

# Phosphoric acid: Human health tier II assessment

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- Preface
- Chemical Identity
- Import, Manufacture and Use
- Restrictions
- Existing Work Health and Safety Controls
- Health Hazard Information
- Risk Characterisation
- NICNAS Recommendation
- References

## 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.

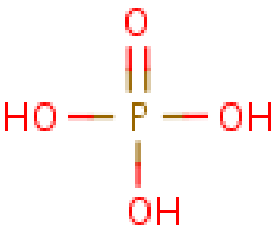
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### Acronyms & Abbreviations

## Chemical Identity

Synonyms	orthophosphoric acid white phosphoric acid hydrogen phosphate o-phosphoric acid
Structural Formula	
Molecular Formula	H3O4P
Molecular Weight (g/mol)	98.00
Appearance and Odour (where available)	Colourless crystalline substance or viscous liquid
SMILES	O=P(O)(O)O

# Import, Manufacture and Use

## Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

Phosphoric acid has reported potential cosmetic, domestic or commercial uses in:

- cleaning/washing agents or additives; and
- pH regulating agents.

The chemical has reported commercial use as an electroplating agent and site-limited use as a process regulator.

The following non-industrial uses of this chemical have been identified in Australia:

- as a food additive; and
- in adjuvants for pesticides and in dairy cleansers.

## International

The following international uses have been identified through: the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

Phosphoric acid has reported functions as a pH adjuster and fragrance ingredient in cosmetic products including:

- aftershave lotions;
- bath oils, preparations, soaps and detergents;
- hair products including shampoos, bleaches, colouring preparations, conditioners, dyes, lighteners, rinses, hair wave sets and hair grooming aids such as tonics and dressings;
- cleansing products such as cold creams, liquids and pads and eye makeup removers;
- colognes, fragrances, feminine hygiene deodorants and toilet waters;
- makeup including eyeliners, face powders and foundations;
- skin products such as moisturisers, fresheners, night skin care preparations, eye lotions, foot powders and sprays;
- mouthwashes, toothpastes and breath fresheners; and
- nail products such as cuticle softeners, nail creams and lotions, nail polish and manicuring preparations.

The chemical has reported domestic uses, including in:

- soap-making products;
- bleaching agents;
- cleaning/washing agents including pet shampoos and cleaners for wheels, grout, paint, tile, concrete and toilet bowls;
- colouring agents;

- corrosion inhibitors;
- fertilisers;
- fillers;
- flame retardants and extinguishing agents;
- insulating materials;
- odour agents;
- paints, lacquers and varnishes;
- surface treatment; and
- surface active agents.

The chemical has reported commercial uses, including in:

- anti-freezing agents;
- anti-set-off and anti-adhesive agents;
- anti-static agents;
- construction materials;
- cutting fluids;
- fixing agents;
- flux agents for casting;
- lubricants and additives;
- oxidising agents;
- photochemicals;
- pH regulation agents;
- reprographic agents;
- softeners;
- solvents; and
- process engraving.

Phosphoric acid has site limited uses:

- in manufacturing superphosphate fertilisers, phosphate salts and detergents; and
- as an acid catalyst when making ethylene or purifying hydrogen peroxide.

Non-industrial uses include:

- in pesticides;
- in dental cement; and

- as a food additive.

## Restrictions

### Australian

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

#### Schedule 5

'PHOSPHORIC ACID (excluding its salts and derivatives) in preparations containing 35 per cent or less of phosphoric acid (H<sub>3</sub>PO<sub>4</sub>) **except:**

(a) in preparations containing 15 per cent or less of phosphoric acid (H<sub>3</sub>PO<sub>4</sub>);

(b) in solid or semi-solid preparations; or

(c) in professional dental kits.'

#### Schedule 6

'PHOSPHORIC ACID (excluding its salts and derivatives) **except:**

(a) when included in Schedule 5;

(b) in preparations containing 15 per cent or less of phosphoric acid (H<sub>3</sub>PO<sub>4</sub>);

(c) in solid or semi-solid preparations; or

(d) in professional dental kits.'

