Morpholine: Human health tier II assessment

01 July 2016

CAS Number: 110-91-8

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.

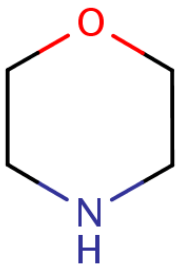
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	tetrahydro-2H-1,4-oxazine diethylene imidoxide diethyleneimide oxide diethylene oximide
Structural Formula	
Molecular Formula	C4H9NO
Molecular Weight (g/mol)	87.1
Appearance and Odour (where available)	colourless hygroscopic liquid with characteristic odour
SMILES	C1CNCCO1

Import, Manufacture and Use

Australian

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

The chemical has reported uses in:

- cleaning agents and additives;
- dishwashing and laundry detergents;
- fabric softeners;
- colouring agents;
- corrosion inhibitors; and
- photochemicals.

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was <100 tonnes.

International

The following international uses have been identified through European Union Registration, Evaluation Authorization and Restriction of Chemicals (EU REACH) dossiers; the Organisation for Economic Co-operation and Development Screening Information Data Set International Assessment Profile (OECD SIAP); Galleria Chemica; Substances and Preparations in Nordic Countries (SPIN) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has many industrial uses. The most common uses are described below.

The chemical has reported cosmetic uses as:

- a stabiliser; and
- pH regulating agent.

The chemical has reported domestic uses in:

- paints, lacquers and varnishes;
- cleaning and washing agents; and
- bleaching agents.

The chemical has reported commercial uses in:

- adhesive and binding agents;
- tanning agents;
- surface treatments;
- surface-active agents and emulsifiers;
- solvents for resin, waxes and casein dyes;

- reprographic agents;
- reducing agents;
- process regulators;
- lubricants and additives;
- hydraulic fluids and additives;
- petroleum additives;
- fillers;
- cutting fluids;
- corrosion inhibitors;
- colouring agents; and
- anti-condensation agents.

The chemical has reported site limited use as an intermediate.

Restrictions

Australian

No Australian restrictions were identified.

International

The chemical and its salts are listed 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;
- China list of banned substances for use in cosmetics;
- EU Cosmetic Directive 76/768/EEC Annex II: List of substances which must not form part of the composition of cosmetic products;
- Health Canada list of prohibited and restricted cosmetic ingredients (The "Hotlist");
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain: Table 1; and
- Philippines Restricted Ingredients for use in Cosmetics—List of substances which must not form part of the composition of cosmetic products.

The chemical is also listed on the following (Galleria Chemica):

- US American Cleaning Institute Cleaning Product Ingredient Inventory;
- US Food and Druge Administration (FDA) Indirect Food Additives;
- Adhesives and Components of Coatings—Substances for use only as components of adhesives; and

- Switzerland Ordinance of the Federal Department of Home Affairs (FDHA) on articles and materials—Annex 6, List of additives, Part B : non-evaluated substances.

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):

C; R34: Causes burns

Xn; R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

Exposure Standards

Australian

The chemical has an exposure standard of 20 ppm or 71 mg/m^3 time weighted average (TWA) and skin notation, which indicates that absorption through the skin may be a significant source of exposure.

International

The chemical has the following exposure limits identified (Galleria Chemica):

- European Union (EU) Commission Directive 2006/15/EC establishing a second list of indicative occupational exposure limit values (IOELVs) of 10 ppm or 36 mg/m^3 for eight hours and 20 ppm or 72 mg/m^3 for short-term exposure;
- German recommended exposure Limits—MAK values of 10 ppm or 32 mg/m^3. Use in metal-working fluids is not permitted. Reaction with nitrosating agents can result in the formation of carcinogenic N-nitrosomorpholine;
- UK workplace exposure limits (WELs) of 10 ppm or 32 mg/m^3 long-term exposure limit, 20 ppm and 72 mg/m^3 short-term exposure, and skin notation;
- US American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLV) of 20 ppm;
- US National Institute for Occupational Safety and Health (NIOSH) recommended exposure limits (RELs) of 20 ppm or 72 mg/m^3 TWA, 30 ppm and 105 mg/m^3 short term exposure limit (STEL) and skin notation; and
- US Occupational Safety and Health Administration (OSHA) permitted exposure levels (PELs) of 20 ppm or 70 mg/m^3 and skin notation.

