Stannane, dibutylbis[(1-oxododecyl)oxy]-: Human health tier II assessment

01 July 2016

CAS Number: 77-58-7

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.

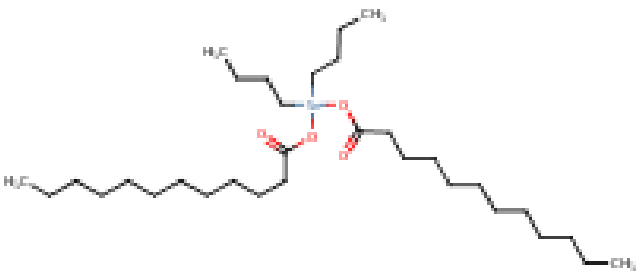
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	dibutyltin dilaurate dibutyltin didodecanoate bis(lauroyloxy)di(n-butyl)stannane tin, di-n-butyl-, di(dodecanoate) DBTL
Structural Formula	
Molecular Formula	C32H64O4Sn
Molecular Weight (g/mol)	631.56
Appearance and Odour (where available)	Colourless oily liquid with faint odour
SMILES	C(=O)(CCCCCCCCCCC)O[Sn](CCCC)(CCCC)OC(=O)CCCCCCCCCCC

Import, Manufacture and Use

Australian

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

The chemical has reported commercial use as an insulating agent and in industrial adhesives and sealants. The chemical has reported potential domestic use in surface coatings.

The National Pollutant Inventory (NPI) holds data for all sources of organotin compounds emissions in Australia.

International

The following international uses have been identified through: the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Organisation for Economic Co-operation and Development (OECD) Screening information data set International Assessment Report (SIAR); Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and various international assessments (EFSA 2004; ATSDR 2005; WHO 2006; OECD 2009).

Dibutyltin compounds are used as chemical intermediates, stabilisers for polyvinyl chloride (PVC) and as catalysts for various products including polyurethane, silicone, and polyester systems. Specifically the chemical is reported to be used in the manufacture of silicones and polyurethane foam manufacture.

The chemical has reported commercial uses including:

- in paints, lacquers and varnishes;
- in construction materials as an insulator;
- as a defoamer/ emulsion breaker;
- in petroleum and natural gas production;
- in resins;
- as a vulcanising agent; and
- in manufacturing paper products.

The chemical has reported domestic uses including in home improvement products such as sealants, fillers and adhesives. Concentrations reported in consumer sealant products are typically < 1 % (Household Products Database, US Department of Health and Human Services; CPCat). Earlier food related applications (baking and cooking silicone moulds and silicone coated baking paper) are now regarded as historical uses which have ceased following voluntary action by the industry (but previously expected to represent 95 % of the market) (RPA 2007; European Commission 2009). In Europe, the use of organotin compounds in products that are likely to come into contact with consumers is restricted (refer **Restrictions** section).

The chemical has reported non-industrial use as an anti-tapeworm drug for poultry.

Restrictions

Australian

These chemicals are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 7 (SUSMP, 2016).

TIN ORGANIC COMPOUNDS, being dialkyl, trialkyl and triphenyl tin compounds where the alkyl group is methyl, ethyl, propyl or butyl **except**:

a) when separately specified in this Schedule;

b) in plastics;

c) in semi-solid sealants, adhesives or elastomers containing 1 per cent or less of the dialkyl, trialkyl or triphenyl tin component; or

d) in paint containing 1 per cent or less of such compounds calculated as tin in the non-volatile content of the paint.

Schedule 7 chemicals are described as: 'Dangerous poisons – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.' (SUSMP 2016).

International

The chemical is listed on the following (Galleria Chemica);

- Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals and;
- Annex XVII to the REACH Regulations. The chemical cannot be used in in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin. Organostannic compounds are also restricted for biocide and water treatment uses (European Parliament and Council 2006).

The chemical is permitted for use in food contact materials in accordance with the United States of America CFR - Code of Federal Regulations Title 21 (US FDA).

Existing Work Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

Tin organic compounds (as Sn) have an exposure standard of 0.1 mg/m^3 time weighted average (TWA) and 0.2 mg/m^3 short-term exposure limit (STEL) with skin notation. Skin notation indicates that absorption through the skin could be a significant source of exposure.

