2-Furanmethanol: Human health tier II assessment

21 April 2016

CAS Number: 98-00-0

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.

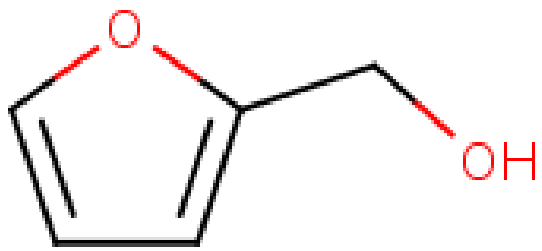
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	2-hydroxymethylfuran furfuryl alcohol 2-furylcarbinol
Structural Formula	
Molecular Formula	C5H6O2
Molecular Weight (g/mol)	98.10
Appearance and Odour (where available)	Clear to yellowish liquid with a faint odour
SMILES	C1(CO)=CC=CO1

Import, Manufacture and Use

Australian

The chemical has been reported under previous mandatory calls for information. No specific Australian use or manufacturing information has been identified.

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers;
- Galleria Chemica;
- the Scientific Committee on Cosmetic Products and Non-Food Products; and,
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use as an ingredient in perfumes and aromatic raw materials.

The chemical has reported commercial uses, including as:

- a viscosity reducer in epoxy resins;
- an accelerator or liquefier for amine curatives of epoxy resins; and
- a solvent in textile printing and in alkaline paint strippers.

The chemical has reported site-limited use as a reactant in acid-catalysed polymerisation reactions to form furan resins.

Restrictions

Australian

No known restrictions have been identified.

International

The chemical is prohibited under the International Fragrance Association (IFRA) Standards (48th amendment) (IFRA, 2015).

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);

- T; R23 (acute toxicity);
- Xn; R21/22 (acute toxicity);
- Xn; R48/20 (repeated dose toxicity); and
- Xi; R36/37 (irritation).

Exposure Standards

Australian

The chemical has an exposure standard of 40 mg/m^3 (10 ppm) time weighted average (TWA) and 60 mg/m^3 (15 ppm) short-term exposure limit (STEL) (Safe Work Australia).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 20–200 mg/m^3 (5–50 ppm) TWA and 40–60 mg/m^3 (10–15 ppm) short-term exposure limit (STEL) has been set in different countries such as the USA (Hawaii, Minnesota, Tennessee and Vermont), Canada (Alberta, Quebec & Yukon), Estonia, Greece, Ireland, Sweden and Switzerland.

Health Hazard Information

Toxicokinetics

Based on animal studies, the main metabolic route of the chemical is through oxidation to the equivalent aldehyde, furfural, then subsequent biotransformation into the main metabolite: furoyl glycine. Other metabolites consisted of furoic acid, furanacrylic acid and furanacrylolglycine. Excretion is primarily through the urine, with smaller amounts in the faeces. In humans, the metabolic pathway of the chemical is considered similar based on experiments using furfural (MAK, 1996; NTP, 1999).

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 the absence of more comprehensive information, a recommendation to amend the current classification of the chemical is not warranted.

Median lethal doses (LD50) of 110 to 451 mg/kg bw in rats were reported (MAK, 1996; NTP, 1999; REACH). Information on the adverse effects from chemical exposure is not available. However, based on rodent studies conducted in related furfuryl derivatives, liver toxicity is expected following exposure to the chemical (JECFA, 2000).

Dermal

The chemical is classified as hazardous with the risk phrase ‘Harmful in contact with skin’ (Xn; R21) in the HSIS (Safe Work Australia). Although some data do not support the current classification of the chemical, in the absence of more comprehensive information, amendment of the current classification is not warranted.

The LD50 values after topical application of the chemical were determined to be 657 mg/kg bw, 4920 mg/kg bw, and 8500 mg/kg bw for rabbits, mice, and guinea pigs, respectively (MAK, 1996). According to REACH, LD50 values of 400 mg/kg bw in rabbits and 3825 mg/kg bw in rats were reported. The only effect reported was convulsions in rabbits (REACH).

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Toxic by inhalation’ (T; R23) in the HSIS (Safe Work Australia). The data support the current classification of the chemical.

