Australian Government
Department of Health and Ageing
NICNAS

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Phosphoric acid, tributyl ester

CAS Registry Number: 126-73-8

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take three years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

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.

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

For more detail on the new program please visit: www.nicnas.gov.au

ACRONYMS & ABBREVIATIONS

ACToR	Aggregated Computational Toxicology Resource (US)
AICS	Australian Inventory of Chemical Substances
ASTDR	Agency for Toxic Substances and Disease Registry (US)
bw	bodyweight
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations (US)
CHO	Chinese hamster ovary
CosIng	Cosmetic Ingredients and Substances database (EU)
d	day
DNA	Deoxyribonucleic acid
EC	European Commission
EC3	Estimated concentration three
ECHA	European Chemicals Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU RAR	European Union Risk Assessment Report
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia and New Zealand
g	gram
g/mol	grams per mole
GHS	Globally Harmonized System of Classification and Labelling of Chemicals*
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPMT	Guinea Pig Maximisation Test
h	hour
HGPRT	hypoxanthine guanine phosphoribosyltransferase
HPV	high production volume
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
HVICL	High Volume Industrial Chemicals List
IARC	International Agency for Research on Cancer
INCHEM	International Programme on Chemical Safety (also known as IPCS)
INCI	International Nomenclature of Cosmetic Ingredients
ip	intraperitoneal
IRIS	Integrated Risk Information System (US)
IUCLID	International Uniform Chemical Information Database
iv	intravenous
kg	kilogram
L	litre
LC50	median lethal concentration
LD50	median lethal dose
LCLo	lowest published lethal concentration
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw/d	milligrams per kilogram bodyweight per day
min	minute
mL	millilitre
µg	microgram
µL	microlitre
(m)SDS	(material) Safety Data Sheet

NIOSH	National Institute for Occupational Safety and Health (US)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
PCBU	person conducting a business or undertaking
PEL	permissible exposure limit
PND	postnatal day
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
REACH	Registration Evaluation Authorisation of Chemicals (ECHA)
SD	Sprague Dawley
SIAP	SIDS Initial Assessment Profile (OECD)
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SMILES	simplified molecular-input line-entry system
SPIN	Substances in Preparations In the Nordic countries
STEL	short-term exposure limits
STV	short-term value
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)
TCLo	lowest published toxic concentration
TEEL	temporary emergency exposure limits
TSCA	Toxic Substances Control Act (US EPA)
TG	test guideline
TGA	Therapeutic Goods Administration
TLV	threshold limit values
TWA	time weighted average
UN	United Nations
US	United States of America
US EPA	United States Environmental Protection Agency
WHS	Work, Health and Safety
wt	weight
w/w	weight per weight

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:
Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and
Part 2: IPCS Glossary of Key Exposure Assessment Terminology.
The IPCS Risk Assessment Terminology can be accessed at:
http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

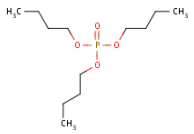
*****Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

******The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Phosphoric acid, tributyl ester

CAS No: 126-73-8

Chemical Identity

Synonyms	Butyl phosphate Tributyl phosphate (TBP) Tri-n-butyl phosphate Phosphoric acid, tribuyl ester
Structural Formula	
Molecular Formula	C12H27O4P
Molecular Weight (g/mol)	266.32
Appearance and Odour (where available)	Colourless, odourless liquid.
SMILES	C(CCC)OP(=O)(OCCCC)OCCCC

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified via European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) Dossiers, Galleria Chemica, and the Substances in Preparations in the Nordic countries (SPIN) database.

The chemical has reported domestic use including:
- adhesives, binding agents;
- cleaning/washing agents;
- colouring agents;
- corrosion inhibitors;
- fillers;
- paints, lacquers and varnishes;
- surface treatment; and
- surfactants.

The Organisation for Economic Cooperation and Development Screening Information Data Set Initial Assessment Report (OECD SIAR) stated that there are no known consumer products containing the chemical (OECD, 2001). However, the REACH dossier listed domestic uses for the general public, such as coatings for indoor and outdoor use and in adhesives (ECHA, 2011).

The chemical has reported commercial use including:
- construction materials;
- hydraulic fluids and additives;
- lubricants and additives;
- process regulators;

- reprographic agents;
- softeners; and
- solvents.

Restrictions

Australian

No known restrictions have been identified.

International

The Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

EU Cosmetic Directive 76/768/EEC Annex II: List of Substances which must not form part of the Composition of Cosmetic Products.

New Zealand Cosmetic Products Group Standard - Schedule 4: Components Cosmetic Products Must Not Contain - Table 1.