International

The following exposure standards are identified for tin organic compounds (as Sn) (Galleria Chemica);

An exposure limit of 0.1 mg/m^3 time weighted average (TWA) and 0.2 mg/m^3 short-term exposure limit (STEL) in different countries such as Bulgaria, Canada, Chile, Denmark, Egypt, Estonia, France, Greece, Malaysia, Mexico, South Africa, Spain, Sweden, Switzerland, Taiwan, the United States of America and United Kingdom.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 2 mg/m^3 TWA as Sn. 'This value is intended to minimize the potential for adverse effects on immune function and the central nervous system. A TLV–STEL of 0.2 mg/m^3 STEL as Sn is also recommended to minimize acute symptoms such as eye and upper respiratory tract irritation, headached and nausea.' (ACGIH, 2011).

Health Hazard Information

Organotin compounds are characterised by a tin-carbon bond and have the general formula $R_xSnX_{(4-x)}$. The toxicity of organotin compounds depends largely on the organotin moiety (R group) with the anionic ligand (X) mostly influencing physicochemical properties. The chemical is hydrolysed in the stomach to dibutyltin dichloride (DBTC—CAS No. 683-18-1) (refer **Toxicokinetics** section); therefore, data for DBTC are considered relevant for assessing the toxicity of the chemical via repeated oral exposure. Data are also included for dibutyltin diacetate (CAS No. 1067-33-0) which is also assumed to be hydrolysed in the stomach to DBTC. In a number of cases, the purity of the chemical tested and in particular the levels of tributyltin (TBT) impurities were not available. Therefore, the relative contribution of TBT impurities cannot be established.

Toxicokinetics

Limited data are available on the kinetics and metabolism of organotin compounds.

The chemical was tested at low pH (1-2) at 37 °C and the degree of acid hydrolysis was determined. The half life of the chemical was reported to be < 30 minutes and degree of hydrolysis to DBTC, after 2 hours, reported to be 87.8 % (ECHA, 2015).

Organotin compounds can be absorbed following all routes of exposure, although they are reported to have limited gastrointestinal bioavailability (ACGIH, 2011). In addition to hydrolysis, the chemical is expected to be metabolised by oxidative dealkylation similarly to other organotin compounds (ATSDR, 2005; ACGIH, 2011).

DBTC was found to be distributed to all tissues. Concentration changes at various tissue sites was used to predict a half-life for the chemical of 3-5 days (NICNAS). There is evidence of placental transfer for dibutyltin diacetate (ATSDR, 2005).

Acute Toxicity

Oral

The chemical has low to moderate acute toxicity based on results from animal studies. The reported median lethal dose (LD50) concentration ranges in rats are between 45 — 2071 mg/kg bw (ATSDR, 2005; OECD, 2009; HSDB; REACH; RTECS).

Study details were not available for the majority of LD50 values reported. Based on results from an oral gavage study conducted in according to OECD Test Guideline (TG) 401, hazard classification for acute toxicity is not recommended. The chemical was administered at 500, 1000, 2500 or 5000 mg/kg bw as a single dose to Tif: RAif rats (10 animals/dose). Mortalities occurred at all doses, but the mortality rate was < 50 % at doses up to 2500 mg/kg bw. Observed sub-lethal effects included: dyspnoea (shortness of breath); ruffled fur; curved body position; and diarrhoea in animals at all dose groups. In addition, exophthalmos (protuding eyes) was reported at doses of 2500 mg/kg bw and greater. Sedation was reported at the highest dose. Effects were reversible within 11-14 days. The LD50 was determined to be 2071 mg/kg bw/day (OECD, 2009; REACH).

Dermal

The chemical has low acute toxicity based on results from animal tests following dermal exposure. The LD50 in rats is > 2000 mg/kg bw.

In a study according to OECD TG 402, Wistar rats were administered the test chemical at 2000 mg/ kg bw under semi-occlusive conditions, applied to the back and flanks for 24 hours. Observed sub-lethal effects included hunched posture, piloerection, dehydration, emaciation and pallor of the extremities in one animal only. Tiptoe gait and/or hunched posture were noted in two other females. Adverse dermal reaction was indicative of dermal corrosion (See **Corrosivity**) (REACH).

Mortalities during dermal irritation studies have been attributed to intestinal disorder (OECD, 2009).

