

Urea, compound with hydrogen peroxide (H₂O₂) (1:1): Human health tier II assessment

05 February 2016

CAS Number: 124-43-6



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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.

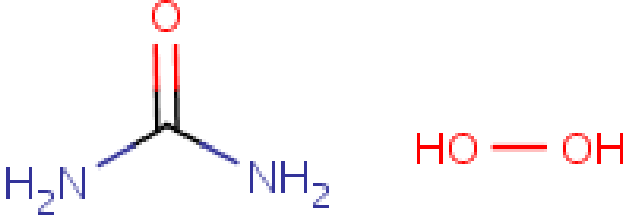
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Acronyms & Abbreviations

Chemical Identity

Synonyms	carbamide peroxide urea peroxide hydrogen peroxide urea hydrogen peroxide carbamide urea dioxide
Structural Formula	
Molecular Formula	CH ₄ N ₂ O.H ₂ O ₂
Molecular Weight (g/mol)	94.1
Appearance and Odour (where available)	White, odourless, crystalline powder
SMILES	C(N)(N)=O_OO

Import, Manufacture and Use

Australian

The chemical has reported cosmetic use for teeth whitening, and for softening and removal of ear wax in Australia (ACCC, 2014).

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

International

The chemical is not registered with the European Chemicals Agency (ECHA) at the time of assessment. It may be solely used in cosmetic products and/or in small quantities (SCCP, 2007), although no current use information is available.

The following international uses have been identified through the European Commission (EC) Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature Cosmetic Ingredients (INCI) dictionary; the US Household Products database; the Substances in Preparations in Nordic countries (SPIN) database; the US National Library of Medicine ChemIDplus; Haz-Map; and Galleria Chemica.

The chemical has reported cosmetic uses, including in:

- oral hygiene products (such as mouth rinses, dentifrices and tooth bleaching/whitening products);
- ear wax removers; and
- products for waving, straightening and fixing hair.

The chemical has reported domestic use as a bleaching disinfectant.

The chemical has reported commercial use as a photochemical.

The chemical has reported site-limited uses, including in:

- plastic making;
- blueprint developers; and
- the manufacture of modified starches.

The chemical has reported non-industrial uses, including in:

- plant foods (oxygen sources); and
- pharmaceuticals (antiseptic, cerumenolytic, dental bleach for professional use).

Restrictions

Australian

The chemical is listed in the *Poisons Standard*—the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP, 2015) in Schedules 5, 6 and 10.

Schedule 5: Carbamide peroxide in preparations containing 18 % or less of carbamide peroxide except in preparations containing 9 % or less of carbamide peroxide.

Schedule 5 chemicals are labelled with 'Caution' and described as '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'.

Schedule 6: Carbamide peroxide except:

- a) when included in Schedule 5; or
- b) in other preparations containing 9 percent or less of carbamide peroxide.

Schedule 6 chemicals are labelled with 'Poison' and described as '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'.

Schedule 10/Appendix C: Carbamide peroxide (excluding its salts and derivatives) in teeth whitening preparations containing >18 % of carbamide peroxide except:

- a) in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice; or
- b) when in Schedule 5; or
- b) when in Schedule 6.

Schedule 10/Appendix C chemicals are described as 'Substances of such danger to health as to warrant prohibition of sale, supply and use' for listed purpose(s).

Dental use of the chemical is restricted under the Australian Health Practitioner Regulation Agency (AHPRA <www.ahpra.gov.au>) regulations.

International

The chemical is listed in the:

- EC Cosmetics Regulation Annex III (List of substances with restricted use in cosmetic products; CosIng): release of hydrogen peroxide (H₂O₂) limits to 12 % in hair products; 4 % in skin products; 2 % in nail hardening products and products intended for eyelashes products; =0.1 % in oral hygiene products; and >0.1 % to =6 % in teeth whitening or bleaching products.
- Health Canada List of prohibited and restricted ingredients (The Cosmetic Ingredient Hotlist): 1. the pH of the cosmetic product containing the chemical should be =4; 2. product labelling should meet all cautionary statement requirements; 3. submission of safety evidence that the product does not cause the saliva or soft tissue of the oral cavity to exceed 3 % H₂O₂, and is safe when used as directed.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS, Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following workplace exposure standards are identified (Galleria Chemica):

- Russian Maximum Allowed Concentration (PDK) = 0.3 mg/m³.
- US Temporary Emergency Exposure Limits (TEELs) = 1.2, 13, and 79 mg/m³.

Health Hazard Information

During use, the chemical (which will be referred to as 'carbamide peroxide' in the **Health Hazard Information** section) breaks down into urea and H₂O₂. Urea (CAS No. 57-13-6), also known as carbamide, has been assessed as a chemical of low concern (NICNASa). Therefore, the toxicity of H₂O₂ (CAS No. 7722-84-1) is considered representative for carbamide peroxide (NICNASb). An approximate conversion factor is that 10 % carbamide peroxide is equivalent to 3.6 % H₂O₂ (ACCC, 2014; Goldberg et al., 2010; SCCP, 2007).