Health Hazard Information

Morpholine is corrosive (due to its high pH) by all routes of exposure. In most cases, the systemic health effects of morpholine were tested on salts of morpholine to avoid corrosive effects and to distinguish between symptoms caused by local effects and those that are due to systemic toxicity. The salts of morpholine are expected to dissociate upon dissolution in vivo. The anions are not expected to contribute to the toxicity of the morpholine.

Toxicokinetics

Morpholine has a low molecular weight, and is water and lipid soluble; therefore, it is expected to be readily absorbed. Following inhalation (in rabbits) and oral (in rats) exposure, absorption of 55 % or 90 % was reported, respectively. Morpholine is primarily distributed to the kidneys, intestine and muscles, with the highest concentration expected to be present in the kidneys.

The metabolism of morpholine involves various oxidative processes including N-oxidation, followed by deamination and conjugation, leading to detoxification and excretion. The primary excretory pathway for morpholine is urinary excretion and most of the administered dose is excreted in its non-metabolised form.

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in the HSIS (Safe Work Australia).

In rats, the oral median lethal dose (LD50) values were 1050–1900 mg/kg bw. Clinical signs reported included breathing abnormalities, oral–nasal wetness and/or staining, effects on the gait, postural abnormalities, and red crusted eyes and nose. Irritation or corrosion (bleeding) of the gastrointestinal tract was found at gross necropsy (OECD, 2013).

In guinea pigs, the oral LD50 value was 900 mg/kg bw. Prostration, diarrhoea and haemorrhage into the stomach were reported.

Dermal

The chemical is classified as hazardous with the risk phrase 'Harmful in contact with skin" (Xn; R21) in the HSIS (Safe Work Australia).

In rabbits, a dermal LD50 of 500 mg/kg bw was reported following a 24-hour occluded dermal exposure. In another study, rabbits dermally exposed to 900 mg/kg bw showed blackened, necrotic skin, and inflamed and oedematous skin at the application site. The surviving animals had severe burns at the treatment site.

Inhalation

The chemical is classified as hazardous with the risk phrase 'Harmful by inhalation' (Xn; R20) in the HSIS (Safe Work Australia).

In rats, 100 % mortality was reported following exposure to vapour concentrations of 21.14 mg/L (nominal) for 5.5 hours or 18.1 mg/L (nominal) for six hours. Distinct irritation of the mucous membrane, severe nasal and ocular discharge, dyspnoea, convulsions, and widespread corrosion of the nose and paws were reported. The median lethal concentration dose (LC50) was not determined. In another study, 33 % mortality was reported in rats exposed to 28.8 mg/L (nominal) for three hours.

No mortality was reported in rats exposed to 24 mg/L (nominal) for four hours. However, stained hair and signs of irritation were reported.

Corrosion / Irritation

Corrosivity

The chemical is classified as hazardous with the risk phrase 'Causes burns' (C; R34) in the HSIS (Safe Work Australia). Undiluted morpholine was corrosive to the skin and eyes of rabbits (OECD, 2013).

In a primary dermal irritation study using a semiocclusive dressing, the chemical was applied to the shaved skin of rabbits (one/sex) for four hours. The chemical caused an irreversible necrotic effect at the application site (REACH).

Rabbits treated with the chemical (99.2 %) for up to 15 minutes under occlusive conditions showed haemorrhagic areas, oedema and parchment-like necrosis after 24 hours, which declined to leathery-like necrosis after eight days (OECD, 2013; REACH).

In a Draize study, rabbits treated with the chemical under occlusive conditions showed severe erythema, severe oedema and necrosis. In another study, where the chemical was applied to the shaved skin of rabbits using a semiocclusive dressing, severe erythema, severe oedema and necrosis were also reported when observed at 24 hours after patch removal. Fissuring and/or sloughing of the skin at the application site was observed on days 7–14 (REACH).

In an eye irritation study, the chemical was instilled into the conjunctival sac of the left eye of three rabbits and observed for various exposure times. All three exposure times caused eye irritation and necrosis in and around the eyes. After a 24-hour exposure, burns (corrosion) were observed. Two of the animals also showed corrosion both inside and around the eyes after a 30-second exposure. The corrosive effects were not reversible (REACH).

