Trisodium phosphate: Human health tier II assessment

01 July 2016

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Phosphoric acid, trisodium salt	7601-54-9
Phosphoric acid, trisodium salt, dodecahydrate	10101-89-0

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

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

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

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

Trisodium phosphate and trisodium phosphate dodecahydrate are both listed on the AICS under separate CAS numbers. The toxicity of the two substances is expected to be identical.

Import, Manufacture and Use

Australian

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

Trisodium phosphate dodecahydrate has reported potential cosmetic, domestic or commercial use in cleaning and/or washing agents or additives.

The following non-industrial uses of these chemicals have been identified in Australia:

- as a food additive; and
- in oral rehydration products for horses.

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).

Both chemicals have reported cosmetic use in toothpaste.

Trisodium phosphate has reported buffering and chelating functions in cosmetic products including:

- bath soaps and detergents;
- cleansing products (cold creams and lotions);
- cuticle softeners;
- eye makeup;
- hair rinses and lighteners;
- paste masks; and
- permanent wave products.

The chemicals have reported domestic uses including in:

- wood and rubber cleaners;
- brass and copper metal polish;
- all purpose cleaners;
- multi-purpose cleaners and disinfectants;
- aluminium siding and driveway cleaners;
- surface treatment;
- corrosion inhibitors; and
- adhesives and binding agents.

The chemicals have reported commercial uses including in:

- battery cleaners;
- rubber cleaners;
- concrete floor cleaners;
- all-purpose cleaners, deodorisers, disinfectants and degreasers;
- photochemicals;
- manufacturing paper and leather;
- fixing agents; and
- removing boiler scale.

Trisodium phosphate dodecahydrate has reported commercial uses in:

- removing paint;
- cleaning batteries; and
- surface treatment.

Trisodium phosphate has reported commercial uses:

- in softening water;
- in clarifying sugar;
- in reprographic agents;
- as a process regulator; and
- as an anti-setoff and anti-adhesive agent.

Both chemicals have site-limited use as electroplating agents.

Trisodium phosphates were widely used in laundry detergents and dishwashing products. Use is being phased out in many countries because of environmental concerns.

Restrictions

Australian

These chemicals are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedules 5 and 6 and Appendix C (SUSMP, 2015).

Schedule 5:

'ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination:

(a) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 11.5 but less than or equal to 12.5;

(c) in other solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or

(d) in liquid or semi-solid preparations, the pH of which is more than 11.5, unless;

(i) in food preparations for domestic use; or

(ii) in automatic dish washing preparations for domestic use with a pH of more than 12.5, except when separately specified in these Schedules.'

Schedule 6:

‘ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for non-domestic use:

(a) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or

(b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.'

Appendix C

‘ALKALINE SALTS, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for domestic use:

(a) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or

(c) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.'

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).

Appendix C chemicals are described as 'Substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use' (SUSMP, 2015).

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The constituent ions of trisodium phosphate and its hydrated salt (sodium ion and phosphate ion) are normal physiological components of living things. Absorbed trisodium phosphate rapidly dissociates into sodium and phosphate ions, which then enter the body's electrolyte pool. As a consequence, potential systemic effects from the constituent ions are not expected to occur.

Sodium ions are a normal component of the blood. The excess is excreted in the urine. In mammals, the kidneys are the key regulator of sodium content. Homeostatic regulation of Na^+ concentration in the blood is achieved primarily through renal excretion and reabsorption.

Phosphate is one of the most abundant minerals 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 metabolism, cell signalling, regulating protein synthesis, skeletal development, and bone integrity (Penido & Alon, 2012). The phosphate ion exists in equilibrium with the other conjugate bases of phosphoric acid, monohydrogen phosphate and dihydrogen phosphate, which play an important role in

buffering the pH of urine. NICNAS (2012) identified mono- and dihydrogen phosphate as being of low concern to human health (NICNAS, 2012).

The normal pH of blood is 7.35–7.45 and the absolute range of pH is 7.0–7.8. Blood pH is homeostatically regulated by a number of mechanisms but high or repeated ingestion of trisodium phosphates or other alkaline substances can lead to alkalosis (elevated pH of the blood). Symptoms of alkalosis include confusion (which can progress to stupor or coma), prolonged muscle spasms, nausea and vomiting (US NIH/NLM).

As the constituent ions of trisodium phosphate are naturally present in the body and effective homeostatic mechanisms work to maintain these levels, chronic systemic health effects (apart from alkalosis) such as repeated dose toxicity, carcinogenicity and reproductive toxicity are not expected following exposures at non-irritating concentrations. Sodium phosphates are permitted to be used in processed foods as a food additive in Australia, reflecting its low potential for chronic toxicity (FSANZ, 2014).

Acute Toxicity

Oral

Limited data are available on the acute toxicity of these chemicals. Trisodium phosphate is of low acute toxicity with a median lethal dose (LD50 >2000 mg/kg bw in a study conducted in accordance with OECD Test Guideline (TG) 420 and good laboratory practice (GLP). The dose was administered as an aqueous suspension by gavage. Thus, there would have been limited opportunity for corrosivity to be expressed because the chemical was deposited into the stomach which is highly acidic and would subsequently neutralise the corrosive nature of these chemicals.