Schedule 5 chemicals are 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 5 chemicals are labelled with 'Caution' (SUSMP, 2015).

Schedule 6 chemicals are 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 6 chemicals are labelled with 'Poison' (SUSMP, 2015).

### International

No known restrictions have been identified.

## Existing Work Health and Safety Controls

### Hazard Classification

Phosphoric acid is classified as hazardous with the following risk phrase for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- C, R34 (corrosivity).

## Exposure Standards

### Australian

Phosphoric acid has an exposure standard of 1 mg/m<sup>3</sup> time weighted average (TWA) and 3 mg/m<sup>3</sup> short term exposure limit (STEL).

### International

The following exposure standards are identified (Galleria Chemica).

An exposure limit of 1–2 mg/m<sup>3</sup> TWA and 2–3 mg/m<sup>3</sup> STEL in different countries such as the USA (California, Hawaii, Minnesota, Tennessee), Canada (Alberta, Quebec, Yukon), Japan, France, Germany, Iceland and Indonesia.

## Health Hazard Information

Phosphoric acid is in equilibrium with its conjugate bases in aqueous solutions, including monohydrogen phosphate and dihydrogen phosphate ions. These forms of phosphate are normal physiological components of living things and play an important role in buffering the pH of urine. Phosphate is one of the most abundant ions in the body and serum levels are regulated by a complex set of processes occurring in the intestine, skeleton, and kidneys. Maintaining extracellular and intracellular phosphate levels within a narrow range is important for many biological processes, including energy production, cell signalling, regulating protein synthesis, skeletal development and bone integrity (Penido & Alon, 2012). NICNAS identified mono- and di-hydrogen phosphate as being of low concern to human health (NICNAS, 2012).

Exposure to concentrated phosphoric acid through ingestion or skin contact can cause corrosion of mucous membranes of the mouth, throat and oesophagus, with immediate pain and dysphagia. The chemical causes ulceration of all membranes and tissues that it comes in contact with and can ultimately lead to circulatory collapse with clammy skin, weak and rapid pulse, shallow respirations and scanty urine. Uncorrected circulatory collapse of several hours' duration can lead to renal failure and ischaemic lesions in the liver and heart. Circulatory shock is often the immediate cause of death (HSDB).

As the conjugate bases of phosphoric acid are naturally present in the body and effective homeostatic mechanisms work to maintain these levels, chronic systemic health effects such as repeated dose toxicity, carcinogenicity and reproductive toxicity are not expected following exposures at non-irritating concentrations. The available animal data for repeated dose toxicity, genotoxicity and reproductive toxicity are negative and supports this conclusion (OECDa, 2009). Phosphoric acid is permitted to be used in processed foods as a food additive in Australia (FSANZ, 2014), indicating its low potential for chronic toxicity.

## Toxicokinetics

Phosphoric acid can be absorbed by ingestion, inhalation and dermal contact. Absorbed phosphate is widely distributed in the body. Phosphate is present in plasma and extracellular fluid, in cell membranes and intracellular fluid, and in collagen and bone tissue. More than 90 % of plasma phosphate is filterable, of which 80 % is actively reabsorbed. Phosphate excreted in the urine represents the difference between the amount filtered and that reabsorbed (OECDa, 2009).

## Acute Toxicity

### Oral

Phosphoric acid is of low acute oral toxicity with a median lethal dose (LD50) of approximately 2000 mg/kg in a study conducted on 12 female Sprague Dawley (SD) rats in accordance with the Organisation for Economic Co-operation and Development Test Guideline (OECD TG) 423 and good laboratory practice (GLP) using 20 % phosphoric acid. Female rats were gavaged with phosphoric acid at 300 or 2000 mg/kg (six animals per dose). Sublethal signs include salivation, staining around the mouth and lacrimation. 'Yellow brown' or dark fluid was found in the stomach with adsorption of dark contents in the glandular stomach (OECDb, 2009).