In another eye irritation/corrosion study, rabbits were exposed by applying the undiluted chemical into the conjunctival sac. The eyes were not washed out and observations were taken 24-hours post application. Overall, the treatment caused oedema, opacity, staphyloma and corrosion of the eye mucous membranes. The chemical was regarded as corrosive under the conditions of this study (REACH).

Severe corneal necrosis was observed in a range-finding study in which the eyes of albino rabbits were treated with 40 % morpholine. The number of applications was not specified and the number of animals tested was also not reported (REACH).

Respiratory irritation

There are no available data on the respiratory irritation effects for the chemical. However, respiratory irritation was observed following acute and chronic inhalation of the chemical. In a repeated vapour inhalation study, rats were exposed (whole body) to morpholine in various concentrations for 104 weeks and 13 weeks. The chemical caused necrosis of the nasal turbinates at 0.186 mg/L and focal erosion of the turbinates at 0.89 mg/L, respectively.

Sensitisation

Skin Sensitisation

The sensitising potential of the chemical was tested on guinea pigs using the Buehler method. The chemical (2 % in vaseline) did not induce sensitisation (OECD, 2013; REACH).

Repeated Dose Toxicity

Oral

Based on the available data, the chemical caused liver, kidney, lungs and stomach effects in rats, and kidney effects in mice, due to the corrosive nature of the chemical. Effects were less pronounced when a salt of the chemical was used.

In a repeated dose oral toxicity study, Sprague Dawley (SD) rats were administered the chemical by gavage (0, 160, 320 and 800 mg/kg bw/day) for 30 days. Swelling, congestion, necrosis and/or desquamation of the liver, kidneys, lungs and stomach were observed. The lowest observed adverse effect level (LOAEL) was determined as 160 mg/kg bw/day. In another study, moderate adiposis of the liver was observed in rats administered 500 mg/kg bw/day morpholine in the diet for 56 days (OECD, 2013; REACH).

Morpholine was administered to guinea pigs by gavage (0, 90, 180 or 450 mg/kg bw/day) for 30 days. Prostration, sneezing, coughing, kidney effects (cloudy swelling, congestion and necrotic tubules), liver effects (cloudy swelling, congestion, necrosis

and fatty degeneration), and necrosis in the spleen and stomach were observed in all treated animals. The LOAEL was determined as 90 mg/kg bw/day (OECD, 2013).

In mice, morpholine oleic acid salt (MOAS; CAS No. 1095-66-5) was administered in drinking water (0, 140, 200, 400 and 700 mg/kg bw/ day) for 91 days. The no observed adverse effect level (NOAEL) was determined to be 400 mg/kg bw/day based on cloudy swelling of the proximal tubules of the kidney observed at 700 mg/kg bw/day. In another study, MOAS was administered in drinking water at 0, 400–500 and 1500 mg/kg bw/day to male and female mice for 96 weeks followed by tap water alone for eight weeks. A NOAEL was not estabilised in this study because of the reduction in body weight in females from 500 mg/kg bw/day (the lowest dose tested) and in both sexes at 1500 mg/kg bw/day (OECD, 2013; REACH).

Dermal

In a repeated dose dermal toxicity study, diluted morpholine (1:2, morpholine:water) was applied to rabbits at a daily dose of 900 mg/kg bw to the clipped skin under occlusive conditions. All rabbits (7/7) died before the eleventh dose was administered. Necrosis at the application site, and inflammation and congestion of the underlying organs were evident upon gross examination. Microscopic lesions of the liver and effects on kidneys and spleen were observed (REACH).

Inhalation

In rats, a systemic no observed adverse effect concentration (NOAEC) of 0.543 mg/L was determined following repeated whole body vapour inhalation exposure to morpholine at concentrations of 0, 0.036, 0.186 and 0.543 mg/L, six hours/day, five days/week for 104 weeks. A local NOAEC was determined as 0.036 mg/L. Eye iritation and necrosis of the nasal turbinates were observed at 0.186 mg/L (OECD, 2013; REACH).

In a similar study, a systemic NOAEC of 0.89 mg/L was established in rats exposed to morpholine at concentrations of 0, 0.089, 0.36 and 0.89 mg/L, six hours/day, five days/week for 13 weeks. A local NOAEC of 0.36 mg/L was determined. Focal erosion of the turbinates was observed at 0.89 mg/L (OECD, 2013; REACH).