Inhalation

Limited data are available for the chemical. In a study reported in limited detail, the median lethal concentration (LC50) value in mice was reported to be 150 mg/m^3/two hours for dibutyltin dilaurate. Observed sub-lethal effects included somnolence, kidney/ureter/bladder changes including changes in tubules, acute renal failure and acute tubular necrosis, and changes in bone marrow (RTECS). Other dibutyltin compounds also cause fatality following inhalation (OECD, 2009; NICNAS). In the absence of further information, classification is considered warranted.

Corrosion / Irritation

Corrosivity

Corrosive chemicals are considered to cause irreversible effects on the skin. Based on the results of several animal studies, hazard classification for this endpoint is considered warranted for the chemical (refer **Recommendation** section).

The chemical was reported to cause severe erythema with necrosis and moderate erythema in New Zealand White rabbits after application of 0.5 mL of the chemical under occlusive conditions for four hours (TSCATS). Erythema, oedema, subdermal haemorrhages, and severe, diffused second degree chemical burns with mean primary irritation scores of 5.0, 5.3 and 5.8 at 60 seconds, 30 and 60 minutes after application of the chemical, respectively (TSCATS).

Moderate to severe erythema and signs of corrosivity including blanching and scabbing of the skin and chemical burns resulting in fibrosis have been observed in several studies with unknown or 24 hour exposure periods (OECD, 2009; REACH; TSCATS).

Available in vitro skin corrosion data from skin models using reconstituted human epidermis (RHE) indicate that the chemical does not have corrosive effects and specific corrosive effects have not been reported in a single study in humans (see **Observation in humans**).

Eye Irritation

The chemical was reported to irritate the eyes when tested according to OECD TG 405. The chemical was installed in the conjunctival sac of two male New Zealand White rabbits for 72 hours. The mean irritation scores at 1, 24, 48 and 72 hours were 12, 18, 43.5, and 39 respectively. The average scores for iris, redness and chemosis of the conjunctivae were given as 1.0, 2.0, and 2.0, respectively, and were reversible within 72 hours after application. Slight corneal opacity and moderate iridial inflammation were also reversible within 21 days (REACH).

The chemical was also assessed for ocular irritation in a non-guideline study in six New Zealand White rabbits by instillation of 0.1 mL of the chemical undiluted into the conjuctival sac for up to 168 hours. The primary irritation index was reported to be 11.8 and 14.4, with and without rinsing respectively. Fatalities occurred in two animals with unrinsed eyes, which was attributed upon necropsy to intestinal disorder. Redness, chemosis, and discharge of the conjunctivae was reported in rinsed and unrinsed eyes at 4 and 7 days after application. Rinsing the treated eye increased the irritating effects of the compound (OECD, 2009).

Whilst the chemical meets the criteria for classification as hazardous with the risk phrase 'Irritating to the eye' (R36) in the HSIS, given the proposed clasification for corrosivity, specific classification for eye irritation is not required.

Observation in humans

Workers handling dibutyltin compounds have reported dermal and ocular irritation (NTP). A saturated solution of the chemical (solvent not specified) was reported not to cause irritation when applied once to back of hands of volunteers (Government of Japan, 2009).

Sensitisation

Skin Sensitisation

No animal data are available for the chemical or for the metabolite chemical, dibutyltin dichloride (NICNAS). The chemical is considered to be corrosive to skin.

Repeated Dose Toxicity

Oral

Based on the available data for the chemical and DBTC, the chemical is considered to have potential to cause serious damage to health following oral exposure. In targeted studies, dibutyltins and dibutyltin dilaurate cause well established immunotoxicity. Hepatotoxicity and evidence of neurotoxicity have also been reported (see Neurotoxicity section). Hazard classification consistent with the classification for DBTC is considered warranted (refer **Recommendation** section). This is supported by the 2015 opinion of the European Committee for Risk Assessment (ECHA, 2015).

Dibutyltin dilaurate was assessed for repeated dose oral toxicity in a 13 week (non-guideline) feeding study in rats and three shorter term studies focussing on brain effects, immunotoxicity and liver enzymes.

In the 13 week study, Simonsen rats (10 animals/sex/dose) were exposed to doses of 25, 50, 100, 200, 400, 500, 1000 or 2000 ppm (equivalent to 1.6, 3.3, 6.7, 13.3, 20.6, 33.3, 66.6, 133.3 mg/kg bw/day), via the diet. At 1000 ppm, weight gain and food intake were significantly reduced compared to control animals. Mortalities occurred at doses of 1000 ppm or greater and enlargement of the bile duct was reported to be treatment-related at these doses (ECHA, 2015; REACH). The NOAEL based on from the effects at 500 ppm, was reported to be 20.6 mg/ kg bw/day. It is not clear whether the thymus was evaluated in this study.