Existing Worker Health And Safety Controls

Hazard classification

The chemical is classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):
Carc.Cat.3; R40
Xn; R22 (acute toxicity)
Xi; R38 (irritation)

Exposure standards

Australian

The chemical has an exposure standard of 2.2 mg/m³ (0.2 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):
An exposure limit (TWA) of 2.2 - 11 mg/m³ (0.2 - 1 pm) in USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

Toxicokinetics

Rats given a single oral dose of 14C-labelled chemical at 14 mg/kg bw, 50 percent of the dose was excreted in the urine, 10 percent was excreted in exhaled air, and 6 percent was excreted in the faeces. After 5 days, 82 percent of the total dose was eliminated. Similarly, rats given a single oral dose of 10 or 350 mg/kg bw of 14C-labelled chemical, eliminated the major portion of the recoverable radioactivity within 48 h in the urine and faeces. The major route of elimination was via the kidneys (OECD, 2001).

A single intra-peritoneal (i.p.) dose of the chemical at 250 mg/kg bw to rats resulted in 11 phosphorus-containing metabolites in the urine within 24 h. The principal metabolic pathway resulted in stepwise debutylation, through hydroxylated intermediates, to give dibutyl hydrogen phosphate (40-64% of identified dose) and butyl dihydrogen phosphate (11-21% of identified dose) (OECD, 2001).

In human skin penetration studies, a maximum dermal steady state penetration rate of 0.18 ug/cm³/min was reported (OECD, 2001).

Acute Toxicity

Oral

The chemical is currently classified in Australia with the risk phrase ‘Harmful if swallowed' (Xn; R22) (HSIS, Safe Work Australia). The data available support this classification.

The chemical was reported to have slight to moderate acute toxicity via the oral route. Reported acute oral toxicity values (LD50) in rodents range from 1390 to 3350 mg/kg bw in rats and from 400 to 1240 mg/kg bw in mice. Three hen studies with oral LD50s ranging from 1500 to 1800 mg/kg bw were also reported. The effects produced were not reported in the above studies (OECD, 2001).

Dermal

The chemical was reported to have low acute toxicity via the dermal route (LD50 >3100 mg/kg bw in rabbits and >9700 mg/kg bw in guinea pigs) (OECD, 2001).

Inhalation

The chemical is reported to be acutely toxic in animal tests following inhalation. The data available (LC50 = 4242 mg/m³ in male rats) support the need for classification of the chemical with the risk phrase 'Harmful by inhalation' (Xn; R20).

Male and female Wistar rats were exposed to the chemical (according to OECD TG 403) at doses 0, 511, 801, 2140 or 4242 mg/m³ air (4 h). Observed symptoms included diminished motility, ataxia, adynamia in the hindpaw, prostration, piloerection, untended fur, nose secretion, sniffing sounds, difficulties in breathing or abnormally slow breathing (bradypnoea), breathing sounds, blood-stained tears (chromodacryorrhea), red-coloured urine, inflated abdomen, bloody snout, loss of myotactic reflex and reduction of body weight. At 4242 mg/m³ air, 2 of 5 male rats died. The female rats in this dose group had no mortalities. The LC50 was >4242 mg/m³ air in the male rat (OECD, 2001).

Corrosion / Irritation

Skin irritation

The chemical is currently classified with the risk phrase ‘Irritating to skin’ (Xi; R38) in Australia (Safe Work Australia – HSIS). The data available support this classification.

Skin irritation studies conducted in rabbits, guinea pigs and humans (see Observation in Humans below) show the chemical to be irritating to highly irritating, using a range of application methods to intact or abraded skin (OECD, 2001; REACH 2011).

Eye irritation

The chemical is reported to be a slight eye irritant in rabbits. The data available do not support classification of the chemical as an eye irritant.

Three irritation studies showed the chemical to be irritating (slight or transient irritation) to the eyes of rabbit (OECD, 2001). The eye irritation scores are not available.

The chemical (100 µL) was administered into one eye of 3 rabbits (the other eye remained untreated), and washed out after 24 hours with NaCl. The animals were observed for 21 days after administration of the chemical. The chemical was slightly irritating to the rabbit's eye (conjunctivae reddening was not fully reversible by day 14) (REACH, 2011).

Observation in humans

Symptoms in exposed workers included nausea, headache, skin irritation, and skin rashes (OECD, 2001). One human case study with cotton swabs soaked in 10, 50, and 75 percent solutions of the chemical and applied to skin occlusively for 3, 24, and 48 hours, respectively resulted in irritation at the 50 and 75 percent solution levels (OECD, 2001).

Sensitisation

Skin sensitisation

The chemical is not considered to be a skin sensitiser.

In an open epicutaneous test in guinea pigs, no skin sensitisation was observed with 10% concentration of the chemical in mineral oil (OECD, 2001).

