



# Paraformaldehyde: Human health tier II assessment

28 June 2019

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## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
<b>Poly(oxymethylene), .alpha.-acetyl-.omega.- (acetyloxy)-</b>	25231-38-3
<b>Poly(oxymethylene)</b>	9002-81-7
<b>Paraformaldehyde</b>	30525-89-4

## 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](http://www.nicnas.gov.au)

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## ACRONYMS & ABBREVIATIONS

## Grouping Rationale

The chemicals covered by this assessment are linear polymers of formaldehyde and are collectively known as paraformaldehyde. Paraformaldehyde contains a number of repeated monomers (x) averaging about 30 units (PubChem).

Paraformaldehyde is a significant source of free formaldehyde. It emits formaldehyde gas when it is heated to decomposition. It is also hydrolysed by hot water and alkali, forming formaldehyde.

Paraformaldehyde is imported as prills or powder in 25 kg bags. The concentrations of formaldehyde in these prills/powder range from 81 % to 99 %. Most of the imported paraformaldehyde is used in the resin manufacture (NICNAS, 2006). In these applications, the formaldehyde resin and/or products manufactured contains free formaldehyde or can release the formaldehyde (formaldehyde donors). The hazardous properties of free formaldehyde or released formaldehyde are expected to dominate the toxicity profile of these chemicals despite minor differences in individual solubility in biological systems.

## Import, Manufacture and Use

### Australian

The information provided by industry during the information gathering stage of the NICNAS Priority Existing Chemical (PEC) assessment of formaldehyde (available at [www.nicnas.gov.au](http://www.nicnas.gov.au)) indicated that the main industrial use of formaldehyde and paraformaldehyde is for the manufacture of formaldehyde-based resins, which are widely used in a variety of industries, predominantly the wood industry. The polymer resins may be used as adhesives to make pressed wood products (plywood, particle board and medium density fibreboard (MDF)).

Paraformaldehyde and/or formaldehyde is also used directly or in formulations including embalming in funeral homes, film processing, surface coatings, textile treatments and leather tanning.

Formaldehyde-containing products may also be used as a preservative, drying agent and/or surfactant in a wide range of cosmetic, personal care and household products (fabric softener, surface liquid cleaners and dishwashing liquid).

The concentrations of formaldehyde in these products range from 40 % in embalming and film processing solutions, to <0.2 % in the majority of cosmetic and consumer products (NICNAS, 2006).

## International

As paraformaldehyde has similar applications to formaldehyde, the uses of paraformaldehyde are not specifically described in this section.

The following international uses of formaldehyde and formaldehyde polymers have been identified through Galleria Chemica, the United States (US) Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), the European Commission Cosmetic Ingredients and Substances (CosIng) database, the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary, the US Department of Health and Human Services Household Products Database, the Substances in Preparations in Nordic Countries (SPIN), the Health Canada and Environment and Climate Change Canada report (Government of Canada, 2016), and the European Chemicals Agency (ECHA) report on formaldehyde and formaldehyde releasers (ECHA, 2017).

Formaldehyde polymers have reported cosmetic uses including as film forming agents, in nail conditioning, in skin conditioning, in hair conditioning, and as antimicrobial agents.

Formaldehyde polymers have reported domestic uses, including:

- as antimicrobial preservatives in household cleaning products (dishwashing and laundry liquids, surface cleaners and polishes);
- in specialty paints;
- in adhesives and sealants;
- in lubricants; and
- in wall insulation.

Formaldehyde polymers have reported commercial uses, including:

- as binders;
- as defoaming agents;
- in epoxy hardeners; and
- in the production of resins for the manufacture of pressed wood products, textile treatments, paper treating and coating.

Formaldehyde polymers have reported site-limited uses including as intermediates in the manufacture of synthetic adhesives.

Formaldehyde polymers have reported non-industrial uses, including as antiseptics, fungicides, bactericides, and fungicides.

## Restrictions

### Australian

Paraformaldehyde is listed in Schedule 2, Schedule 6 and Schedule 10 of the *Poisons Standard— the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP, 2019) as follows:

in Schedule 2:

'PARAFORMALDEHYDE (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 Medicine' and are 'substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person'.

in Schedule 6:

'PARAFORMALDEHYDE (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 Schedule 10:

'PARAFORMALDEHYDE (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 chemicals are 'substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use'.

