Phosphoric acid, mixed ethylmethylphenyl and phenol and trimethylphenyl and xylyl triesters: Human health tier II assessment

02 March 2018

CAS Number: 68988-42-1

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	Available information for this substance indicates that this is a mixed phosphate ester of isopropyl phenols, methyl phenols (cresyl), dimethyl phenols (xylyl) and phenols. The nomenclature ‘xylyl’ refers to reaction products obtained from xylenols containing dimethyl phenol and ethyl phenol components. The presence of trimethylphenyl triesters is uncertain.
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight (g/mol)	Unspecified
SMILES	c1(OP(Oc2cc(C(C)C)ccc2)(Oc2ccccc2)Oc2ccccc2)c(C)cc(C)cc1

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified for the assessed substance.

International

No specific use, import, or manufacturing information has been identified for the assessed substance.

Structurally related triaryl phosphate esters have commercial and site-limited uses as functional fluids, plasticisers and flame retardants (NICNASa-f).

Restrictions

Australian

No known restrictions have been identified.

International

In Maine, United States of America (USA) – Legislation is being implemented to restrict a flame retardant chemical or mixture that includes flame retardant chemicals to 0.1 % in new residential upholstered furniture containing fabrics, other coverings or cushioning materials. The restriction takes effect in 2019 (Maine Legislature, 2017).

The substance trixylyl phosphate (TXP; CAS No. 25155-23-1), potentially present as a component in the assessed substance, is listed on the candidate list of substances of very high concern (SVHC) and has been prioritised for inclusion in Annex XIV in the European Union (EU) with no proposed exempted uses (ECHA, 2013; ECHA 2016).

The commercial substance tricresyl phosphate (TCP; CAS No. 1330-78-5) potentially present as a component in the assessed substance is listed on the following (NICNASa):

- EU Cosmetics Regulation 1223/2009 Annex II: List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard, Schedule 4: Components cosmetic products must not contain;
- Health Canada List of prohibited and restricted cosmetic ingredients (the cosmetic ingredient "Hotlist"); and
- ASEAN Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

Existing Work Health and Safety Controls

Hazard Classification

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

The components of the assessed substance have the following hazard categories and hazard statements for human health in the HCIS (Safe Work Australia):

- the substance TXP (CAS No. 25155-23-1) is classified as Reproductive toxicity – category 1B; H360F (May damage fertility)

- CAS No. 78-30-8 (listed as tricresyl phosphate (o-o-o-, o-o-m-, o-o-p-, o-m-m-, o-m-p-, o-p-p-)) is classified as Specific target organ toxicity (single exposure) – Category 1; H370 (Causes damage to organs).

Several additional classifications have been recommended as part of the IMAP assessments (NICNASa-f).

Exposure Standards

Australian

No specific exposure standards are available for the assessed substance.

Potential components have the following exposure standards (Safe Work Australia):

- Tricresyl phosphate (o-o-o-, o-o-m-, o-o-p-, o-m-m-, o-m-p-, o-p-p-) has an exposure limit of 0.1 mg/m^3 time weighted average (TWA); and
- Triphenyl phosphate (TPHP; CAS No. 115-86-6) has an exposure standard of 3 mg/m^3 TWA.

International

No specific exposure standards are available for the assessed substance.

Potential components of the assessed substance have the following international exposure standards (Galleria):

TXP

- Occupational Exposure Limit (OEL) of 0.1 mg/m^3 in Canada-Ontario (Galleria Chemica; ECHA, 2013).

Triphenyl phosphate (TPHP)

- TWA of 3 mg/m^3 in various countries including Austria, Canada, Finland, Indonesia, Korea (South), Malaysia, Singapore and the United States of America (USA); and
- US Department of Energy, Temporary Emergency Exposure Limits (TEELs); TEEL-1 of 9, TEEL-2 of 360 and TEEL-3 of 2,100 mg/m^3.

