Formamide: Human health tier II assessment

22 November 2013

CAS Number: 75-12-7

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.

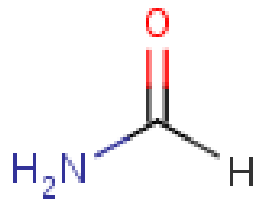
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Chemical Identity

Synonyms	carbamaldehyde methanamide methanoic acid, amide formic acid, amide formimidic acid
Structural Formula	

	
Molecular Formula	CH3NO
Molecular Weight (g/mol)	45.04
Appearance and Odour (where available)	Slightly viscous, colourless liquid with a faint ammonia odour
SMILES	C(N)=O

Import, Manufacture and Use

Australian

No specific Australian use information has been identified except that the chemical is found in very low levels in articles available for children (foam play mats and toys) (ACCC, 2013).

The total volume introduced into Australia reported under previous mandatory and/or voluntary calls for information was low.

International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers, the Organisation for Economic Cooperation and Development Screening information data set Initial Assessment Report (OECD SIAR), Galleria Chemica, Substances and Preparations in the Nordic countries (SPIN) database, the European Commission Cosmetic Ingredients and Substances (CosIng) database, United States (US) Personal Care Products Council International Nomenclature Cosmetic Ingredients (INCI) directory and other data sources via eChemPortal including Canadian Assessments (Challenge Batch List 5).

The chemical has reported domestic use including:

- in cleaning/washing agents;
- in adhesives, binding agents;
- in fibre, felt-tip pens and markers; and
- as a surface treatment on wooden toys.

The chemical has reported commercial use including:

- as solvents, used in manufacturing inks for fibre, felt-tip pens & markers; processing of plastics and non-aqueous electrolysis;
- as a softener used in manufacturing paper & pastes;
- in construction materials;
- in corrosion inhibitors;
- as a curing agent for epoxy resins;
- as an affinity enhancer for dyes;

- as a monomer in the manufacturing of polymers, e.g. heat-resistant coatings;
- in hydraulic fluids and additive to lubricating oil;
- in drilling mud additive/oil recovery agent/ oil well treating agent;
- as a plasticiser; and
- as an analytical reagent.

The chemical has reported site-limited use including as:

- an organic intermediate in the production of heterocyclic chemicals; and
- a laboratory chemical.

Restrictions

Australian

No known national restrictions have been identified.

Formamide is also listed as a prescribed precursor chemical and listed in Regulations for the purpose of section 71D of the *Drugs, Poisons and Controlled Substances Act 1981*.

The following state restriction has been identified (Galleria Chemica):

'South Australia Controlled Substances (Poisons) Regulations—Schedule C—Certain substances declared as poisons—Section 17C precursors. The sale of Section 17C precursors requires the purchaser to produce photographic identification and an End User statement to be completed'.

International

The following international restrictions have been identified (Galleria Chemica):

Cosmetics

The Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

The European Union (EU) Cosmetic Directive 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.

Food

United States Food and Drug Administration (US FDA) Indirect Food Additives: Adhesives and components of coatings—substances for use only as components of adhesives.

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):

Repr. Cat. 2; R61 (developmental toxicity)

Exposure Standards

Australian

The chemical has an exposure standard of 18 mg/m³ (10 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

Time weighted average—TWA: 15–20 mg/m³ (10 ppm) [Canada (Alberta, Quebec), Denmark, Norway, Spain, Switzerland, Sweden, USA (California, Hawaii, NIOSH)]

TWA: 30–37 mg/m³ (20 ppm) [UK, Canada (Yukon), France, USA (Minnesota, Tennessee, Vermont]

Short-term Exposure Limit—STEL: 30–56 mg/m³ (15–30 ppm) [Canada, USA, Sweden, UK]

Health Hazard Information

Toxicokinetics

Formamide is readily absorbed after inhalation, oral and dermal application (Government of Canada, 2009). Peak plasma levels are reached within two hours in rats and mice after a single oral administration, with an elimination half-life of 15 hours in rats and 4–6 hours in mice. Intravenous injection and inhalation exposure, used to study the metabolism and distribution of formamide in rats and mice, showed that 30 % was excreted unchanged in urine within 72 hours, and additionally 30 % (for rats) and 50 % (for mice) was excreted in breath as carbon dioxide. A minor quantity was reported to be excreted in faeces (1–3 %). Metabolism of formamide is primarily attributed to the CYP2E1 enzyme (OECD, 2007). Studies indicate a low potential for bioaccumulation (REACH).