The definition of free formaldehyde in Part I of the Poisons Standard (SUSMP, 2019) is as follows:

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

## International

Paraformaldehyde is a source of free formaldehyde or can release formaldehyde, and may be subject to the restrictions on formaldehyde, under certain conditions.

Using formaldehyde in cosmetics in the European Union (EU) is subject to the restrictions described in EU Regulation, Annex III (List of substances which cosmetic products must not contain except subject to the restrictions laid down) and Annex V (List of

preservatives allowed in cosmetic products) (CosIng).

Formaldehyde may be present in the following cosmetic and personal care products (CosIng):

- nail hardening products at a maximum concentration of 5 % in ready for use preparation; if the concentration exceeds 0.05 %, the label must indicate 'Contains formaldehyde';
- preservative for oral products with a maximum concentration of 0.1 % as free formaldehyde in ready for use preparation; if the concentration exceeds 0.05 %, the label must indicate 'Contains formaldehyde'; and
- preservatives for other products with a maximum concentration of 0.2 % as free formaldehyde in ready for use preparation; if the concentration exceeds 0.05 %, the label must indicate 'Contains formaldehyde'.

## Existing Worker Health and Safety Controls

### Hazard Classification

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

### Exposure Standards

#### Australian

There are no Australian exposure standards for paraformaldehyde; however, Safe Work Australia has an exposure standard for formaldehyde of 1.2 mg/m<sup>3</sup> (1 parts per million (ppm)) time weighted average (TWA) and 2.5 mg/m<sup>3</sup> (2 ppm) short term exposure limit (STEL) apply (Safe Work Australia).

#### International

There are no international exposure standards for paraformaldehyde.

## Health Hazard Information

The assessment of health effects for paraformaldehyde focused on the presence or absence of health effects information relevant to formaldehyde. It is considered that the formaldehyde released from the decomposition of these polymer resins will be the critical driver of toxicity. Free formaldehyde is extremely reactive, and its key health hazards are those identified in the NICNAS Priority Existing Chemical (PEC) assessment of formaldehyde (NICNAS, 2006) and the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Tier II Human Health assessments of formaldehyde donors (NICNAS).

Paraformaldehyde emits formaldehyde gas when it is heated to decomposition. It is also hydrolysed by hot water and alkali forming formaldehyde. It behaves like methanol-free formaldehyde of the same concentration once it dissolves in water (Lewis, 1996).

Breathing formaldehyde vapour can result in irritation of sensory nerve endings in the eyes and nose, which may cause burning, stinging or itching sensations, a sore throat, teary eyes, blocked sinuses, runny nose, and sneezing (NICNAS, 2006).

The most likely health effects arising from the release of formaldehyde from textile products such as blankets and clothing are irritation of the eyes and nose, and allergic reactions on skin in contact with the fabric. Instances of dermatitis arising from wearing garments containing high levels of formaldehyde have been documented (NICNAS, 2006).

Skin contact with formaldehyde solution can cause skin rashes and allergic skin reactions. For individuals allergic to formaldehyde, exposure to very low levels of formaldehyde are likely to cause allergic skin reactions (NICNAS, 2018).

## Risk Characterisation

### Critical Health Effects

Paraformaldehyde is a source of free formaldehyde and the critical health effects for risk characterisation include sensory irritation and allergic skin reactions.

Sensory irritation is defined as irritation of the nerve endings in the eyes and nose and can produce symptoms such as stinging or burning sensations in the eyes, nose and/or a sore throat. The level of formaldehyde in the air at which these symptoms have been known to start to occur is 0.5 ppm. Long term exposure to higher levels of gaseous formaldehyde may lead to certain cancers (NICNAS, 2006).

### Public Risk Characterisation

The main potential of public exposure to paraformaldehyde, is through inhalation of indoor air, which generally contains higher levels of formaldehyde than outside air. The levels of formaldehyde in the air in a home will depend on a number of factors, including the presence of emission sources (pressed wood products, such as plywood, particle board and MDF; and 'permanent press' type fabric, such as carpets, curtains, blankets, garments and sheets), the age and use patterns of the sources, the temperature and humidity, and ventilation of the home. NICNAS has recommended an indoor air guidance value for formaldehyde of 80 parts per billion (ppb) (NICNAS, 2006).

