Dimethyltin alkyl mercaptoacetates: Human health tier II assessment

26 October 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Acetic acid, 2,2'-[(dimethylstannylene)bis(thio)]bis-, diisooctyl ester	26636-01-1
8-Oxa-3,5-dithia-4-stannatetradecanoic acid, 10-ethyl-4,4-dimethyl-7-oxo-, 2-ethylhexyl ester	57583-35-4

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

The chemicals are organostannic mercaptoacetates—dimethyltin bis(2-ethylhexyl mercaptoacetate) (DMT(2-EHMA), CAS No. 57583-35-4) and dimethyltin bis(isooctyl mercaptoacetate) (DMT(IOMA), CAS No. 26636-01-1). They are structurally similar and are expected to have similar physicochemical and toxicological properties (OECD, 2008a; OECD, 2008b).

Di-substituted organotin compounds have the general formula R_2SnX_2. The toxicity of organotin compounds depends largely on the organotin moiety (R group), with the anionic ligand (X) mostly influencing physicochemical properties. These chemicals are grouped together for risk assessment due to their similar end uses and expected toxicity profiles (ATSDR, 2005; OECD, 2006; WHO, 2006).

The two mercaptoacetates have similar physicochemical and toxicological properties (NICNASb).

Import, Manufacture and Use

Australian

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

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

The following site limited uses were identified for organotin compounds by the NPI in 2016–17:

- glass and glass product manufacturing; and
- polymer product manufacturing.

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 (SIDS) International Assessment Reports (SIAR) (OECD, 2008a; OECD, 2008b); World Health Organization (WHO) Concise International Chemical Assessment Document (CICAD) 73 (WHO, 2006); Classification, Labelling and Harmonisation (CLH) report (CLH, 2012); and Galleria Chemica.

The chemical DMT(2-EHMA) has reported commercial use in articles for food contact applications.

The chemicals DMT(2-EHMA) and DMT(IOMA) have reported site-limited use as heat stabilisers in the production of polyvinyl chloride materials. Small amounts are expected to be present in articles manufactured from those materials.

The chemical DMT(IOMA) was reported to be used historically; DMT(2-EHMA) is now reported to be the more dominant product (OECD, 2008b).

The chemicals DMT(2-EHMA) and DMT(IOMA) are commonly manufactured as mixtures with their corresponding monomethyltin (MMT) counterparts. Mixtures with greater than 50 % DMT are considered to be dimethyltin substances, whereas mixtures with less than 50 % DMT are considered to be monomethyltin substances (OECD, 2008a).

Restrictions

Australian

Tin organic compounds are listed in the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in Schedule 7 (SUSMP, 2018). This entry covers the chemicals in this group.

"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 % or less of the dialkyl, trialkyl or triphenyl tin component; or

d) in paint containing 1 % 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 2018).

Tin and its compounds are listed in the Work Health and Safety Regulations (2016 revision) as restricted hazardous chemicals—the restricted use is 'abrasive blasting at a concentration of greater than 0.1 % as tin' (Galleria Chemica)."

International

Tin compounds (organic) are listed on the following (Galleria Chemica):

- Council of Europe Resolution AP (92) 2 on control of aids to polymerisation for plastic materials and articles intended to come into contact with foodstuffs—Limits for finished articles; a limit of 0.05 mg/kg (as Sn) applies.
- Europe Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys—Maximum Migration Limits; limits of 0.2, 0.9 and 12 mg/kg of organic tin applies in sticky toy material, dry or brittle or powder like material, and scraped-off toy material, respectively.

- Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up —Table 3 Maximum allowed concentrations of impurities in products for tattoos and PMU; a limit of 50 ppm tin (Sn) applies.

Existing Worker Health and Safety Controls

Hazard Classification

The chemical DMT(2-EHMA) (CAS No. 57583-35-4) is classified as hazardous, with the following hazard categories and hazard statements for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

- Acute toxicity – Category 4; H302 (Harmful if swallowed)
- Skin sensitisation – Category 1A; H317 (May cause an allergic skin reaction)
- Specific target organ toxicity (repeated exposure) – Category 1; H372 (Causes damage to the nervous system and immune system through prolonged or repeated exposure)
- Reproductive toxicity – Category 2; H361d (Suspected of damaging the unborn child)

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).

International

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

An exposure limit of 0.1 mg/m^3 TWA and 0.2–0.4 mg/m^3 STEL in different countries such as Bulgaria, Canada (Alberta, British Columbia, Ontario, Quebec, Saskatchewan, Yukon), Chile, Denmark, Egypt, Estonia, France, Greece, Hungary, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Spain, Sweden, Taiwan, the United Kingdom and the United States of America (California, Hawaii, Minnesota, Tennessee, Vermont, Washington).

Health Hazard Information

Only limited data are available for the chemicals. When data for the chemicals being assessed are not available, health hazard information for DMTC, EHMA and IOMA has also been included in this report as read across, to cover other aspects of toxicity caused by both the tin and the mercaptoacetate moieties. Data for DMTC are considered relevant for systemic endpoints only, since the higher molecular weight and the lower volatility of the chemicals DMT(2-EHMA) and DMT(IOMA) are expected to minimise dermal and inhalation exposure. DMTC will be a tin compound present under acidic conditions similar to the gastric environment; EHMA or IOMA are also formed during metabolism (see **Toxicokinetics** section).

For the specific toxicological data for MMTC, EHMA and IOMA, refer to the separate IMAP Tier II assessments (NICNASa; NICNASb).

