# Formic acid: Human health tier II assessment

**22 March 2013**

## CAS Number: 64-18-6



## 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.

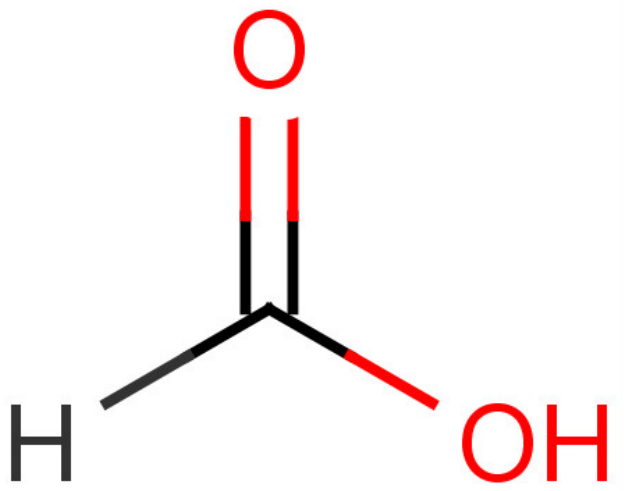
For more detail on this program please visit:www.nicnas.gov.au

**Disclaimer**



Acronyms & Abbreviations

## Chemical Identity

| | |
|---|---|
| Synonyms | Methanoic acid<br>Hydrogen carboxylic acid<br>Aminic acid<br>Acidum formicum<br>Myrmicyl |
| Structural Formula |  |
| Molecular Formula | CH2O2 |
| Molecular Weight (g/mol) | 46.03 |
| Appearance and Odour (where available) | Colourless fuming liquid with a pungent, penetrating odor. |
| SMILES | C(=O)O |

# Import, Manufacture and Use

## Australian

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

## International

The following international uses have been identified through the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR), Galleria Chemica, Substances and Preparations in the Nordic countries (SPIN) database and the European Commission Cosmetic Substances and Ingredients (CosIng) database:

The chemical has reported cosmetic use as:

- a preservative;
- a fragrance compound; and
- a pH adjuster.

The chemical has reported domestic use. The chemical is reported to be present in a range of domestic products including home maintenance products such as paint strippers up to a concentration of 15%, cleaning products up to a concentration of 5% and fabric softeners (concentration not stated) (Household Products Database, US Department of Health and Human Services; HSDB).

The chemical has reported commercial use including:

- a decalcifier in dyeing wool and in tanning leather; and
- corrosion inhibitors.

The chemical has reported site limited use including:

- manufacture of refrigerants and other commercial chemicals including cellulose formate and vinyl resin plasticisers.

The chemical has reported non-industrial use including:

- food additive.

# Restrictions

## Australian

This chemical is listed in the Poisons Standard for the Uniform Scheduling of Medicines and Posions (SUSMP) in Schedule 5, except in preparations containing 0.5 per cent or less of formic acid.

Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

## International

**European Union:** The use of the chemical in cosmetics in the European Union is subject to the restrictions described in EU Regulation ((EC) No 1223/2009) Annex V (Ref 14). This preservative may be used in cosmetics and personal care products at a maximum concentration of 0.5% (as acid).

**New Zealand:** New Zealand Cosmetic Products Group Standard - Schedule 7: Preservatives Cosmetic Products May Contain With Restrictions; maximum authorised concentration, 0.5 % (expressed as the acid).

**US Cosmetic Ingredient Review** (CIR, 1997)**:** The CIR considers the chemical to be safe for use in cosmetics as a pH adjustor with a limit of 64 ppm for the free acid.

# 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; R35.

## Exposure Standards

### Australian

The chemical has an exposure standard of 9.4 mg/m³ (5 ppm) time weighted average (TWA) and 19 mg/m³ (10 ppm) short term exposure limit (STEL).

### International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 9 – 9.4 mg/m³ (5 ppm) and STEL of 19 mg/m³ (10 ppm) in different countries such as Denmark, France, Germany, Japan, UK and USA.

# Health Hazard Information

## Toxicokinetics

The chemical is absorbed via the gastrointestinal tract, lungs and skin (HSDB, 2013).

## Acute Toxicity

### Oral

The chemical was reported to have moderate acute toxicity in animal tests following oral exposure. The lowest reported median lethal dose (LD50) in rats is 730 mg/kg bw. Observed sub-lethal effects included bloody nose and blood in urine. Histopathological changes in the stomach, liver and kidney were observed (OECD, 2008; EPA, 2001).

### Dermal

There are no available dermal toxicity data on the chemical (OECD, 2008).

### Inhalation

The chemical was reported to have moderate acute toxicity in animal tests following inhalation exposure. The median lethal concentration (LC50) in rats is 7.4 mg/L (vapour). Observed sub-lethal effects included corrosion of the nose and eye, corneal opacity and noisy breathing. Symptoms persisted until termination at day 14.

Inflated lungs and dilated hearts were observed in the animals that died.

Exposure to a saturated vapour concentration of the chemical for a period of three minutes has been shown to cause death in rats (OECD, 2008; REACH, 2011).

## Corrosion / Irritation

## Corrosivity

The chemical is classified as hazardous with the risk phrase ‘Causes severe burns’ (C; R35) in HSIS (Safe Work Australia). The data available ( pH < 2 (pKa = 3.75 at 20 °C)) support this classification (OECD, 2008). There are no skin and eye irritation studies available on the chemical (OECD, 2008).

Corrosive chemicals are also considered to cause irreversible effects on the eyes. This is supported by eye damage reported in acute toxicity studies (see above). Evidence of irritation of the respiratory tract was also observed in acute and repeat dose toxicity studies (as summarised elsewhere in this report).