Tri-ortho cresyl phosphate (TOCP)

- TWA of 0.02–0.5 mg/m^3 in multiple countries including China, Austria, Argentina, Canada, Egypt, Finland, South Korea, Malaysia, New Zealand, United Kingdom (UK), and United States;
- short-term exposure limits (STEL) of 0.2-0.3 mg/m^3 in Poland, South Africa, Argentina, Egypt, Finland, UK, and Mexico;
- US Department of Energy, Temporary Emergency Exposure Limits (TEELs); TEEL-1 of 0.3, TEEL-2 of 13 and TEEL-3 of 40 mg/m^3; and
- The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.1 mg/m^3 TWA. A skin notation applies. 'This value is intended to minimize the potential for cholinergic effects and the central and peripheral neuropathies that are considered unrelated to its cholinergic activity' (ACGIH, 2011).

Isopropyl triphenyl phosphate (IPTPP)

- A MAK value of 1 mg/m^3 of was identified in Germany

Health Hazard Information

The assessed substance is a UVCB—a substance that is of unknown or variable composition, a complex reaction product or biological material. The constituents include triaryl phosphate esters with unalkylated and alkylated phenyl rings with a varying degree of alkylation of the phenol ring(s) as well as the size of the alkyl group. Each of the substitutions may also occur as various isomers with the substitution present at the meta, ortho, or para positions of the phenyl ring. The main constituents are expected to be cresyl, xylyl and isopropyl phosphate (alkylated) and phenyl phosphate (unalkylated). The 'xylyl' constituent contain dimethyl phenyl and ethyl phenyl components (ECHA, 2013).

No health hazard or toxicokinetic data are available for the assessed substance. However, the health hazards of most of the potential components—tricresyl phosphate, triphenyl phosphate, trixylyl phosphate and isopropylated triphenyl phosphate—have been evaluated by NICNAS (NICNASa-f). The health hazard information for these substances is considered relevant, and used in the absence of information specific for the assessed substance.

Toxicokinetics

Triaryl phosphate esters are generally readily absorbed via oral and dermal routes and excreted in urine (Sjogren et al., 2010).

Triaryl phosphate esters may be metabolised via various pathways but it generally mostly involves loss of one of the ester moieties to form phosphate diesters.

Highly specific metabolic pathways exist for certain phosphate triesters and can result with neurotoxic metabolites:

1. The ortho-methyl phenyl isomers can be oxidised to hydroxymethyl species, then to aldehyde and carboxylic acid and converted to the neurotoxic cyclic phenyl saligenin phosphate (NICNASa). However, alternative degradation pathways are provided with further substitution of the phenyl ring (xylyl fraction of the assessed chemicals) or with the increased size of the substituent (propyl fraction), leading to inactive excretable products (Sjogren et al., 2010).

2. The para-ethyl phenyl isomers can be hydroxylated to give alpha-hydroxyethyl group, which is then transformed to an acetyl group which leads to potentially neurotoxic metabolites (Eto et al., 1971).

Acute Toxicity

Oral

The potential constituents TOCP (CAS No. 78-30-8) and cresyl diphenyl phosphate (CAS No. 26444-49-5) have moderate acute toxicity (NICNASa; NICNASb). Other aryl phosphate esters potentially present in the assessed substance (including non-ortho substituted cresyl phosphates) have low acute toxicity via oral route (NICNASc-f).

The acute toxicity of the assessed substance is expected to depend on the proportion of ortho methylated phosphate esters present. The substance TOCP usually occurs only as a contaminant in commercial mixtures and usually at very low concentrations (NRC, 2000). Therefore, the assessed substance is not expected to be acutely toxic via oral route. This is supported by the low toxicity observed for commercial TCP (NICNASa).

Dermal

Data available for the triaryl phosphates support the absence of acute toxicity via dermal route (NICNASa,c-e). The known dermal LD50 values for aryl phosphate constituents are >2000 mg/kg bw.

Inhalation

In general, triaryl phosphates have low acute toxicity by inhalation route of exposure (Weiner and Jortner, 1999). Data available for TCP and other triaryl phosphates support the absence of toxicity (NICNASa,c,e).

Corrosion / Irritation

Skin Irritation

The potential constituents TCP, TXP, TPHP and IPTPP are considered to be, at most, slight skin irritants in rabbits (NICNASa-e). Therefore, the assessed substance is not expected to be a skin irritant.