Acute Toxicity

Oral

The chemical was of low acute toxicity in animal tests—with a reported oral median lethal dose (LD50) in rats of >2000 mg/kg bw (Government of Canada, 2009). Observed sub-lethal effects included poor general state, ruffled fur, irregular respiration, apathy, atony, lateral recumbent position and reduced food consumption (REACH).

Dermal

The chemical was of low acute toxicity in animal tests—with a reported dermal LD50 in rats of >2000 mg/kg bw (REACH). Two separate 90-day repeated dose rat studies conforming to OECD Test Guideline (TG) 411 reported mortalities (1/20 and 3/20, respectively) in groups of the animals receiving the highest dose of 3000 mg/kg bw/day (OECD, 2007).

Inhalation

The chemical was of low acute toxicity in animal tests following inhalation exposure. The median lethal concentration (LC50) in rats is >21 mg/L based on a four-hour exposure in which one rat in the high dose group died. Observed sub-lethal effects included lethargy, hunched posture, ocular and nasal discharges, partially-closed eyes, diarrhoea, brown-stained perineum and weight loss (REACH).

Corrosion / Irritation

Respiratory Irritation

No data are available.

Skin Irritation

The chemical was reported to slightly irritate skin in animal studies that did not conform to OECD test guidelines (OECD, 2007). The effects were not sufficient to warrant a hazard classification.

Eye Irritation

The chemical was reported to slightly irritate the eyes when tested in rabbit studies conforming to OECD TG 405. Conjunctivitis was the most prominent effect; the other effects were milder. The effects were reversible and were not sufficient to warrant a hazard classification (OECD, 2007).

Sensitisation

Skin Sensitisation

No data are available. However, the chemical does not contain functional groups commonly associated with skin sensitisation.

Repeated Dose Toxicity

Oral

Based on non-neoplastic lesions (hyperplasia and inflammation) reported in pancreatic ducts in a mouse study, a lowest observed adverse effect level (LOAEL) of 80 mg/kg bw/day was determined. While the levels at which the effects were observed do not meet the criteria for classification in HSIS, the data meet the criteria under GHS.

In a four-week short-term gavage study (similar to OECD TG 407), rats of both sexes were administered doses of 34, 113, 340 and 1130 mg/kg bw/day. A NOAEL of 34 mg/kg bw/day was reported. The lowest observed adverse effect level (LOAEL) was 113 mg/kg bw/day. Effects observed at this dose and higher concentrations (340 and 1130 mg/kg bw/day) included loss of appetite, extreme body weight loss and failure of reflexes. Prostration and general organ atrophy, and tissue disintegration was also noted. Mortalities occurred at doses of 340 and 1130 mg/kg bw/day at 50 % and 100 %, respectively (OECD, 2007). Surviving animals showed marked recovery in the 14-day period post exposure, but recovery was not complete in comparison with the control animals. Histopathological changes were seen at 340 mg/kg bw/day and above and these included gastric ulcerations, intestinal hyperaemia, lipid depletion including reddish-brown colouration of adrenal glands, necrotic area in the adrenal cortex and dilation of blood vessels, renal changes (greyish white radial stripes in both cortex and medulla), and fibrosis of spleen and thymus. At the highest dose (1130 mg/kg bw/day), particularly significant degeneration of the testes was noted (OECD, 2007).

In a 90-day oral gavage study, rats were treated with 0, 10, 20, 40, 80, and 160 mg/kg bw/day. No deaths were reported (OECD, 2007). Significant reduction in body weight was observed at 80 and 160 mg/kg bw/day, although, this did not include significant organ weight changes. Minimal to mild degeneration of the germinal epithelium of the testes and epididymis was observed in males at the highest dose. A NOAEL of 80 mg/kg bw/day for males was identified based on the reduced body weight (25 %), erythron (erythrocytes) changes, and histopathological changes in the testes and in the epididymis. A NOAEL of 40 mg/kg bw/day for females was identified based on reduced body weights (20 %) at 160 mg/kg bw/day and haematological changes at 80 mg/kg bw/day.