The chemical is known to be corrosive to the skin and gastrointestinal tract of humans (OECD, 2008).

## Sensitisation

### Skin Sensitisation

The chemical was not shown to be a skin sensitiser in a Buehler study (OECD, 2008).

### Observation in humans

Sesitisation in humans has been reported when the patient had been previously sensitised to formaldehyde (HSDB, 2012).

## Repeated Dose Toxicity

### Oral

When the chemical was administered to rats in the diet or drinking water (0.5 to 1%) the body weight gain and size of most organs were reduced (HSDB, 2013). Another study also in rats receiving up to 360 mg/kg of the chemical in drinking water for two to 27 weeks showed only a reduced feed intake and corresponding body weight gain (HSDB, 2013).

### Dermal

There are no repeated dose dermal toxicity data available on the chemical.

### Inhalation

The chemical was tested for repeated inhalation toxicity in 13 weeks studies in both rats and mice (OECD, 2008; US EPA, 2001). The effects seen were primarily limited to irritant effects of the respiratory tract although increased liver weights and decreased lung weights were also observed. The NOAEC in rats was 64 ppm based on the irritant effects seen at higher concentrations. Although the NOAEC is sufficiently low to allow classification, as the effects were due to the irritant nature of the chemical and there is no significant evidence of systemic toxicity observed, no hazard classification for repeat dose inhalation toxicity is recommended. However, a classification for respiratory irritation is warranted.

## Genotoxicity

The chemical was not genotoxic in reverse mutation assays both with and without metabolic activation, although a test from 1951 which did not follow current protocols produced slightly positive results (US EPA, 2001).

The chemical produced ambiguous results for chromosome aberrations in Chinese hamster ovary cells at pH levels that were only slightly above being cytotoxic. At higher pH levels the chemical did not produce chromosome aberrations (US EPA, 2001).

The chemical was negative in two sister chromatid exchange assays and in a SOS chromotest (US EPA, 2001).

An *in vivo* sex-linked recessive lethal test in *Drosophila melanogaster* with the chemical administered as a 0.1% vapour or in the diet resulted in mutations that were statistically significant, although when buffered in the feeding study to a pH of 7.5 there was no increase in mutation (OECD, 2008).

As the chemical only produced mutations at low pH levels where the effects are likely to be due to the acidic nature of the chemical rather any underlying genotoxicity, the chemical is not considered to be genotoxic.

## Carcinogenicity

There are no carcinogenicity studies available on the chemical. However, in two carcinogenicity studies with the analogue potassium hydrogen diformate (CAS number 20642-05-1) no evidence of increased carcinogenicity was seen (OECD, 2008).

## Reproductive and Developmental Toxicity

There are no reproductive or developmental studies available on the chemical. However, in the repeated dose studies on rats and mice with the chemical, no adverse effects on reproductive organs were evident (OECD, 2008). Developmental studies with the analogues potassium hydrogen diformate (CAS number 20642-05-1) and sodium formate (CAS number 141-53-7) in rats, rabbits and pigs showed no effects on the developing foetuses with NOAEL values of 1000 mg/kg bw/d (OECD, 2008).

# Risk Characterisation

## Critical Health Effects

The main critical effect to human health is corrosion. The chemical also possesses hazardous properties such as acute toxicity following inhalation or oral exposure.

### Public Risk Characterisation

Although use in cosmetic products in Australia is not known the chemical is reported to be used in cosmetic products overseas only as a pH adjuster, preservative and fragrance compound. In such cosmetic formulations, the chemical is expected to be used at low concentrations and neutralised into various formate salts.

Although concentrations in domestic products may be higher, any domestic (or cosmetic) products where the concentration of free acid is greater than 0.5% will be labelled with 'Caution', with the label also containing a number of first aid and safety directions.

The current controls are considered adequate to minimise the risk to public health posed by domestic and cosmetic products containing the chemical. Therefore the risk to public health is not considered to be unreasonable.

### Occupational Risk Characterisation

During formulation of products, dermal, ocular and inhalation exposure of workers to the chemical may occur particularly where manual or open processes are used. This may include during transfer and blending activities, quality control analysis and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur during use of 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 effects of the chemical, the chemical may pose an unreasonable risk to workers if adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are not implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) e.g. employer at a workplace 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

Assessment of the chemical is considered to be sufficient provided that the recommendation is adopted for the amendment of the classification and labelling of the chemical and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

### Regulatory Control

#### Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP).

#### Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This does not consider classification of physical hazards and environmental hazards.

| Hazard | Approved Criteria (HSIS)[a] | GHS Classification (HCIS)[b] |
|---|---|---|

| 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) Toxic if inhaled - Cat. 3 (H331) |
| Irritation / Corrosivity | Irritating to respiratory system (Xi; R37) Causes severe burns (C; R35)* | May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335) 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 label instructions.

## Advice for industry

***Control measures***

Control measures to minimise the risk from 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 storage, handling and use of a hazardous chemical are dependent 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:

- use of closed systems or isolation of operations;
- use of local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimisation of manual processes and work tasks through automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of 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 be relied upon on its own to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selection of 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 hazardous chemical are prepared; and
- management of risks arising from storage, handling and use of 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 physical hazards of the chemical has not been undertaken as part of this assessment.

## References

OECD (2008). SIDS Initial Assessment Profile (SIAP) on Formic acid and Formates. Accessed at http://webnet.oecd.org/Hpv/UI/handler.axd?id=81d8d2fe-5244-4699-93ab-c501433db94c

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U.S. EPA HPV Chemical Challenge Program Test Plan for the Formates Category (2001). Accessed February 2013 at http://www.epa.gov/chemrtk/pubs/summaries/formates/c13438.pdf

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