Toxicokinetics

Toxicokinetic information for carbamide peroxide, exogenous urea or H₂O₂ is limited. In contact with moist tissues, such as during the teeth whitening process, urea is rapidly decomposed into carbon dioxide and ammonia, while H₂O₂ is dissociated into oxygen and water, through intermediate powerful bleaching agents (such as the peroxide monoanion (HO₂⁻) and hydroxyl radical (OH)) (Goldberg et al., 2010; SCCP, 2007; US EPA, 2011).

Given that the release of H₂O₂ is low from the current allowable concentrations of carbamide peroxide in consumer products (SUSMP), as well as urea being an endogenous product of protein and amino acid catabolism, and H₂O₂ being a normal metabolite in the aerobic cells, their concentrations following absorption, distribution, metabolism and excretion are expected to be well controlled and regulated in biological systems (for review of H₂O₂ and urea toxicokinetics, refer to NICNASb; IARC, 1999; SCCP, 2007; US EPA, 2011).

Acute Toxicity

Oral

The available data indicate that carbamide peroxide has moderate acute oral toxicity.

The oral median lethal dose (LD₅₀) in rats is 1855 mg/kg bw, which is estimated using mixture rules on hydrogen peroxide and urea data (Chemical Classification and Information Database (CCID), NZ EPA). For teeth whiteners containing 10–22 % of carbamide peroxide, an LD₅₀ >5000 mg/kg bw was reported for rats, and LD₅₀ = 87.2–143.8 mg/kg bw for mice (SCCP, 2007), although it is not clear whether the values are for the chemical or the products.

Rats fed a single dose of carbamide peroxide by gavage showed dose-dependent ulceration of the gastric mucosa, resulting in a lowest observed effect level (LOEL) of 15 mg/kg bw (or 5.4 mg/kg bw H₂O₂) and a no observed effect level (NOEL) of 5 mg/kg bw (or 1.8 mg/kg bw H₂O₂). Lesions were clearly visible after one hour and healed after 24 hours. The toxic effects could be worsened due to the use of hydrophobic gel and oxygen-release inhibitors in commercially available teeth bleaching products. No adverse effects were observed in the kidney or liver (Dahl & Becher, 1995; Goldberg et al., 2010; SCCP, 2007).

Dermal

No data are available.

Inhalation

No data are available.

Observation in humans

Reviews of teeth whitening products indicate that carbamide peroxide, in excessive amounts, can cause serious damage to the teeth, oral cavity, oesophagus and stomach. Ingestion may cause irritation and damage to the oesophagus and stomach, resulting in ulceration, bleeding or sudden distension (ACCC, 2014; Goldberg et al., 2010).

Corrosion / Irritation

Respiratory Irritation

On the basis that 10 % carbamide peroxide releases 3.6 % H₂O₂, the hazard classification of 35–50 % H₂O₂ solutions with the risk phrase R37 'Irritating to respiratory system' (HSIS, Safe Work Australia) is considered applicable to pure carbamide peroxide.

Hazardous Substance Fact Sheet (HSFS, New Jersey Department of Health and Senior Services) indicates that breathing carbamide peroxide or H₂O₂ vapour 'can irritate the nose and throat causing coughing and wheezing'.

Skin Irritation

On the basis that 10 % carbamide peroxide releases 3.6 % H₂O₂, the hazard classification of 35–50 % H₂O₂ solutions with the risk phrase R38 'Irritating to skin' (HSIS, Safe Work Australia) is considered applicable to pure carbamide peroxide.

Teeth whiteners containing 10–22 % carbamide peroxide did not cause irritation to the skin of rabbits. No further information is available (SCCP, 2007).

Eye Irritation

On the basis that 10 % carbamide peroxide releases 3.6 % H₂O₂, the hazard classification of 35–50 % H₂O₂ solutions with the risk phrase R41 'Risk of serious eye damage' (HSIS, Safe Work Australia) is considered applicable to pure carbamide peroxide.

According to the Australian Competition and Consumer Commission (ACCC, 2014), direct exposure to high concentrations of carbamide peroxide or H₂O₂ may cause severe irritation to the eyes with permanent adverse effects.

Observation in humans

Local undesirable effects of carbamide peroxide or H₂O₂ are widely reviewed in the literature of teeth whitening products and methodologies. They include mainly tooth hypersensitivity, enamel surface alteration and gingival irritation (for review see Carey,

2014; Goldberg et al., 2010; SCCP, 2007).

Between 2005 and 2011, there was an increasing trend of mouth injuries attributed to teeth whitening not provided by dentists, and at least 63 injuries involving teeth whitening products were reported to the Australian Poisons Information Centres (ACCC, 2014).