Dibutyltins are documented to cause adverse effects on the thymus upon repeated exposure (EFSA, 2004; ATSDR, 2005; WHO, 2006). The immunotoxicity of the chemical was assessed in a two week repeated dose study with doses of 0, 2, 4, 8 or 16 mg/kg bw/day of the chemical administered to Wistar rats by the oral route (further information not specified). The purity of the chemical was not specified. Necropsy analysis was targeted to immunotoxic effects. At doses of 8 mg/kg bw/day and greater, both peripheral and mesenteric lymph nodes had significantly reduced weights. Relative spleen weight was reduced at the highest dose. Thymus weight and cellularity of the thymus reduced in a dose-dependent manner from 2 mg/kg bw/day (OECD, 2009; ECHA, 2015).

In a 15 day feeding study focusing on liver effects, decreased liver enzyme activities were observed following exposure to 17.5 mg/kg bw/day (ECHA; 2015). This is consistent with liver toxicity observed with other butyltin compounds (ATSDR, 2005).

The chemical DBTC is classified as hazardous with the risk phrase ‘Danger of serious damage to health by prolonged exposure via the oral route’ (T; R48/25) in the HSIS (Safe Work Australia). For the chemical, thymus atrophy with lymphoid depletion was observed at low doses in several studies (ATSDR, 2005; OECD, 2009; ECHA, 2015).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the weight of evidence from the genotoxicity studies for DBTC together with support from one in vivo rat study for the chemical, the chemical is considered to be potentially genotoxic. Hazard classification consistent with the classification for DBTC is considered warranted (refer **Recommendation** section). This is supported by the 2015 opinion of the European Committee for Risk Assessment (ECHA, 2015).

The chemical produced negative results in several bacterial reverse mutation assays conducted in accordance with OECD TG 471. *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100 and *Escherichia coli* were tested at concentrations up to 1000 µg/plate. No increases in revertant colonies were observed in any of the test strains in the presence or absence of metabolic activation (OECD, 2009; ECHA, 2015; REACH; TSCATS). A dose-dependent increase in DNA damage was observed in a rat in vivo single cell gel electrophoresis assay focussing of cerebral cortical cells (ECHA, 2015).

The chemical DBTC is classified as hazardous—Category 3 mutagenic substance—with the risk phrase 'Possible risk of irreversible effects' (R68) in the HSIS (Safe Work Australia). A positive result was reported in one in vivo micronucleus test for dibutyltin dichloride (NICNAS).

Carcinogenicity

No data are available for the chemical. Another dibutyltin ester, dibutyltin diacetate, was considered to be not carcinogenic to male rats and male or female mice based on results of a 78 week study in rats. The loss of the tissues prevented a conclusion being made with regard to female rats (ATSDR, 2005).

Reproductive and Developmental Toxicity

Based on available information, the chemical is considered to have adverse effect on reproduction and development of the unborn child. Hazard classification consistent with the classification for DBTC is considered warranted (refer **Recommendation** section). This is supported by the 2015 opinion of the European Committee for Risk Assessment (ECHA, 2015).

Reproductive Toxicity

No data are available for the chemical. The chemical DBTC is classified as hazardous with the risk phrase ‘May impair fertility’ (T; R60) in the HSIS (Safe Work Australia). Reported adverse observed effects included increased numbers of non-pregnant females, increased pre-implantation loss and increased early resorptions (ECHA, 2015; NICNAS).

Developmental Toxicity

The developmental toxicity of the chemical was assessed in Wistar rats administered 0 or 80 µmol/kg bw (equivalent to 5 mg/kg bw) as a single dose on gestation day (GD) 8 (10 animals/dose). Significant increase in mandible complications such as cleft mandible, cleft lower lip, ankyloglossia (an oral anomaly characterised by a short, thick tongue web (lingual frenulum)) or schistoglossia (congenital fissure or cleft of the tongue), exencephaly, anomaly of mandibular fixation or cranial hypoplasia were reported in the offsping in the absence of maternal toxicity. Skeletal malformations were also observed (OECD, 2009; ECHA, 2015; HSDB; REACH).