From the results of a 90-day study on mice using dose levels of 0, 10, 20, 40, 80, 160 mg/kg bw/day, a NOAEL of 40 mg/kg bw/day was determined. Treatment did not result in any mortalities. The NOAEL was based on a decrease in body weight gains, and increased incidences of non-neoplastic lesions (hyperplasia and inflammation) reported in pancreatic ducts at doses of 80 and 160 mg/kg bw/day. All males receiving 160 mg/kg bw/day had abnormal residual bodies in sections of the testes tubules.

Dermal

Based on treatment-related effects in a repeated dose dermal toxicity study, the chemical is not considered to cause serious damage to health from repeated dermal exposure. The available data do not warrant a hazard classification.

Two 90-day dermal rat studies are available. In the first study (OECD TG 411; applications of 0, 300, 1000, and 3000 mg/kg bw/day), haematological changes (increased erythrocyte counts and haemoglobin) were seen in all exposed groups (OECD, 2007). Clinical signs (erythema, reduced general condition, apathy, reduced food consumption, decreased body weight) and pathological findings (decreased absolute weights of liver, kidney, spleen, adrenal glands and testes; increased relative weights of liver and kidneys) and an increased incidence of bilateral testicular tubular atrophy were limited to the high dose level. A follow-up study was conducted at lower dose levels (0, 30, 100, 300 mg/kg bw/day). No treatment-related effects were seen at 30 and 100 mg/kg bw/day. However, in the high dose group, the observations in the previous study were reproduced. Therefore, the NOAEL was derived to be 100 mg/kg bw/day based on the described adverse effects at 300 mg/kg bw/day and above.

Inhalation

Based on treatment-related effects in a repeated dose inhalation toxicity study, the chemical is not considered to cause serious damage to health from repeated inhalation exposure. The available data do not warrant a hazard classification.

In a 14-day repeated dose inhalation toxicity study in male and female Sprague Dawley (SD) rats, the no observed adverse effect concentration (NOAEC) for the chemical was reported to be 190 mg/m³; the lowest observed adverse effect concentration (LOEAC) was 930 mg/m³ based on haematological effects (OECD, 2007). At the highest concentration in this group (2800 mg/m³), there was a 30 % mortality rate and clinical signs of toxicity (weakness and hunched posture). Haematology revealed mild thrombocytopaenia in the mid and high dose group both during exposure and during recovery, and lymphopaenia and hypocholesterolaemia in the high dose group. Histopathology of the high dose rats showed microscopic lesions in the kidneys and an increase in kidney weight was recorded (Government of Canada, 2009) along with testicular degeneration (OECD, 2007).

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemical is not considered to be genotoxic.

The chemical was not mutagenic in a valid Ames test (*Salmonella typhimurium* TA100, TA97, TA 98, TA1535, and TA1537) both with and without metabolic activation up to 10000 µg/plate. In vitro cell transformation assays reported conflicting results (OECD, 2007). The chemical was negative in a cell transformation assay using rat embryo cells at test concentrations of 0.01 to 100 µg/mL, whereas a statistically significant and dose-related increase in the number of transformed colonies was obtained with Syrian hamster embryo cells that were exposed to the chemical in the range of 200 to 550 µg/mL for seven days.

In in vivo studies, the chemical did not induce micronuclei in the peripheral blood of male and female mice after oral doses of up to 160 mg/kg bw/day for three months (OECD, 2007). The chemical produced positive results for clastogenicity in a micronucleus test using mouse bone marrow (OECD TG 474) following intraperitoneal dosing with ≥900 mg/kg bw. However, at the dose of 160 mg/kg bw/day, increased incidences of lesions of several tissues/organs and decreased body weights were seen in mice, suggesting that the observed induction of micronuclei may be attributed to the cell damage. The chemical (412 mg/kg bw) administered intraperitoneally was negative in a dominant lethal assay (OECD TG 478) using male mice (Government of Canada, 2009).

