Oxazolidine, 4,4-dimethyl-: Human health tier II assessment

29 June 2018

CAS Number: 51200-87-4

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.

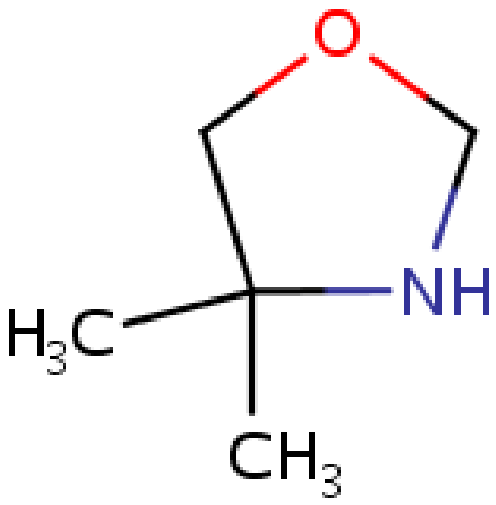
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	4,4-dimethyl-1,3-oxazolidine dimethyl oxazolidine Oxaban-A
Structural Formula	
Molecular Formula	C5H11NO
Molecular Weight (g/mol)	101.15
Appearance and Odour (where available)	Colourless to slightly yellow liquid with a fishy odour.
SMILES	C1(C)(C)COCN1

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through 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 Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS); the Handbook of Cosmetic and Personal Care Additives (Ash & Ash, 1994); the US Household Products database; the Good Scents Company database; eChemPortal; and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

Dimethyl oxazolidine has reported cosmetic use as a preservative in moisturising preparations, tonics and other hair grooming products.

The chemical has reported domestic use including in:

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

The chemical has reported commercial use including in:

- metalworking cutting fluids;
- resin emulsions
- oil recovery drilling muds; and
- industrial processing chemicals.

According to international information, the chemical is used in non-industrial applications as a pesticide and bactericide.

Restrictions

Australian

The chemical is a formaldehyde donor. Formaldehyde donors are specifically included in the definition of free formaldehyde in the *Poisons Standard* (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) as follows:

“**Free formaldehyde**” includes all hydrated and non-hydrated formaldehyde present in aqueous solution, including methylene glycol and formaldehyde released from formaldehyde donors.

Formaldehyde is listed in Schedules 2, 6 and 10 of the SUSMP as follows:

- in Schedule 2:

'FORMALDEHYDE (excluding its derivatives) for human therapeutic use **except**:

(a) in oral hygiene preparations containing 0.1 per cent or less of free formaldehyde; or

(b) in other preparations containing 0.2 per cent or less of free formaldehyde.'

Schedule 2 chemicals are labelled with 'Pharmacy medicines' and are 'substances, the safe use of which may require advice from a pharmacist and should be available from a pharmacy or, from a licensed person'.

- in Schedule 6:

'FORMALDEHYDE (excluding its derivatives) in preparations containing 0.05 per cent or more of free formaldehyde **except**:

(a) for human therapeutic use;

(b) in oral hygiene preparations;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde;

(d) in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the statement: PROTECT CUTICLES WITH GREASE OR OIL;

(e) in all other cosmetic preparations; or

(f) in other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.'

Schedule 6 chemicals are labelled with 'Poison' and are 'substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'.

- in Appendix C:

'FORMALDEHYDE (excluding its derivatives):

(a) in oral hygiene preparations containing more than 0.1 per cent of free formaldehyde;

(b) in aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde;

(c) in nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde; or

(d) in all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde **except** in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.'

Schedule 10 are 'substances of such danger to health as to warrant prohibition of sale, supply and use - Substances which are prohibited for the purpose or purposes listed for each poison.'

International

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

- the EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products—Annex V List of preservatives allowed in cosmetic products, with a maximum authorised concentration of 0.1 % with pH >6;
- the New Zealand Cosmetic Products Group Standard—Schedule 7: Preservatives cosmetic products may contain with restrictions—Table 1: List of preservatives allowed; and
- the ASEAN Cosmetic Directive Annex VI—Part 1—List of preservatives allowed for use in cosmetic products.