Genotoxicity

Based on the weight of evidence from the available data, the chemical is not considered to be genotoxic.

The chemical gave negative results in the following in vitro assay:

- reverse mutations in *Escherichia coli (E. coli WP2uvrA)* or *Saccharomyces cerevisiae*, or in three studies with *Salmonella typhimurium* (*S. typhimurium*; TA 1535, TA1537, TA 98 and TA100);
- sister chromatid exchanges (Chinese hamster ovary (CHO) cells); and
- unscheduled DNA synthesis (rat hepatocytes) (OECD, 2013).

Weak positive results for point mutations were noted in an in vitro assay (*S. typhimurium*; TA 1535, TA1537, TA 98 and TA100) and for clastogenicity in an in vitro mammalian cell transformation assay (BALB/3T3 mouse) at high and/or cytotoxic doses (OECD, 2013).

The chemical did not induced increases in chromosomal aberrations or frequency of micronuclei in vivo in Syrian golden hamster embyos.

Carcinogenicity

Studies conducted on the chemical via inhalation and oral exposures indicate that the chemical is not carcinogenic.

In a combined chronic/carcinogenicity study, the chemical was administered by whole body inhalation exposure to SD rats (see **Repeat dose toxicity: Inhalation**) for 104 weeks. There was no evidence of increased incidence of carcinogenesis due to

chronic inhalation (OECD, 2013; REACH).

The effects of dietary morpholine administration to male Fischer 344 (F344) rats were investigated for a period of 23 weeks (i) in combination with sodium nitrite in drinking water following an initiation phase, (ii) without sodium nitrite following an initiation phase and (iii) in combination with sodium nitrite without an initiation phase. Morpholine alone was not tested. The combination of initiation phase followed by sodium nitrite and morpholine caused an increase in the number and area of glutathione S-transferase P-form (GST-P) positive liver foci compared with the group that was only initiated, indicating that morpholine plus sodium nitrite, but not morpholine alone, has a tumour-promoting effect. No tumours were induced by morpholine plus sodium nitrite in the absence of initiation. No DNA adducts related to morpholine treatment were detected immunohistochemically (REACH).

Reproductive and Developmental Toxicity

The available information indicate that the chemical does not cause reproductive and developmental toxicity.

In a developmental toxicity study, pregnant rats were administered with morpholine hydrochloride by oral gavage at doses 0, 75, 250 and 750 mg/kg bw/day on gestation days 6–19. The maternal NOAEL was 75 mg/kg bw/day based on haematological changes. Foetal findings were limited to skeletal variations (slight increase in delayed ossification) in the mid- and high-dose groups. These effects were considered transient and secondary to maternal toxicity. A NOAEL for development toxicity of 750 mg/kg bw/day (the highest dose tested) was determined (OECD, 2013; REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- systemic acute effects (acute toxicity from all routes of exposure);
- systemic long-term effects to the liver and kidneys; and
- local effects (irritation and corrosivity from all routes of exposure and/or at the site of contact).

Public Risk Characterisation

Although use in cosmetic products in Autralia is not known, the chemical is reported to be used overseas as a stabiliser and pH regulating agent in cosmetics. Considering the range of cosmetic products that could contain the chemical, the main route of public exposure is expected to be through the skin. There is no information on the concentration of the chemical in cosmetic products, but within the normal pH range for cosmetic products, low levels of free morpholine would be expected.

The chemical has domestic use in Australia and overseas; therefore, there is potential for the public to be exposed to the chemical. The general public could be exposed through the skin, eyes or by inhalation when using domestic products containing the chemical. Based on limited US health and safety information on household products (HHPD), the highest concentration (10 %) of the chemical is found in car-wash products. These products are not expected to have pH levels that are sufficiently high to cause corrosive effects. Therefore, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

Given the critical effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise 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.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory.

If any information becomes available to indicate significant consumer exposure to the chemical in Australia (i.e. higher concentrations or quantities in cosmetics or domestic products), risks to public health and safety may have to be managed by changes to the Posions Standard.

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 and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful in contact with skin (Xn; R21)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Causes burns (C; R34)*	Causes severe skin burns and eye damage - Cat. 1 (H314)

[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 oral, dermal, ocular and 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 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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