In a study conducted in Crl:[WI]WU BR rats (five animals/sex/dose), vapours of the chemical were administered once by nose-only inhalation exposure at doses of 0.51, 0.82 or 2.07 mg/L for four hours. Most of the animals in the high dose group died during exposure and the survivors were sacrificed immediately for humane reasons. No deaths in the other exposed groups were reported. Decreased breathing rates were observed in all dose groups. This effect was resolved in the low dose group after the last hour of exposure while 'sniffing' persisted the day after exposure in the 0.82 mg/L group. In the high dose group, the following effects were observed: red or dark red discoloured lungs, foam in the trachea, and haemorrhagic (blood flow due to damaged blood vessels) or foamy discharge from the nose and mouth. No treatment-related changes were observed in the other dose groups. The median lethal concentration (LC50) value in this study was determined to be between 0.82 mg/L and 2.07 mg/L (REACH).

Corrosion / Irritation

Respiratory Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R36) in HSIS (Safe Work Australia). The limited data support the classification.

In a two-year inhalation study in rats and mice (see **Carcinogenicity** section), squamous metaplasia of the nasal epithelium was observed. This represents an adaptive response to chronic irritation (NTP, 1999).

Skin Irritation

The chemical is reported to irritate skin in an animal study. In the absence of more comprehensive information, a recommendation to classify the chemical for this particular endpoint is not warranted.

In a non-guideline study conducted in guinea pigs (unspecified strain), irritating effects were reported upon daily application of the chemical (50 % solution in acetone) on the skin for 12 days. The effects included skin dryness, hyperaemia, desquamation and necrosis (REACH).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The available data support this classification.

Application of the chemical (56 mg) in rabbits' eyes caused inflammation, mucous secretion, and clouding of the cornea which reversed within 40 to 64 days. At a lower dose (23 mg), the ocular effects of the chemical were less severe and recovery was observed within two to eight days (MAK, 1999; REACH).

In an eye irritation study in rats, vapours of the chemical at 2800 mg/m^3 caused redness in the eyes within eight minutes of exposure (REACH).

Corneal degeneration was also observed in female B6C3F1 mice exposed to the chemical at a dose of 32 ppm (equivalent to 128.3 mg/m^3) for two years. This degeneration was characterised by mineralisation of the stroma beneath the corneal epithelium. Hyperplasia, ulceration, and slight infiltrate of inflammatory cells in the mineralisation site was observed in more severe cases (NTP, 1999).

Sensitisation

Skin Sensitisation

The chemical is considered to be a skin sensitiser based on the positive results seen in several local lymph node assays (LLNA). The EC3 values (estimated concentration needed to produce a stimulation index of 3.0) of 4.68% and 25.6% were reported. Therefore, the chemical is recommended to be classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in the HSIS.

In a LLNA study conducted in female CBA/J mice (four animals/dose), the chemical (in 4:1 v/v solution of acetone/olive oil) was administered at doses of 0 %, 1 %, 5 %, 10 %, 20 % or 40 %. Disintegrations per minute (DPM) values of 21.0, 16.9, 21.6, 185.7, 193.2 and 440.9 were reported for each dose, respectively. Stimulation indices (SI) in the 10 %, 20 % and 40 % group had statistically significant scores of 8.8, 9.2, and 21.0, respectively. The SI scores of the lower dose groups were lower than 3.0. An EC3 value of 4.68 % was determined for the chemical, which indicates sensitisation potential.

In another LLNA study conducted in female BALB/c mice, SI values of 1.3, 2.9, 4.3 and 5.9 were determined for the chemical when applied at doses of 10 %, 20 %, 50 % and 75 %, respectively, in vehicle. An EC3 value of 25.6% was determined in this study, which supports the sensitisation potential of the chemical (REACH).

Repeated Dose Toxicity

Oral

Considering the lowest observed adversed effect level (LOAEL) available from a 13-week study, repeated oral exposure to the chemical is not considered to cause serious damage to health.