As part of the European Union Biocidal Products Regulation, the chemical was determined to be not approved for a number of uses. Active substances need to be approved before an authorisation for a biocidal product containing them can be granted (European Commission, 2014).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The chemical, dimethyl oxazolidine, has reported use as a preservative in cosmetics; the mode of action is formaldehyde release into aqueous solutions (De Groot et al., 2009). The degree of completeness of formaldehyde release in a cosmetic product will depend on the concentration of the preservative in the product, the percentage of water in the product, the rate of formaldehyde release from the specific preservative, and the length of time since formulation.

Methods have been developed to allow the determination of the free formaldehyde in the presence of non-dissociated preservative (SCCNFP, 2002).

For skin sensitisation and systemic toxicity, it is considered that the formaldehyde released from the decomposition of this chemical will be the critical driver of these modes of toxicity. There are limited toxicological data available for the chemical. However, the hydrolysis product, formaldehyde (CAS No. 50-00-0) is considered the critical driver for toxicity due to its formation under physiological conditions. The toxicology of formaldehyde donor chemicals has previously been assessed by NICNAS (NICNAS, 2006; NICNASa), and has been considered in this assessment. Where appropriate, data for these chemicals are read across to fill data gaps in the assessment.

Acute Toxicity

Oral

Based on the reported median lethal dose (LD50) of 950–1308 mg/kg in rats (HSDB; RTECS), dimethyl oxazolidine is considered to have moderate toxicity and hazard classification is warranted (see **Recommendation** section).

Dermal

Based on test results, the chemical has low to moderate acute dermal toxicity in rats (>2000 mg/kg) and rabbits (1400 mg/kg) respectively (HSDB; RTECS). Hazard classification is recommended because the preferred species for this endpoint is the rabbit (see **Recommendation** section).

Inhalation

Dimethyl oxazolidine was reported to have an LC50 value of 11700 mg/m^3 (11.7 mg/L) in rats (RTECS), warranting hazard classification (see **Recommendation** section).

Corrosion / Irritation

Skin Irritation

While no data are available from guideline studies on the chemical, skin irritation was observed in rats and rabbits exposed to dimethyl oxazolidine following repeated applications (see **Repeated dose toxicity** and **Reproductive and developmental toxicity** sections). Reading across from data available for other formaldehyde donors and chronic dermal studies of the chemical, hazard classification is warranted (see **Recommendation** section).

Eye Irritation

Dimethyl oxazolidine is reported to have 'effects as a severe eye irritant' but no study details are available (HSDB). Sensory irritation from formaldehyde vapour release is not expected from products containing the chemical as a preservative, given that formaldehyde is unlikely to be volatile from aqueous solutions at low concentrations. However, if the chemical is applied directly to the eye, irritation could occur due to the severe irritancy of formaldehyde. Reading across from data available for other formaldehyde donors (NICNASa) and the limited information for this chemical, hazard classification is warranted (see **Recommendation** section).

Sensitisation

Respiratory Sensitisation

No data are available on the chemical, but formaldehyde is not classified as a respiratory sensitiser (NICNAS, 2006), nor is it likely to be volatile from the low concentration solutions present in products containing these preservatives.

Skin Sensitisation

There are no data available for the chemical.

Based on the available data for the hydrolysis product, formaldehyde, which is a strong skin sensitiser in solutions (NICNAS, 2006), the chemical is expected to be a skin sensitiser, warranting hazard classification (see **Recommendation** section). The available data from animal studies and human data for other formaldehyde donors support this classification (NICNASa).

Repeated Dose Toxicity

Oral

There are no data available for the chemical. Based on the lack of systemic toxicity of formaldehyde in oral studies (NICNAS, 2006), repeated oral exposure to the chemical is not expected to cause serious damage to health.