Eye Irritation

In general, triaryl phosphates are not eye irritants (Sjogren et al., 2010). The potential constituents TCP, TXP, TPHP and IPTPP are considered to be, at most, slight eye irritants in rabbits (NICNASa-e). Therefore, the assessed substance is not expected to be an eye irritant.

Sensitisation

Skin Sensitisation

Based on data available for the cresyl phosphate and for TPHP, the assessed substance is not expected to be a skin sensitiser (NICNASa,c).

Repeated Dose Toxicity

Oral

In general, all alkyl substituted triaryl phosphate including the methylated, dimethylated (xylyl) and isopropylated triaryl phosphate constituents, cause damage to health by prolonged exposure and are recommended to be classified for repeat dose toxicity, category 2 (NICNASa,b,d,e,f). As these alkyl triaryl phosphates may be components of the assessed substance, the classification is considered warranted (see ***Recommendation*** section).

In oral repeat dose toxicity studies in rats, alkylated triaryl phosphates including TCP, TXP, and IPTPP consistently induce treatment-related effects including histopathological changes in the adrenals and ovaries. The reported lowest observable adverse effect levels (LOAEL)s for TCP, TXP, and IPTPP are 25, 50, and 25 mg/kg bw/day, respectively (NICNASa,d,e,f). Whilst the mechanisms by which the adrenal and ovary effects occur is not fully understood, inhibition of neutral cholesterol ester hydrolase (nCEH), an enzyme that catalyses the conversion of stored cholesteryl esters in the adrenocortical and ovarian interstitial cells has been suggested (ATSDR, 2012).

The unalkylated triaryl phosphate ester component, TPHP did not cause serious damage to health from repeated oral exposure (NICNASc).

Dermal

Based on the data available, the assessed substance may cause damage to health by prolonged dermal exposure and the classification is considered warranted (see ***Recommendation*** section). This takes into account the:

- adverse effects in the adrenals and ovaries observed for several constituents following oral exposure (see ***Repeated dose toxicity: Oral*** section);
- effects observed with IPTPP in a 28 day dermal study in rats (NICNASe); and

- expected dermal absorption (see ***Toxicokinetics*** section).

Inhalation

Based on the data available, the assessed substance may cause damage to health by prolonged inhalation exposure and the classification is considered warranted (see ***Recommendation*** section). This takes into account the:

- adverse effects in the adrenal glands and ovaries observed for several constituents following oral exposure (see ***Repeated dose toxicity: Oral*** section);
- effects observed with IPTPP in a 90 day inhalation study in rats (NICNASe); and
- expected absorption following inhalation exposure.

Genotoxicity

The potential components TCP, TXP, TPHP and IPTPP are not genotoxic in in vitro or in vivo studies (NICNASa-e). Therefore, the assessed substance is not expected to be genotoxic.

Carcinogenicity

Based on two carcinogenicity studies with TCP in rats and mice showing lack of carcinogenicity (NICNASa) the assessed substance is not expected to be carcinogenic.

Reproductive and Developmental Toxicity

In general, all alkyl substituted triaryl phosphate including the methylated, dimethylated (xylyl) and isopropylated triaryl phosphate components present in the assessed substance, are reproductive toxins (NICNASa,b,d,e,f). While the methylated and dimethylated triaryl phosphates are recommended to be classified for reproductive toxicity, category 1B (NICNASa,b,d), there are no data available for the chemical and therefore, category 2 classification is considered warranted (see ***Recommendation*** section).

In reproductive toxicity studies in rats, alkylated triaryl phosphate esters including TXP, TCP, and IPTPP consistently induced treatment-related changes in organ weight and histology in reproductive organs including ovaries, epididymis and testes. The reported LOAELs for TCP, TXP, and IPTPP are 62.5, 25 and 25 mg/kg bw/day, respectively (NICNASa,d,e). In contrast to the neurotoxicity, the data is not sufficient to demonstrate that the reproductive toxicity would be specific to certain isomers. Reproductive effects consistent with those observed with TCP were observed in studies with the structurally related chemical cresyl diphenyl phosphate that is stated to be free of o-cresyl content (NICNASb,f). Based on limited available data, the unalkylated triaryl phosphate ester component, TPHP did not have adverse reproductive effects in rats (NICNASc).