In a non-guideline study the chemical was sensitising to 6 (out of 14) guinea pigs. In this study, paper (manufactured using the chemical) was directly applied to the skin of the animals. No other details were available (REACH, 2011).

Observation in humans

A human patch test showed no sensitisation potential in 53 volunteers exposed to 15 applications of a <5% solution of the chemical (OECD, 2001).

Repeat Dose Toxicity

Oral

In the absence of treatment related effects reported in various repeat dose oral studies, the chemical is not considered to have high repeat dose oral toxicity.

In 24 month oral gavage studies in rodents, NOAELs of 200 ppm (10.2 mg/kg/ bw/d) for rats and 150 ppm (26.5 mg/kg/ bw/d) for mice were reported. Effects observed in 13 weeks to 24 months studies included cellular and/or weight changes in the liver, kidney, and bladder. Other observations noted included spleen weight changes and microscopic testicular changes. However, these effects were not considered dose related as they were found only in one or two short term studies at high doses (>400 mg/kg bw/d), and were not confirmed in any of the longer term studies, even at comparable doses. Blood chemistry, when reported, indicated decremental changes in kidney function. Dietary exposures and oral gavage studies did not show any cholinesterase depression when reported (OECD, 2001).

Dermal

No data are available.

Inhalation

Based on the limited data available, the chemical is not considered to cause severe effects following repeated inhalation.

Two inhalation studies, in rats and rabbits, conducted over 4 months are available. Exposure levels were 5.1 and 13.6 mg/m³ for the rat study, and 4.8 and 13.6 mg/m³ for the rabbit study. In both species, the cholinesterase activity was decreased by 33% at the high dose, although the activity returned to normal in the post exposure period. There was no effect on cholinesterase activity at the low dose (OECD, 2001).

Genotoxicity

Based on the negative results of several genotoxicity studies (both *in vitro* and *in vivo*), the chemical is not considered genotoxic.

Five Ames assays gave negative results with and without metabolic activation. Three other in vitro assays (cytogenetic and mammalian cell gene mutation assays) were also negative (OECD, 2001).

Results of two in vivo genotoxicity studies confirm the negative finding of the in vitro studies. These included a rat cytogenetic assay where there was no increase in aberrant cells in bone marrow after dosing at the maximum tolerated dose of 1200 mg/kg bw via gavage (OECD, 2001).

Carcinogenicity

The chemical is currently classified as hazardous with the risk phrase 'Limited evidence of carcinogenic effect' (Xn; R40 Cat. 3 carcinogen). The available data from two lifetime carcinogenicity studies in rats (Sprague Dawley) and mice (CD-1) support that the chemical is an animal carcinogen when administered in the diet at high doses, although there was a lack of concordance in the two studies with regard to target organ and tumour type.

The NOAEL was 200 ppm or 10.3 mg/kg bw in a 24 month rat study (dosed at 200, 700, or 3000 ppm in the diet). All tissues and organs underwent histopathological examination and only urinary bladder changes were observed. There was a dose related increase in the incidences and severity of hyperplasia and the incidences of papillomas of the urinary bladder epithelium, in the mid and high dose groups. Transitional cell carcinomas were noted in the bladders of 6/49 males and 2/50 females in the high dose

groups. A squamous cell carcinoma was observed in the bladder of 1 of the 49 high dose males (OECD, 2001).

The NOAEL was 150 ppm or 25 mg/kg bw in a 18 month mice study (dosed at 150, 1000, and 3500 ppm in the diet). The only histological change considered to be treatment related was a statistically significant increase in the incidence of hepatocellular adenomas in high dose male mice. No other tumour type was attributed to the chemical on the basis of microscopic examination or statistical analysis (OECD, 2001).

Reproductive and developmental toxicity

The chemical is not considered a reproductive/developmental toxin. Based on the available data, the chemical does not induce reproductive effects in rats (NOAEL for reproductive toxicity >225 mg/kg bw/day). Developmental toxicity was observed in the two generation rat study, but only at maternal toxic doses (NOAEL for maternal toxicity <15 mg/kg bw/day).

A two generation reproductive toxicity study in Sprague Dawley rats received oral doses of 200, 700, or 3000 ppm (approx. 15, 53, or 225 mg/kg bw/day), but showed no evidence of treatment related reproductive organ histopathology. There was no pre or post natal mortality at any dose. In adults, dose levels of 700 and 3000 ppm produced reductions in body weights, body weight gain, and food consumption during the F0 and F1 pre-breeding dosing periods. The 200 ppm feeding level produced transient effects on body weight and food consumption in adults and also reduced the body weights of pups. The only treatment related postnatal effect was reduced pup weight in the high dose group, which was associated with maternal toxicity. Based on these effects, the reproductive toxicity NOAEL was >3000 ppm (>225 mg/kg bw/day), while the maternal toxicity NOAEL and post-natal toxicity NOAEL were both less than 200 ppm (OECD, 2001).