In a 13-week study, the chemical (in corn oil) was administered by oral gavage at doses of 0, 38, 75, 150 or 300 mg/kg in F344/N rats; or 0, 38, 75, 150, 300 or 600 mg/kg bw/d in B6C3F1 mice. In the 150 and 300 mg/kg bw/d groups, all rats died before the end of the study and significant mortalities were observed in mice at doses of 300 and 600 mg/kg bw/d. The mean body weights of surviving rats were similar to controls while the mean body weights of the surviving mice at the highest dose (600 mg/kg bw/d) were lower than in control by 15 %. In rats, the mean absolute liver and kidney weights in the 75 mg/kg bw/d group was significantly higher compared to controls, while no other significant differences in organ weights were observed in mice. Liver and kidney lesions were observed in rats (at the 75 mg/kg bw/d and above) and in mice (at 300 mg/kg bw/d and above). The liver lesions in rats consisted of degeneration of individual hepatocytes and cytoplasmic vacuolisation. The kidney lesions in rats consisted of tubular epithelial cells in the renal cortex. The lesions in mice were more severe than in rats, and included necrosis in both kidneys and liver (NTP, 1999). The LOAEL values were determined to be 75 mg/kg bw/d and 300 mg/kg bw/d for rats and mice, respectively.

Dermal

No data are available.

Inhalation

The chemical is classified as hazardous with the risk phrase 'Harmful: danger of serious damage to health by prolonged exposure through inhalation' (Xn; R48/20) in the HSIS (Safe Work Australia). The data support the current classification of the chemical.

In a 14-week study, F344/N rats and B6C3F1 mice (10 animals/sex/dose) were exposed to the chemical at concentrations of 0, 2, 4, 8, 16 or 32 ppm (equivalent to 0.0, 8.0, 16.0, 32.0, 64.2 or 128.3 mg/m^3) for six hours per day, five days per week. No deaths occurred in either species. In rats, swelling around the face and eyes as well as stained urine were observed in all exposed groups. The final mean body weights, body weight gain, and absolute liver and lung weights were significantly lower compared with controls. Treatment-related increases in incidences of degeneration, hyperplasia, metaplasia and surface exudate of the olfactory epithelium were also observed. Transient erythrocytosis was observed from 4 ppm and above; however, by day 23, haematological parameters were similar to controls. In the two highest dose groups, the incidence of cellular infiltrate of the lamina propria of the nose was significantly increased compared with controls. In mice, except for the highest dose group, the final mean body weight and body weight gain were significantly greater compared with controls. Treatment-related changes including chronic inflammation of the respiratory epithelium, hyaline droplets in the respiratory epithelium and squamous metaplasia of the submucosal gland of the cuboidal epithelium were also observed in the exposed groups. The absolute and relative heart weights of the high dose group were significantly lower compared with controls (NTP, 1999). The no observed adverse effect concentration (NOAEC) values in rats and mice were determined to be 16.0 mg/m^3 and 128.3 mg/m^3, respectively (REACH).

In a 2-year study, F344/N rats and B6C3F1 mice (50 animals/sex/dose) were exposed to the chemical at concentrations of 0, 2, 8 or 32 ppm (equivalent to 0.0, 8.0, 32.0 or 128.3 mg/m^3) for six hours per day, five days per week. In rats, all high dose males died by week 99 of the study; the survival of the other exposed groups are comparable to controls. Mean body weights of the high dose males were lower compared with controls from week 19 of the study. Nephropathy, which was regarded as a common condition to this specific rat strain and not considered as treatment-related effect, was reported. In mice, survival of the exposed groups was similar to controls. Mean body weights of exposed males were comparable with controls but were lower in exposed females from weeks 39 to 59 of the study. Treatment-related nephropathy was observed in all exposed groups, which consisted of necrosis and regeneration of the renal tubule epithelium as well as inflammation and fibrosis in the interstitium. In both rats and mice, treatment-related severe nasal effects were observed. These effects included non-neoplastic lesions, suppurative inflammation of the epithelial lining or within the nasal lumens, multiple layers of polyhedral epithelium in Bowman's glands, hyperplasia and squamous metaplasia of the respiratory epithelium, hyaline degeneration of the respiratory and olfactory epithelium, and connective tissue fibrosis in the olfactory epithelium (NTP, 1999). The systemic NOAEC value for both rats and mice was determined to be 32.0 mg/m^3 (REACH).