Overall, the risk to the public using the above products is low, from absorption of formaldehyde into the skin and provided that the recommended indoor air guideline value is adopted from breathing formaldehyde vapour (NICNAS, 2006).

The function of formaldehyde in cosmetic and household cleaning products is as a preservative, drying agent and/or surfactant. In these applications, the biocidal effects mechanism involves release of formaldehyde into aqueous solutions secondary to hydrolytic degradation of the polymers (Anderson et al., 2007). The level of exposure to formaldehyde through use of products that contact the skin will vary according to the intended use and individual habits in application. While the risk of health effects is generally low, individuals already sensitised to formaldehyde can experience skin reactions even at low concentrations, and so caution is recommended in the use of formaldehyde-containing products that come into contact with the skin.

The SUSMP specifies limits for the levels of paraformaldehyde and formaldehyde in cosmetic and domestic products (SUSMP, 2019). The current controls for paraformaldehyde in Schedule 2, 6 and 10 of the SUSMP (see **Restrictions: Australian** section) are considered adequate to minimise the risk to public health posed by domestic and cosmetic products containing paraformaldehyde. Therefore, paraformaldehyde is not considered to pose an unreasonable risk to public health provided the concentrations of the free formaldehyde present in products meet the SUSMP limit.

### Occupational Risk Characterisation

Available information on Australian use scenarios indicates that workers are potentially exposed to formaldehyde by both inhalation and skin contact. Ingestion is unlikely to be a route of exposure in the occupational environment.

Dermal exposure may occur from spills and splashes and exposure to aerosol droplets during formulation process.

The risk of sensory irritation in embalmers and workers in medicine-related industries, such as forensic/hospital mortuaries and pathology laboratories, is high due to high concentrations of formaldehyde products handled and relative long exposure durations.

Given the critical health effects, products containing the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure to the products are implemented. These chemicals should be appropriately 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. Paraformaldehyde can release formaldehyde and is a major source of formaldehyde. Therefore, the current classification and labelling stipulated in the HCIS for formaldehyde should be applied to ensure appropriate risk management measures are implemented for paraformaldehyde.

Occupational risks to formaldehyde exposures can be mitigated by ensuring effective ventilation when these products are used in indoor environments. Handling and storage of pressed wood products should only be undertaken in well ventilated areas. When machining pressed wood products, the use of local exhaust ventilation which extracts dusts and vapours at source is recommended in controlling exposure to formaldehyde. If symptoms of burning, stinging or itching of the eyes and/or nose, sore throat, watery eyes, blocked sinuses, runny nose or sneezing occurs, the worker is advised to move to an area with fresh air.

## NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Companies using or marketing paraformaldehyde should take appropriate risk management measures to control the hazards of formaldehyde released from paraformaldehyde as stipulated in the HCIS, and the advice and controls in the SUSMP for paraformaldehyde and formaldehyde.

It is recommended that occupational and public health controls for the formaldehyde vapours released from paraformaldehyde be implemented in line with the recommendations of the NICNAS PEC assessment report on formaldehyde (See **Public Risk Characterisation** section) (NICNAS, 2006).

## Regulatory Control

### Public Health

At present, the chemicals in this group fall within the scope of the listing of 'Paraformaldehyde' in Schedules 2, 6 and 10 of the SUSMP. Therefore, products containing paraformaldehyde with more than 0.05 % free or readily available formaldehyde should be labelled in accordance with state and territory legislation (SUSMP, 2019).

### Work Health and Safety

The chemicals are not recommended for classification and labelling under the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. However, paraformaldehyde can release formaldehyde and is used as a major source of free formaldehyde. Therefore, the current classification and labelling for formaldehyde should be applied to ensure appropriate risk management measures are implemented for paraformaldehyde.

The recommendation for GHS classifications 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.

## Advice for consumers

Products containing the chemicals should be used according to the instructions on the label.

## Advice for industry

### Control measures

Control measures to minimise the risk from dermal and inhalation exposure to paraformaldehyde should be implemented in accordance with the hierarchy of controls identified for formaldehyde. 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.