Other Health Effects

Neurotoxicity

Some triaryl phosphates cause organophosphate induced delayed neuropathy (OPIDN), a neurodegenerative disorder characterised by a delayed onset of prolonged ataxia and upper motor neuron spasticity. Except for tri-para-ethyl phosphate, the neurotoxic triaryl phosphates have at least one ortho-alkylphenyl ester group (NICNASb). The tri-para-ethyl and ortho-alkylphenyl phosphate esters can be metabolised into neurotoxic metabolites (see ***Toxicokinetics*** section).

The assessed substance may contain the ortho-alkylphenyl phosphate esters like TOCP. Therefore, the neurotoxicity of the assessed substance is expected to depend on the proportion of the ortho-alkyl (methyl, ethyl or propyl) fractions (NICNASa,b,e,f). Unsymmetrical mono-ortho isomers appear to be more toxic in relation to OPIDN than the symmetrical tri-ortho isomers. While ortho-methylated aryl phosphates are neurotoxic (NICNASb,e), the neurotoxic potential is reduced with further substitution of the phenyl ring (NICNASd) or as the substituent in the o-position becomes larger and more branched (NICNASe). The IPTPP and TXP potential constituents are not as potent neurotoxins as cresyl phosphate substances and only cause neurotoxicity only at very high exposure levels. The unsubstituted triaryl phosphate ester, TPHP, is not neurotoxic (NICNASc).

Especially for the tricresyl phosphate, efforts are made to minimise the amount of the ortho-isomers present in the commercial products (US EPA, 2015). Therefore, the assessed substance may be neurotoxic but the neurotoxicity is expected to occur only at high doses.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are systemic long-term effects and reproductive toxicity. The assessed substance may also have potential for neurotoxicity particularly at high doses. The potency expected to depend on the proportion of the ortho-alkyl fractions (see ***Neurotoxicity*** section).

Public Risk Characterisation

The use of the assessed substance is unknown. However, given the uses identified for the components present, there is a low likelihood that the public will be exposed significantly. The public could come into contact with articles or coated surfaces containing the components, although it is expected that these components will be bound within the articles or coated surfaces. Some of the components could be released from articles through e.g. abrasion or dissolution. Dust originating from indoor environments (e.g. houses, offices, stores) is considered as a major source of human exposure to flame retardants.

Triaryl phosphate ester constituents potentially present in the assessed substance have been reported to be detected in house dust overseas (Van den Eede et al., 2011; Phillips et al., 2017; Kademoglou et al., 2017), but are not expected to cause unreasonable risk to human health (NICNASd,e). Whilst there is particular concern regarding the risk of oral exposure in toddlers or older children, due to hand-to-mouth behaviour and from sucking on toys containing certain phosphate flame retardants (NICNASg), based on the lack of specific Australian and overseas use information for the assessed substance (see ***Import, Manufacture and Use*** section), it is expected to be a minor contributor for the exposure.

The available data indicate that, although public exposure to the components discussed in this assessment could be widespread, it is at a very low level and; therefore, the risk of adults and children being exposed to levels of the substances that would lead to adverse health effects, is very low. Should further information to better characterise exposure become available, further assessment may be required.

Occupational Risk Characterisation

During handling of the substance, dermal, oral and inhalation exposure of workers may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term health effects, the substance could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, oral and inhalation exposure are implemented. The substance 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.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see ***Recommendation*** section).

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.

No further assessment is required unless new information regarding the uses of the substance in cosmetic or domestic products/scenarios or information to characterise public and worker exposure from its use in articles in Australia becomes available.

Regulatory Control

Work Health and Safety

The chemicals are 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. If the relevant formulation can be demonstrated to be non-neurotoxic, the specific target organ toxicity (single exposure) classification may not be required.

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]
Repeat Dose Toxicity	Not Applicable	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging fertility - Cat. 2 (H361f)
Other Health Effects	Not Applicable	May cause damage to organs - Specific target organ tox, single exp Cat. 2 (H371)

[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 industry

Control measures

Control measures to minimise the risk from oral, dermal, and inhalation 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 chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;

- 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 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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