absorption is expected to be poor. Therefore, hazard classification is not warranted for the chemical.

Inhalation

No guideline studies are available for this chemical. However, bioaccessibility studies have shown that the biological dissolution profile of nickel oxide (interstitial fluid) and nickel subsulfide (lysosomal fluid) are similar to that of nickel hydroxide in artificial biological fluids of the lung that are relevant to repeat dose toxicity - inhalation. Therefore, based on principles of read-across (OECD, 2007) it is expected that nickel hydroxide will have a similar toxicity profile to nickel oxide (NICNASa) and nickel subsulfide (NTP, 1996), and is recommended for classification in the HSIS (refer to **recommendation** section).

Additional information about the repeated dose inhalation toxicity of nickel hydroxide is available in a low dose study on nanoscale nickel hydroxide. Male C57BL/6 mice were exposed to nano-nickel hydroxide (78.6, 82.0 or 79.0 μg Ni/m³) for three or five months, for five hours a day, five days a week. Analysis of BALF fluid showed a significant increase in total neutrophil and lymphocyte population as well as a significant increase in protein levels, an indication of inflammation in the lung (Gillespie et al, 2010).

Genotoxicity

Based on the weight of evidence from the available in vitro genotoxicity studies and read-across in vivo genotoxicity studies from nickel oxide (NICNASa) and nickel subsulfide (NTP, 1996), the chemical is recommended for classification. While read-across data on nickel oxide suggest that the chemical is unlikely to be genotoxic in vivo, read-across data on nickel subsulfide suggest the chemical should be classified for genotoxicity.

In vitro

The chemical was reported to induce mutations in the Chinese hamster ovary (CHO) cell line. CHO cells exposed to 1.7 μg/mL of nickel in the form of nickel hydroxide showed abnormalities (smaller DNA band deleted or both bands deleted) detected through polymerase chain reaction (PCR) analysis (REACH). A second study carried out similarly to OECD TG 476 assessed the genotoxicity of the chemical (1.1, 1.7, 2.4, 3.4 and 5.5 μg/mL) in CHO cells. The authors reported that CHO cells exposed to the chemical at a range of doses had the highest nuclear nickel levels at the lowest administered doses. There was a significant increase in the rate of mutations in a dose dependent manner (REACH). A further study carried out according to OECD TG 476 in mouse lymphoma L5178Y cells showed that the chemical induced growth inhibition, increased mutation frequency and clastogenic effects in a dose dependent manner with and without metabolic activation (REACH).

In vivo

There are no in vivo studies available on the chemical. Based on read-across data from nickel oxide (NICNASa), nickel hydroxide is not expected to be genotoxic in vivo. Although, based on read-across data from nickel subsulfide (NTP, 1996), nickel hydroxide could be expected to be genotoxic in vivo.

Carcinogenicity

The chemical is classified as hazardous—Category 3 carcinogenic substance—with the risk phrase ‘Limited evidence of carcinogenic effect’ (Xn; R40) in HSIS (Safe Work Australia). No reliable studies have been conducted according to OECD guidelines. However, based on principles of read-across (OECD, 2007) it is expected that nickel hydroxide will have a similar toxicity profile via inhalation to nickel oxide (NICNASa) and nickel subsulfide (NTP, 1996), and is therefore recommended for amendment of the classification in the HSIS (refer to **recommendation** section).

The International Agency for Research on Cancer (IARC) has classified nickel compounds as ‘Carcinogenic to humans’ (Group 1).

A study was conducted to evaluate the carcinogenic potency of three forms (colloidal, dry and crystalline) of nickel hydroxide. The chemical (equivalent to 7 mg of nickel) was administered intramuscularly (20 injections administered every other day) to male Wistar rats. Tumours (rhabdomyosarcomas and fibrosarcomas) were observed in 26 and 15 % of animals administered the dry and crystalline preparation of the chemical, respectively. Animals administered the colloidal preparation of the chemical were reported to suffer frank haematuria which resulted in mortality of seven animals within the first two weeks of the experiment (REACH).

Epidemiological analysis of Swedish nickel-cadmium battery workers has shown an increased risk of nasal cancers. However, it is not clear whether the increased risk of nasal cancers is attributable to nickel hydroxide, cadmium oxide or a combination of

both chemicals (Jarup et al, 1998).

Reproductive and Developmental Toxicity

No data are available for this chemical. Reading across from nickel oxide (NICNASa) and nickel subsulfide (NTP, 1996), the available data do not warrant classification. For nickel oxide, developmental effects were observed secondary to maternal toxicity.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local long-term effects (carcinogenicity), systemic acute effects (acute toxicity by the oral and inhalation routes of exposure) and local acute effects (skin sensitisation). This chemical may also cause harmful effects (chronic lung inflammation and alveolar hyperplasia) following repeated exposure through inhalation.

Public Risk Characterisation

The chemical has site-limited uses in Australia and overseas. Although the public may come into contact with articles/coated surfaces containing the chemical, it is expected that the chemical will be bound within the article/coated surface and hence will not be bioavailable. Therefore the risk to the public is not considered to be unreasonable.

Occupational Risk Characterisation

During use of 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 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 long-term, systemic acute and 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**). There is also a concern that there is currently no recommended exposure standard in the HSIS. Based on data for nickel oxide, and considering the concentration of 0.5 mg Ni/m^3 identified through inhalation repeated dose toxicity studies at which severe effects are observed (NICNASa), there is a concern that the absence of occupational exposure standards in the HSIS may not be protective of the health of workers. The Scientific Committee on Occupational Exposure Limits (SCOEL) in the EU has proposed an exposure standard (0.005 mg/m^3 - respirable fraction) for 'poorly soluble nickel chemicals' which includes nickel oxide, nickel subsulfide and nickel metal (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 to determine the adequacy of protection to workers under the current exposure control framework.

All other risks are considered to have been sufficiently assessed at the Tier II level provided that the recommended amendment to the classification is adopted, and 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.

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)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	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)

[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 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 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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