DBTC is classified as hazardous with the risk phrase ‘May cause harm to the unborn child' (T; R61)' in the HSIS (Safe Work Australia). This is supported by teratogenic effects observed in several developmental studies (ATSDR, 2005; OECD, 2009; ECHA, 2015; NICNAS).

Other Health Effects

Neurotoxicity

Organotins have reported neurotoxic effects; however, most data available are for trialkylated tin compounds. Dibutyltin compounds have reduced neurotoxic effects compared to these chemicals, and neurotoxic effects are only prevalent at near lethal doses (EFSA, 2004; ATSDR, 2005).

The neurotransmitter/neuromodulator levels within the brain of female Wistar rats treated with the chemical were analysed in a study. The animals were treated by the oral route at 0, 20, 40 or 80 mg/kg bw/day daily for three days. The reported behavioural changes in all treated groups included decreased spontaneous locomotor activity, physical weakness, lethargy and decreased learning. Mortalities occurred at doses of 40 mg/kg bw/day and greater. Monoamines including noradrenaline, dopamine, and serotonin were decreased in specific brain regions in a dose-dependent manner. Areas in which reduction in serotonin, dopamine and noradrenalin were detected were the corpus striatum, the pons medulla, and in the frontal cortex respectively. The most affected areas were the frontal cortex and hypothalamus with noradrenalin, serotonin and dopamine decreased in these areas (HSDB; REACH).

Polyamines are neuromodulators which affect the function of neurotransmitters. Dysfunction of polyamines following exposure to a chemical can result in neurotoxicity. In an oral gavage study in rats exposed to the chemical at doses of 0, 20 or 40 mg/kg bw/day for three days, polyamines (spermine and spermidine) were elevated in the frontal cortex, hypothalamus, hippocampus and pons medulla at the highest dose. Effects were less pronounced at the lower dose (HSDB).

Oral administration of a single dose of dibutyltin dilaurate (80 mg/kg bw) caused no significant change in the levels of diacylglycerol and phosphoinositides in rat cerebrum (forebrain), while daily administration of the chemical (40 or 80 mg/kg bw) for three days decreased the levels of diacylglycerol and phosphoinositides in a concentration-dependent manner without influencing the levels of phosphatidylcholine in rat cerebrum. These studies indicate impairment of the phosphoinositide messenger system in rat cerebrum following repeated exposure to the chemical (REACH).

Changes in various antioxidant enzymes in the brain tissue were observed in a seven week gavage study in rats. Dose-dependent increases in DNA damage and apoptosis were also observed with structural changes in the brain observed at 20 mg/kg bw/day (ECHA, 2015).

Observations in humans

Organotin exposure in humans has been reported to cause non-specific neurological symptoms including memory loss and insomnia (NTP).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (immunotoxicity, mutagenicity, neurotoxicity, reproductive and developmental toxicity), systemic acute effects (acute toxicity from inhalation exposure) and local effects (corrosivity).

Public Risk Characterisation

The general public could be exposed to the chemical when using domestic products, specifically do-it-yourself sealants and adhesives containing the chemical. However, based on the low concentration of the chemical in these products (< 1 %), the minimal dermal contact expected and the low volatility of the chemical, the risk to public health is not considered to be unreasonable. The chemical is currently listed on Schedule 7 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) for preparations containing > 1%. Further risk management for these uses is not considered necessary for public safety.

The public could be exposed to the chemical at low levels based on its use as a PVC stabiliser and catalyst for various products. Internationally, a group tolerable daily intake (TDI) of (0.1 µg/kg bw as Sn) for tributyltins, triphenyltins, dibutyltins and dioctyltins

has been established (EFSA 2004, European Commission 2004). Based on an impact assessment report conducted in Europe (European Commission, 2009), the identified uses of the chemical are not considered to significantly contribute to the overall TDI. The use of the chemical in baking and cooking silicone moulds and silicone coated baking paper has been phased out and therefore this is no longer considered a significant source of exposure. In addition, the dominant contribution to human intake of organotins is via consumption of fish. Exposure levels are expected to reduce over time due to the ban in the use of tributyltin of antifouling paints.

If data become available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment may be required.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation (if aerosols are generated) 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.

Given the critical systemic long-term, acute and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **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.

If data become available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment may be required.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2016).