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. However, concerns about potential genotoxic effects of the chemical have been raised (ECHA, 2015; JECFA, 2012) and to address these concerns, ECHA has required an *In vivo mammalian alkaline comet assay* (OECD TG 489) to be conducted in mice. The results, and subsequent re-evaluation of the chemical for this particular endpoint, is expected to be available by 27 May 2016 (ECHA, 2015).

The chemical has no genotoxic potential based on the following tests (MAK, 1996; NTP, 1999):

- no increase in revertant colonies in *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537, with or without metabolic activation;
- no increase in sister chromatid exchange in cultured human peripheral lymphocytes; and
- negative results in a sex-linked recessive lethal assay and a sex chromosome loss test conducted in *Drosophila melanogaster*.

Carcinogenicity

The chemical is classified as hazardous—Category 3 carcinogenic substance—with the risk phrase ‘Limited evidence of carcinogenic effect’ (Xn; R40) in the HSIS (Safe Work Australia). The available data support this classification.

In a 2-year study, F344/N rats and B6C3F1 mice (50 animals/sex/dose) were exposed by inhalation to the chemical at concentrations of 0, 2, 8 or 32 ppm (equivalent to 0.0, 8.0, 32.0 or 128.3 mg/m^3) for six hours per day, five days per week. In rats, incidences of neoplasms were observed in the nose and kidneys. Nasal neoplasms consisted of lateral wall adenomas, respiratory epithelium adenomas, and squamous cell carcinomas. In the kidneys, adenomas and carcinomas of the renal tubule, nephroblastoma and stromal nephroma were observed. Except for the incidence of squamous cell carcinoma in the nose, incidences of neoplasms in the nose and kidneys were not significantly greater compared with controls. In mice, although neoplasms in the nose and kidneys were observed, there was no significant increase compared with controls. However, the incidence of renal tubule adenomas and carcinomas occurred with a positive trend and exceeded the historical control ranges. The study concluded that there was 'some evidence of carcinogenic activity' in male F344/N rats and B6C3F1 mice, 'equivocal evidence of carcinogenicity' in female F344/N rats and 'no evidence of carcinogenic activity' in female B6C3F1 mice (NTP, 1999).

Reproductive and Developmental Toxicity

There are no available studies conducted that specifically examines the reproductive or developmental toxicity of the chemical. Based on available information, the chemical is not expected to cause reproductive or developmental toxicity.

In a repeat dose inhalation toxicity study, exposure to vapours of the chemical at a concentration of 32 ppm (equivalent to 128.3 mg/m^3) resulted in an increase in spermatid counts and number of sperm heads per testes (NTP, 1999).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity), systemic acute effects (acute toxicity from oral, dermal and inhalation exposure) and local effects (skin sensitisation as well as skin, eye and respiratory tract irritation). The chemical can also cause harmful effects following repeated exposure through inhalation. Concerns regarding its potential for being genotoxic is also being investigated.

Public Risk Characterisation

Although use in cosmetic/domestic products in Australia is not known, the chemical is reported to be used in cosmetic/domestic products overseas. The main route of public exposure is expected to be through the skin, eye and inhalation from products applied as aerosols or perfumes.

As the chemical is unlikely to have wide distribution in raw fragrance materials that are broadly available, the distribution of these materials is expected to be controlled by members of IFRA. The prohibition of the chemical under the IFRA Standard is expected to sufficiently manage the public risks associated with chemical exposure through fragrances. It is expected that the consumer risks from low concentration uses outside of the scope of the IFRA Standards will not be significant enough to warrant a concern.

Occupational Risk Characterisation

Given the critical systemic long-term, systemic acute and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation 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.

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

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented 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, 2016).

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)* Toxic by inhalation (T; R23)*	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) Toxic if inhaled - Cat. 3 (H331)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to respiratory system (Xi; R37)*	Causes serious eye irritation - Cat. 2A (H319) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)
Repeat Dose Toxicity	Harmful: danger of serious damage to health by prolonged exposure through inhalation (Xn; R48/20)*	May cause damage to organs through prolonged or repeated exposure through inhalation - Cat. 2 (H373)
Carcinogenicity	Carc. Cat 3 - Limited evidence of a carcinogenic effect (Xn; R40)*	Suspected of causing cancer - Cat. 2 (H351)

[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 that 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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