In three separate teratology experiments (two with rats and one with rabbits), teratogenic (delayed ossification and rudimentary ribs) and developmental (reduced foetal weights) effects were observed only at maternally toxic doses and only in rats. The NOAEL for rabbits was the highest dose tested (400 mg/kg bw/day). The NOAEL for teratogenic effects in rats was 750 mg/kg bw/day, but the NOAEL for maternal toxicity was 62.5 mg/kg bw/day (OECD, 2001).

Other Health Effects

Neurotoxicity

The neurotoxicity of the chemical has been studied in several species including the rat, hen, and rabbit. In these studies, the chemical produced either no signs of neurotoxicity or only slight or transient effects on measured endpoints.

In a 13 week neurotoxicity test in SD rats (daily doses as high as 325 mg/kg/day), the chemical did not result in neurotoxicity and did not alter behaviour, adversely affect motor activity or induce neurohistopathological changes. In general, no treatment related effects were seen. No NOAEL was reported (OECD, 2001; ECHA 2011). In a separate neurotoxicity test in SD rats treated for 14 days, a NOAEL of 1000 mg/kg bw (the highest dose tested) was established. Only transient decreases in male body weights, forelimb gripstrengh and motor activity levels for both sexes were observed. The pattern of effects seen was attributed to an acute, non-specific toxicity without apparent neurotoxicity. No gross pathological findings were seen indicative of a treatment related effect (OECD, 2001; REACH, 2011).

In Wistar rats, oral feeding of 5000 or 10,000 mg/kg diet (chemical at 375 or 750 mg/kg bw) for 10 weeks resulted in higher brain cholinesterase activity in the treated groups than the control group (quantitative data not available). However, no change of cholinesterase activity in the liver and serum was reported. Decreased absolute weight of brain in the high dose group was noted (OECD, 2001).

In delayed neurotoxicity tests in hens, in which the chemical was administered either in a single high dose (1500 mg/kg bw) or in two high doses (1500 mg/kg bw each) 21 days apart, there was no relevant inhibition of brain acetylcholinesterase. The hen is considered the most sensitive species for identifying neurotoxins that cause delayed peripheral neuropathy (OECD, 2001; REACH, 2011).

Risk Characterisation

Critical Health Effects

The main critical effect to human health is carcinogenicity. The chemical will cause skin irritation and harmful effects if ingested.

Public Risk Characterisation

No Australian domestic uses were identified. In 2001, the OECD SIAR also stated that no consumer products containing the chemical are available. However, the more recent REACH dossier (ECHA, 2011) identified domestic use in coatings and adhesives that could be available to the public. Based on the absence of any identified consumer uses in Australia, risk management is not recommended for public use. However, if new information becomes available, NICNAS will consider risk management for public use.

Occupational Risk Characterisation

Given the critical health effects, the risk to workers from this chemical is considered high if adequate control measures to minimise occupational exposure to the chemical are not implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) or employee at a workplace has adequate information to determine appropriate controls.

NICNAS Recommendation

The chemical is sufficiently assessed and risk managed provided the recommendation for classification and labelling is followed.

Regulatory Control

Public Health

Considering the available information to indicate low public exposure from this chemical no regulatory controls are recommended. However, if new information becomes available, NICNAS will consider recommending risk management for public safety.

Occupational Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This does not consider classification of physical hazards and environmental hazards.

	Approved Criteria (HSIS)[a]	***GHS Classification***
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful by inhalation (Xn; R20)	Harmful if swallowed - Cat. 4 (H302) Toxic if inhaled - Cat. 3 (H331)
Irritation / Corrosivity	Irritating to skin (Xi; R38)*	Causes skin irritation - Cat. 2 (H315)
Carcinogenicity	Carc. Cat 3 - Limited evidence of a carcinogenic effect (Xn; R40)*	Suspected of causing cancer - Cat. 2 (H351)

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

* Existing Hazard Classification. No change recommended to this classification.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular 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 storage, handling and use of a hazardous chemical are dependent 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:

- use of closed systems or isolation of operations;

- use of 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;
- minimisation of manual processes and work tasks through automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of 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 be relied upon on its own to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selection of 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 assist with meeting 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 hazardous chemical are prepared; and
- management of risks arising from storage, handling and use of 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 physical hazards of the chemical has not been undertaken as part of this assessment.

References

Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)] Third edition. Accessed at http://www.nohsc.gov.au/pdf/Standards/approved_criteriaNOHSC1008_2004.pdf

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