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Corrosivity

These chemicals are considered to be corrosive under the Approved Criteria (Safe Work Australia, 2004) because the pK_{a3} for phosphoric acid is 12.5 (O'Neil et al, 2013) and so the tribasic phosphate ion can produce solutions with pH close to 12.5. Based on the pH, the chemicals are recommended for classification as corrosive with the risk phrase 'Causes burns' (C; R34) (see **Recommendations** section).

Risk Characterisation

Critical Health Effects

These chemicals are corrosive or irritating to the skin, eyes, gastrointestinal and respiratory tracts, depending on their concentrations.

Public Risk Characterisation

These chemicals may be used in cosmetic products at low concentrations, for example 1–5 % in toothpaste, where the product is formulated to avoid pH extremes. They are also found in domestic products where high 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 phosphate formulations 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, the risk from using the chemical in 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 chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

NICNAS Recommendation

Assessment of these chemicals 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 chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2015).

Work Health and Safety

Neither chemical is currently classified as hazardous under the HSIS. The chemicals in this group are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Causes burns (C; R34)	Causes severe skin burns and eye damage - Cat. 1B (H314)

[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 chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular or inhalational exposure to the chemicals 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 could minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- 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 chemicals.

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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

References

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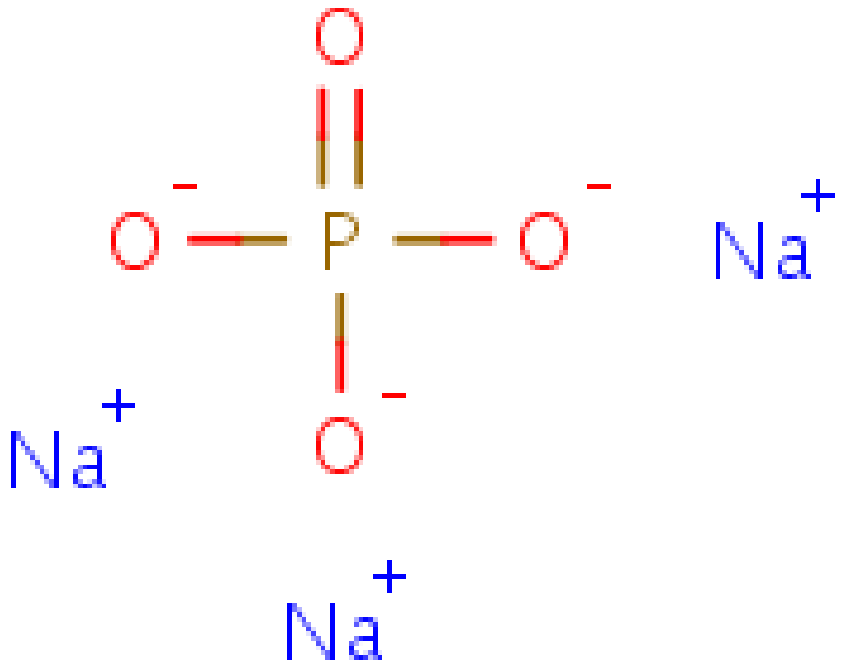
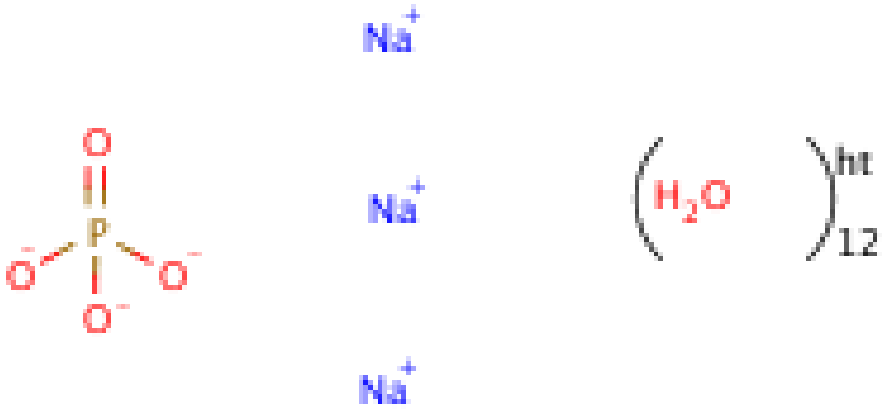
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Phosphoric acid, trisodium salt** trisodium phosphate sodium phosphate, tribasic trisodium orthophosphate
CAS Number	7601-54-9
Structural Formula	

	
Molecular Formula	H3O4P.3Na
Molecular Weight	163.94

Chemical Name in the Inventory and Synonyms	**Phosphoric acid, trisodium salt, dodecahydrate** trisodium orthophosphate, dodecahydrate trisodium phosphate dodecahydrate phosphoric acid, sodium salt, hydrate (1:3:12) sodium phosphate, tribasic
CAS Number	10101-89-0
Structural Formula	

	
Molecular Formula	H3O4P.12H2O.3Na
Molecular Weight	380.12

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