Sensitisation

Skin Sensitisation

No data are available.

Observation in humans

Carbamide peroxide or H₂O₂ is not expected to cause skin sensitisation (for review of H₂O₂ allergic reactions, see NICNASb; Goldberg et al., 2010; SCCP, 2007).

Repeated Dose Toxicity

Oral

No data are available for carbamide peroxide.

For H₂O₂, a no observed adverse effect level (NOAEL) of 20 mg/kg bw/d was established in rats (based on a significantly reduced plasma catalase level at higher dose levels in a 100-day gavage study), and a NOAEL of 26 mg/kg bw/d for mice (based on dose-related reductions in food and water consumption, and on the observation of duodenal mucosal hyperplasia in a 90-day drinking water study) (see NICNASb; IARC, 1999).

Dermal

No data are available.

Inhalation

No data are available.

Observation in humans

Chronic teeth whitening treatment with carbamide peroxide or H₂O₂ may result in local adverse effects, especially when not provided by appropriately registered dental practitioners or if the oral mucosa is already damaged (for review see Goldberg et al., 2010; SCCP, 2007).

In clinical studies, oral mucosal irritation has been reported with the use of a mouth-rinse containing 3 % H₂O₂ solution, three to five times daily (SCCP, 2007). No reliable long-term clinical data or epidemiological studies are available in order to assess the potential adverse effects of carbamide peroxide or H₂O₂ used in oral hygiene and tooth whitening products.

Genotoxicity

Based on the weight of evidence, carbamide peroxide is not expected to have genotoxic potential.

No data are available for carbamide peroxide. The breakdown product H₂O₂ is mutagenic and genotoxic in vitro but there is no adequate evidence in support of a significantly mutagenic or genotoxic potential for H₂O₂ under in vivo conditions. Given that H₂O₂ can 'generate hydroxyl radicals that initiate lipid peroxidation chain reactions within exposed cells and can lead to DNA damage and cell death' (IARC, 1999), long-term use of carbamide peroxide or H₂O₂ may cause oral mucosal damage, hence promoting genotoxic effects, especially when associated with other known carcinogenic agents (e.g. alcohol and tobacco), or when whitening agents are used frequently at high concentrations (for review of the mutagenicity/genotoxicity of H₂O₂ and tooth whiteners, see NICNASb; Almeida et al., 2015; Goldberg et al., 2010; IARC, 1999; SCCP, 2007).

Teeth whiteners containing 10 % carbamide peroxide were negative in reverse mutation assays in *Salmonella typhimurium*, although there was a dose-response effect in TA102 strain without metabolic activation. In vivo genotoxicity tests showed no increased frequency of micronuclei or sister chromatid exchange (SCE) in bone marrow cells of mice and hamsters after single doses. Negative SCE results were also observed after multiple doses in rats at up to 1000 mg/kg bw/d for five days, and in hamsters at up to 2000 mg/kg bw/d, five days per week, for 3–6 months (cited in SCCP, 2005).

There was no statistically significant increase in micronucleus levels in gingival epithelial cells between two groups of patients (n = 19 vs 18) treated with either 10 % or 16 % carbamide peroxide, at three different collection time points (0, 15 and 45 days) (Almeida et al., 2015).

Carcinogenicity

No data are available for carbamide peroxide. Based on the following international and NICNAS evaluation conclusions for its breakdown products, carbamide peroxide is not expected to have carcinogenic potential.

- IARC (1999) and NICNAS IMAP Tier II assessment: 'There is inadequate evidence in humans for the carcinogenicity of H₂O₂. There is limited evidence in experimental animals for the carcinogenicity of H₂O₂.' Therefore, H₂O₂ is not classifiable as human carcinogen (Group 3).
- US EPA (2011): There is 'inadequate information to assess the carcinogenic potential' of urea. As indicated, carbamide is considered a chemical of low concern (NICNASa).

Reproductive and Developmental Toxicity

No data are available.

Risk Characterisation

Critical Health Effects

The chemical has moderate acute oral toxicity. It is a respiratory and skin irritant, and may cause severe irritation to the eyes with permanent adverse effects.

Public Risk Characterisation

The chemical has reported uses in domestic and cosmetic products, particularly as an oxidising agent in teeth whiteners. The use and supply of products containing carbamide peroxide are controlled by scheduling under the *Poisons Standard*. Safety

information is also available for do-it-yourself (DIY) teeth whitening products for use at home. Therefore, the risk to public health of carbamide peroxide is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalational exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section). Given the critical systemic acute and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal, ocular and inhalational 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.

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

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 Globally Harmonized System of Classification and Labelling of Chemicals (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 if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41) Irritating to skin (Xi; R38) Irritating to respiratory system (Xi; R37)	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)

^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 inhalational exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which 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;
- 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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