Dermal

Based on the lack of evidence of systemic toxicity of formaldehyde (NICNASa) and dimethyl oxazolidine (HSDB) in relevant dermal studies, the chemical is not considered to cause serious damage to health from repeated dermal exposure apart from local effects.

In a subchronic toxicity study of the chemical, CD (Sprague-Dawley derived) Crl:CD BRVAF/Plus rats (10/sex/group) were administered dermal doses of aqueous solutions of 75.95 % dimethyl oxazolidine at 0, 1, 30 or 100 mg/kg bw/day. The test site was occluded. Exposure was for 6 hours, five days per week for a total of four or 13 weeks. All the animals in the 100 mg/kg bw/day group were sacrificed after four weeks because of the severity of dermal reactions. No treatment-related dermal effects were observed in animals in the 1 mg/kg bw/day group. In the 30 mg/kg bw/day and 100 mg/kg bw/day treatment groups, histopathology revealed lymphoid proliferation and plasmacytosis (a condition in which there is an usually large proportion of plasma cells) in axillary and/or inguinal lymph nodes in males and females, and sinus histiocytosis (an excessive number of a particular type of immune cells) in males. In addition, microscopic examination of treated skin revealed inflammation, ulceration, and acanthosis (thickening of the skin) in both males and females in these two treatment groups, confirming the clinical observations of scabs on the skin and necrotic patches. Blood neutrophil levels were increased in both males (146 % control value; not statistically significant) and females (160 % control value; $p < 0.05$) at 30 mg/kg bw/day. At 100 mg/kg bw/day, these values were also increased in males (212 % control value) and females (338 % control value), but no statistical tests were performed for this level. Body weight gain was statistically decreased ($p < 0.01$) only for males in the 100 mg/kg bw/day group at 4 weeks. The dermal NOEL is 1 mg/kg bw/day and the dermal LOEL is 30 mg/kg bw/day, based on the microscopically observed changes in the skin. The microscopic changes observed in the axillary and/or inguinal lymph nodes and the elevated neutrophil counts are probably secondary effects (e.g. infections) related to the severe dermal effects elicited by this chemical. No systemic effects were apparent after dermal administration of the chemical at the stated doses for 90 days. The systemic NOEL was 100 mg/kg bw/day and the systemic LOEL >100 mg/kg/day (HSDB).

In a subchronic toxicity study, SD rats (15/sex/group), were administered dermal doses of aqueous ethanolic solutions of Bioban CS 1135 preservative (78 % 4,4-dimethyloxazolidine) to yield dosage levels of 0 (1:1, water/ethanol vehicle), 1.95, 19.5, or 195 mg/kg bw/day. Animals were treated once daily, five days per week, for a total of 13 weeks. Animals in the 195 mg/kg bw/day group showed moderate and severe skin reactions that included thickening and ulcerations. In the 195 mg/kg/day treatment group, histopathological examination revealed a severe ulcerative response in the skin. These animals had enlarged lung, heart, liver, spleen and adrenals. No treatment-related dermal effects were observed in animals in the 1.95 and 19.5 mg/kg bw/day treatment groups. Based on these data, the dermal and systemic NOEL is 19.5 mg/kg bw/day. A second study conducted with the same study conditions but a shorter exposure period (67–68 days) reported the same NOEL value. Skin irritation was slight for the group dosed at19.5 mg/kg bw/day but increased in incidence and severity for the highest dose group. Reduced bodyweight gain observed in females in the high dose group was attributed directly to skin irritation (HSDB).

Inhalation

There are no data available for the chemical

Based on the lack of evidence of systemic toxicity of formaldehyde in inhalation studies (NICNAS, 2006), and the low volatility of formaldehyde from dilute aqueous solutions, the chemical is not expected to be harmful due to repeated inhalation exposure to the formaldehyde released from products containing the chemical.

Genotoxicity

The chemical is not considered to be genotoxic based on the weight of evidence from available data. While the chemical was positive in three of the in vitro studies, the positive results were not confirmed in an equivalent study in vivo.