Work Health and Safety

The chemical 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)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Very toxic by inhalation (T+; R26)	Fatal if inhaled - Cat. 2 (H330)

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)
Repeat Dose Toxicity	Toxic: Danger of serious damage to health by prolonged exposure if swallowed (T; R48/25)	Causes damage to organs through prolonged or repeated exposure if swallowed - Cat. 1 (H372)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Reproductive and Developmental Toxicity	Repro. Cat 2 - May cause harm to the unborn child (T; R61) Repro. Cat 2 - May impair fertility (T; R60)	May damage fertility. May damage the unborn child - Cat. 1B (H360FD)

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

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

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

Advice for consumers

Products containing the chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from 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 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 closed systems or isolating operations;
- using 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;
- 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.

References

Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile For Tin and Tin Compounds. Accessed February 2016 at http://www.atsdr.cdc.gov/toxprofiles/tp55.pdf

Aggregated Computational Toxicology Resource (ACToR), US EPA CAS NO. 77-58-7, Accessed February 2016 at http://actor.epa.gov/actor/GenericChemical?casrn=77-58-7

American Conference of Governmental Industrial Hygienists (ACGIH) 2011. Documentation of the Threshold Limit Values for Chemical Substances, ACGIH Signature Publications, 7th Edition. Tin compounds

European Commission (EC) COMMISSION STAFF WORKING DOCUMENT Impact Assessment Report Proposal for a COMMISSION DECISION amending Council Directive 76/769/EEC on the approximation of the laws, regulationsand administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Organostannic compounds). Accessed 2009 at http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

European Food Safety Authority (EFSA) 2004. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission to assess the health risks to consumers associated with exposure to organotins in foodstuffs. The EFSA Journal (2004) 102, 1-119. Accessed February 2016 at http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/102.pdf

European Parliament and Council 2006. Annex XVII: Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. Regulation (EC) No 1907/2006, Accessed March 2016 at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130701:EN:PDF

Galleria Chemica. Accessed February 2016 at http://jr.chemwatch.net/galleria/

Government of Japan (2009) Ministry of the Environment. Profiles of the Initial Environmental Risk Assessment of Chemicals Volume 8 Dibutyltins. Accessed March 2016 at https://www.env.go.jp/en/chemi/chemicals/profile_erac/profile8/pf1-05.pdf

Hazardous Substances Data Bank (HSDB). National Library of Medicine. Accessed on February 2016 at http://toxnet.nlm.nih.gov.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Human Health Tier II assessment for Dibutlytin chloride and hydrogen borate. Australian Government Department of Health. Accessed February 2016 at http://www.nicnas.gov.au/

National Pollutant Inventory (NPI). Accessed February 2016 at http://www.npi.gov.au/index.html

National Toxicology Program (NTP). Organotin toxicity. Accessed February 2016 at http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/organotins_508.pdf

OECD (2009). SIAR on Dibutyltins. Accessed February 2016 at http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=c05dffb0-e5df-4831-bf0d-0a6942bc80e0&idx=0

REACH Dossier (REACH) on dibutyltin dilaurate (CAS No. 77-58-7). Accessed February 2016 at http://echa.europa.eu/information-on-chemicals/registered-substances.

Registry of Toxic Effects of Chemical Substances (RTECS). Stannane, dibutylbis(lauroyloxy)- (CAS No. 77-58-7), RTECS number: WH7000000. Accessed January 2016 at http://ccinfoweb2.ccohs.ca/rtecs/records/WH7000000.html

Risk& Policy Analysts (2007) Limited Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds. Accessed March 2016 at http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

Safe Work Australia (SWA). Hazardous Substances Information System (HSIS). Accessed February 2016 at http://hsis.safeworkaustralia.gov.au/HazardousSubstance

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The Poisons Standard. Commonwealth of Australia. Accessed February 2016 at https://www.tga.gov.au/publication/poisons-standard-susmp

Substances in Preparations in Nordic Countries (SPIN) Database. Accessed February 2016 at http://195.215.202.233/DotNetNuke/default.aspx

Toxic Substance Control Act Test Submission (TSCATS). Low detail Report Dibutyltin Dilaurate (CAS No. 77-58-7) Accessed February 2016 at http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearch?OpenAgent&CASNumber=77-58-7

US Environmental Protection Agency's Chemical and Product Categories (CPCat). Accessed February 2016 at http://actor.epa.gov/cpcat/faces/search.xhtml

US Food& Drug Administration (US FDA). Indirect Additives used in Food Contact Substances. Dibutyltin dilaurate Accessed Mar 2016 at http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives&id=DIBUTYLTINDILAURATE

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