## Dermal

Based on the limited available information, the chemical has moderate to low acute dermal toxicity depending on the concentration.

The acute dermal toxicity of phosphoric acid was evaluated by applying varying concentrations directly to the clipped, intact skin of one or two New Zealand White rabbits at doses ranging from 631 to 7940 mg/kg for 24 hours using semi-occlusive dressings. The animals were observed for 14 days. The LD50 for 85 % phosphoric acid was reported to be more than 1260 mg/kg bw. While one out of two animals died following the application of 2000 mg/kg bw, the study is limited because of the small number of animals used. Observed sub-lethal effects included reduced appetite and activity, increasing weakness and collapse (OECDb, 2009).

## Inhalation

The chemical has moderate acute inhalation toxicity based on the limited information available for rats and warrants a hazard classification (see **Recommendation** section).

An acute inhalation toxicity study was carried out in male rabbits, rats, mice and guinea pigs, exposed for one hour to smoke, generated from pure unformulated red phosphorus ignited in an air stream, which produces phosphorus pentoxide (the anhydride of phosphoric acid). The target concentrations of smoke ranged from 111 to 6731 mg/m<sup>3</sup> as phosphoric acid.

Expressed as phosphoric acid, the inhalation median lethal concentration (LC50) values were 5337 mg/m<sup>3</sup> (rabbit), 3846 mg/m<sup>3</sup> (rat), 856 mg/m<sup>3</sup> (mouse) and 193 mg/m<sup>3</sup> (guinea pig). Based on one-hour LC50 values, there was a marked species difference in susceptibility to the smoke generated from pure red phosphorus (OECDa, 2009).

## Corrosion / Irritation

### Corrosivity

Phosphoric acid is classified as hazardous with the risk phrase 'Causes burns' (C; R34) in the HSIS (Safe Work Australia). The available data support this finding for concentrated phosphoric acid.

This is consistent with the pKa (a term used to describe the strength of an acid—lower values indicate stronger acids) for phosphoric acid, 2.15. In general, phosphoric acid solutions with a pH <2.5 should be regarded as corrosive (OECDa, 2009). Mild necrosis was observed following exposure to 80 % phosphoric acid (0.5 mL) applied to intact and abraded skin of Vienna White rabbits for 24 hours with a rubberised covering (REACH). Mixed results were reported for skin irritation studies of rabbits exposed to concentrated phosphoric acid solutions (75–85 %) (OECDa, 2009). Results for skin irritation studies at lower concentrations of phosphoric acid showed no evidence of irritation (REACH).

## Risk Characterisation

### Critical Health Effects

Phosphoric acid is corrosive or irritating to the skin, eyes, gastrointestinal and respiratory tracts, depending on the concentration.

## Public Risk Characterisation

Phosphoric acid is used widely in cosmetic products at low concentrations where the product pH is close to neutral. It is also found in domestic products where low pHs are important for product functionality such as various types of cleaning products. The main route of public exposure is expected to be contact with eyes and skin. Labelling for formulations containing phosphoric acid is controlled by the Poisons Standard (SUSMP, 2015). Provided that the appropriate precautions are taken to avoid skin and eye contact or inhaling chemical aerosols when using products with higher concentrations of the chemicals at low pH, the risk from the use of domestic and cosmetic products is not considered to be unreasonable.

## 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.

## NICNAS Recommendation

Assessment of phosphoric acid is considered to be sufficient, provided that the recommended amendments 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 this chemical should be labelled in accordance with state and territory legislation (SUSMP, 2015).

### Work Health and Safety

Phosphoric acid 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) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Harmful by inhalation (Xn; R20)	Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Causes burns (C; R34)*	Causes severe skin burns and eye damage - Cat. 1B (H314)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> 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 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 that could minimise the risk include, but are not limited to:

- 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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