#### 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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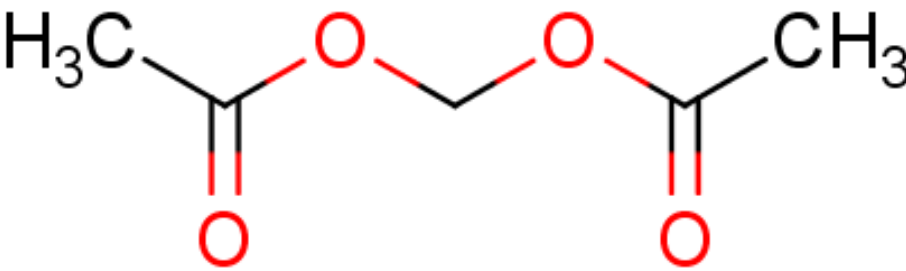
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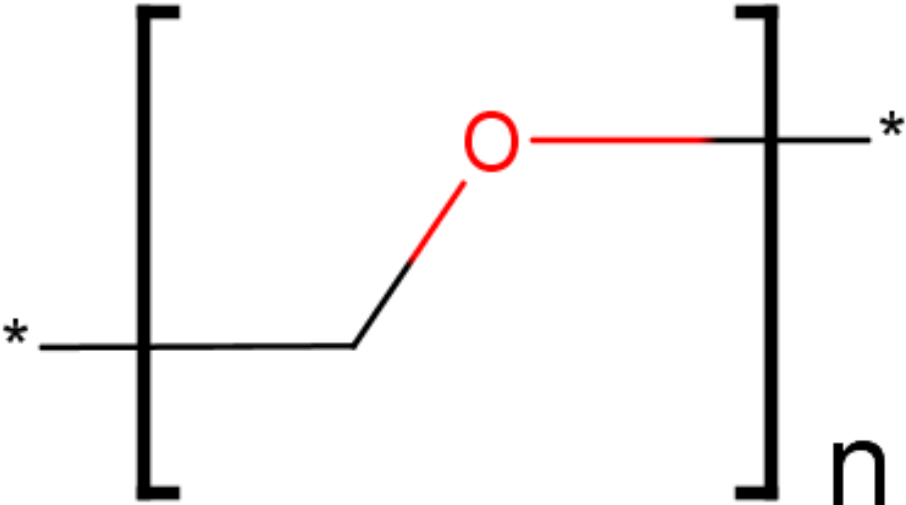
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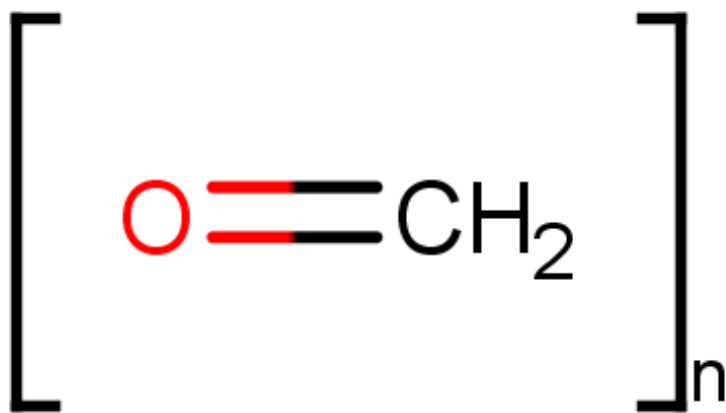
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## Chemical Identities

Chemical Name in the Inventory and Synonyms	<b>Poly(oxymethylene), .alpha.-acetyl-.omega.-(acetyloxy)-Polyoxymethylene diacetate</b>
CAS Number	25231-38-3
Structural Formula	
Molecular Formula	$(\text{CH}_2\text{O})_n\text{C}_4\text{H}_6\text{O}_3$
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Poly(oxymethylene)</b> Formaldehyde, homopolymer
CAS Number	9002-81-7
Structural Formula	
Molecular Formula	(CH <sub>2</sub> O) <sub>n</sub>
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Paraformaldehyde</b> Formaldehyde, polymer
CAS Number	30525-89-4
Structural Formula	



Molecular Formula	(CH <sub>2</sub> O) <sub>x</sub>
Molecular Weight	

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