Carcinogenicity

There is no evidence of carcinogenic activity in rats. However, in one study, there was an increased incidence of haemangiosarcomas (malignant tumour of the cells that form blood vessels) in the liver in male mice. Given that only one sex in one species showed concern, and considering that the relevance of this effect in male mice to humans has not been assessed, further investigation is warranted.

In a carcinogenicity study in rats and mice, the chemical was administered in deionised water via gavage at 0, 20, 40 and 80 mg/kg bw/day to F344/N rats and B6C3F1 mice (both males and females) for five days/week for 104 weeks. There was no reported evidence of carcinogenic activity of the chemical in male or female rats. In male mice the chemical was reported to be carcinogenic based on an increased incidence of haemangiosarcomas in the liver. The incidence was reported to increase with dose, with significant increases occurring at 40 and 80 mg/kg bw/day. In female mice, equivocal evidence of carcinogenic activity was reported based on marginally increased incidences of hepatocellular adenoma or carcinoma (reported to be significant only when adenoma and carcinoma were combined) (Government of Canada, 2009).

Reproductive and Developmental Toxicity

The chemical is classified as hazardous—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 support this classification. In addition, the available data warrant classification for reproductive toxicity (refer **Recommendation** section).

Nine developmental toxicity studies have been documented in the OECD report (OECD, 2007). The chemical was reported to have developmental toxicity in oral gavage studies conducted on rabbits, rats and mice. In these studies, maternal effects included reduced food consumption, reduced body weight gain and vaginal bleeding. Developmental toxicity included reduced foetal weight, increased incidences of foetal death, skeletal malformations, cleft palate, exencephaly (brain located outside the skull) and fused ribs. Developmental effects were observed at or below the maternal toxic dose (OECD, 2007).

The chemical is also reported to be toxic to reproduction, based on a multigenerational toxicity study in mice where the chemical was administered in drinking water at concentrations of 0, 100, 350 or 750 ppm (OECD, 2007). Maternal toxicity was observed at the highest dose, with overall body weight reductions of 7 %, except for week 16 where it was observed to be 14 %. No other clinical signs of toxicity were seen in the dams. Reproductive effects were observed at the highest dose in the parental and offspring generations, and these included significantly decreased fertility rates, reduced live litter sizes, increased days to first litter and reduced seminal vesicle weight. The cross-over

studies revealed that reduced fertility was due to impairment of reproduction in females with fertility levels down to 37 % (compared with 94 % for controls) when high-dose females were mated with control males. In addition, in the F1 generation, females were oestrous for a shorter time and dioestrous for a significantly longer time compared with the controls. In males, a significant increase in relative epididymis and right testis weight were observed in the F1 generation, and in females, ovarian weight was reduced at both mid and high dose levels. Significant reproductive effects were observed in both generations at the maternal toxicity dose level. The effects seen are not considered to be due to secondary effects of maternal toxicity considering limited effects on the dams. The NOAEL for reproductive toxicity was 350 ppm (equivalent to 48–110 mg/kg bw/day).

At higher doses, testicular degeneration was observed in repeated dose toxicity studies through oral, dermal and inhalation exposure (OECD, 2007).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (reproductive and developmental toxicity). A study found an increased incidence of haemangiosarcomas in the liver in male mice. The relevance of this effect in male mice to humans has not been assessed. The chemical may also cause harmful effects following repeated oral exposure.

Public Risk Characterisation

The total volume introduced into Australia reported under previous mandatory and/or voluntary calls for information was low. No specific Australian use information has been identified except in play mats and toys for children. Recent testing undertaken by the Australian Competition & Consumer Commission (ACCC) has shown that the amount of chemical released by these articles is very small and that there is no evidence that these products present any risk to children (ACCC, 2013). Domestic use of the chemical is considered to be limited based on overseas surveys (Government of Canada, 2009). Hence, the public risk from this chemical is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, 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 systemic long-term 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**).

NICNAS Recommendation

The chemical is recommended for Tier III assessment to examine whether a carcinogenic classification is warranted.

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 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 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]
Repeat Dose Toxicity		May cause damage to organs through prolonged or repeated exposure through the oral route - Cat. 2 (H373)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of impaired fertility (Xn; R62) Repro. Cat 2 - May cause harm to the unborn child (T; R61)*	Suspected of damaging fertility - Cat. 2 (H361f) May damage fertility or 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 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 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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