However, genotoxicity concerns arise from the presence of formaldehyde in products containing this preservative. While some in vivo studies reported positive results for genotoxicity, formaldehyde was not classified as mutagenic in the Priority Existing Chemical (PEC) assessment report (NICNAS, 2006).

Mixed results were reported for dimethyl oxazolidine in vitro (HSDB):

- negative results in two reverse bacterial mutation assays in *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100 up to 10 µg/plate, both with or without activation;
- positive results in the five highest concentrations without activation (0.01–0.032 µL/mL) and the two highest concentrations (0.075–0.1 µL/mL) with activation in a gene mutation assay with mouse lymphoma cells. Test concentrations ranged from 0.01–0.1 µL/mL with activation and 0.0024–0.032 µL/mL without activation.
- positive results in a gene mutation assay with L5178Y mouse lymphoma cells tested at concentrations up to 0.01–0.28 µL/mL;
- positive results in a chromosomal aberration test using Chinese hamster ovary cells (0.02–015 µL/mL without activation and 0.07–0.5 µL/mL with metabolic activation);
- negative results in a test for unscheduled DNA synthesis in rat hepatocytes (10–5,000 µg/mL), noting that the chemical produced cytotoxicity at ≥333 mg/mL.

Negative results were reported in an in vivo micronucleus test in mouse bone marrow at 500 mg/kg bw (only one dose tested) (HSDB).

Carcinogenicity

While formaldehyde is classified as hazardous with hazard category 'Carcinogenicity—category 1B' and hazard statement 'May cause cancer by inhalation' (H350i) in the HCIS (Safe Work Australia), this applies to inhaled formaldehyde, at high concentrations (NICNAS, 2006). Formaldehyde is not likely to be volatile from the low concentration solutions present in products containing these preservatives. Therefore, there are no carcinogenicity concerns relating to these chemicals in such products. During formulation of the products, formaldehyde gas could be present.

Reproductive and Developmental Toxicity

Oxaban-A (purity not stated but assumed to be 78 % dimethyl oxazolidine, specific gravity 0.9832) was administered neat to the skin (shaven backs) of mated NZW rabbits (16 females/group) at doses of 0 (deionized water), 30, 100 or 300 mg/kg bw/day for 6 hours/day on gestation days 7 through 19. 'Thrashing in the cage immediately after dosing' was reported in animals treated at low (1/15), medium (5/15) and high (4/15) doses, on days 18 and/or 19 of gestation. A maternal NOEL <30 mg/kg/day was determined (skin irritation) with a developmental NOEL >300 mg/kg/day (HSDB).

Risk Characterisation

Critical Health Effects

In general, the critical health hazards relate to the formation of formaldehyde. In cosmetic products containing the chemical as a preservative, the critical health hazard is skin sensitisation.

For formulation workers, health hazards can arise from the presence of formaldehyde gas (NICNAS, 2006); the preservative chemical may also be a skin and/or eye irritant.

Public Risk Characterisation

Although use in cosmetic and domestic products in Australia is not known, dimethyl oxazolidine is reported to be used in cosmetics at concentrations ranging from 0.05–0.5 % (Ash & Ash, 1994).

The primary risk to consumers using products containing the chemical is due to the release of formaldehyde. The SUSMP limits the amount of free formaldehyde in consumer products, including that released from formaldehyde donors. The current controls

are considered adequate to minimise the risk to public health posed by domestic and cosmetic products containing the chemicals, therefore, the chemical is not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

Where this chemical is handled in a pure or highly concentrated form during formulation, formaldehyde gas could be present and pose unreasonable risks to workers unless adequate control measures to minimise inhalation exposure to the chemicals are implemented. The chemical should be appropriately classified and labelled and the appropriate risk management measures for formaldehyde (NICNAS, 2006) should be applied in these cases.

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, 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

Dimethyl oxazolidine is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1 (H317)

[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 this chemical should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from ocular, dermal and inhalation exposure to dimethyl oxazolidine 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 chemicals are used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals— Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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