The Tier II assessment report for DMTC is available at **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=12638**. The Tier II assessment report for EHMA and IOMA is

available at **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1309**. These reports should be read in conjunction with this Tier II assessment.

Toxicokinetics

Studies have shown that organotin compounds with sulfur or carboxylate based ligands are easily displaced under mild physiological conditions (REACH).

Under simulated gastric conditions, 0.1 mg/mL of the chemical 80:20 % DMT(2-EHMA):MMT(EHMA) in 0.07 M HCl (pH 1–2, 37 °C), rapidly converted (approximately 100 %) to DMTC and released the EHMA ligand within 0.5 hours (OECD, 2008a; CLH, 2012; REACH). The same is expected to occur for DMT(IOMA).

A more direct analysis method (NMR) of the hydrolysis products of DMT(2-EHMA), using 1 g of DMTC(2-EHMA) in 100 mL 0.1 M HCl (pH 1.2, 37 °C) (equivalent to 10000 ppm), indicated that instead of the loss of both mercaptoacetate ligands from the tin ion to form DMTC, one ligand remained attached forming a mono-chloro ester of the chemical. Hydrolysis to the mono-chloro ester was only partial (up to 29 % after 72 hours) and no other tin moieties were identified (KEMI, 2018; REACH).

In the above in vitro studies, a 1000x greater concentration of starting chemical was used in the second study which may have affected the position of the equilibrium. No data are available on the in vivo metabolism of the chemicals.

In an in vitro dermal absorption study (OECD test guideline (TG) 428) using an 80:20 % DMT(2-EHMA):MMT(2-EHMA) compound, human and rat epidermis were treated with (occluded and unoccluded) the chemical at 100 µg/cm^2 for 24 hours. There was no dermal toxicity under these experimental conditions. Tin absorption was faster and to a higher extent in rat epidermis, compared with human epidermis. Percutaneous absorption (the amount remaining in skin and considered potentially absorbable) was 1.5–2 % in human epidermis and 6.5–7.2 % in rat epidermis. (OECD, 2008a; REACH). Overall, this evidence supports that the presence of the mercaptoacetate in DMT compounds increases the molecular weight, compared to DMTC, and contributes to lower volatility, resulting in the reduction in toxicity via the dermal and inhalation routes (OECD, 2008a).

The organotin species and mercaptoacetate esters will be distributed, metabolised and excreted separately (NICNASa; NICNASb).

Acute Toxicity

Oral

The chemical DMT(2-EHMA) is classified as hazardous with hazard category 'Acute toxicity - Category 4' and hazard statement 'Harmful if swallowed' (H302) in the HCIS. Based on the available data, this classification is warranted for both chemicals in this group (see **Recommendation** section).

The following oral median lethal dose (LD50) values were reported for DMT(2-EHMA) (OECD, 2008a; CLH, 2012; REACH):

- 1150 mg/kg bw in male and female Sprague Dawley (SD) rats; and
- 1710 mg/kg bw in male SD rats.

The following oral LD50 values were reported for DMT(IOMA) (OECD, 2008b):

- 1090–1735 mg/kg bw in male and female SD rats; and
- 1214 mg/kg bw in male and female Tif:RAI rats.

Observed sub-lethal effects included breathing difficulties, lethargy, piloerection (hair raised), uncoordination, faecal and urine stains.

Dermal

Based on the available data, the chemicals are considered to have low acute dermal toxicity.

The following dermal LD50 values were reported (OECD, 2008a; OECD, 2008b; REACH):

- >1050 mg/kg bw in male and female New Zealand White (NZW) rabbits exposed to DMT(2-EHMA);
- 1000–2150 mg/kg bw in mammals (other details not specified) exposed to DMT(IOMA); and
- >3100 mg/kg bw in male and female Tif:RAI rats exposed to DMT(IOMA).

No mortality or sub-lethal effects were noted. Compared with DMTC, the higher molecular weight of the chemicals DMT(2-EHMA) and DMT(IOMA) is expected to minimise dermal absorption (OECD, 2008a; see also **Toxicokinetics** section).

Inhalation

Based on the available data, the chemicals are considered to have low acute inhalation toxicity.

The following inhalation median lethal concentration (LC50) values were reported for DMT(IOMA) (OECD, 2008b):

- 132 mg/L/1 hr (equivalent to 33 mg/L/4 hrs) in rats (sex and strain unspecified); and
- >1968 mg/m^3/4 hrs (>1.968 mg/L/4 hrs) in male and female Tif:RAI rats exposed (nose only) to the chemical aerosol.

Observed sub-lethal effects included aggressiveness, excitement, breathing difficulties, ruffled fur, and lying in a lateral position.

Compared with DMTC, the higher molecular weight and the lower volatility of the chemicals DMT(2-EHMA) and DMT(IOMA) are expected to minimise inhalation exposure (OECD, 2008a; see also **Toxicokinetics** section).

Corrosion / Irritation

Skin Irritation

The chemicals are considered to be slight skin irritants. Several studies with 24 hour exposure showed greater irritancy, and in one study unexplained deaths.

In the most recent in vivo skin irritation study (similar to OECD TG 404), NZW rabbits (n = 2 males, 1 female) were exposed to 0.5 mL of DMT(2-EHMA), (62.8 % purity) via a semiocclusive patch on shaved intact skin for 4 hours. After patch removal the sites were monitored at 60 minutes, 24, 48 and 72 hours. Erythema was not present to well defined between 60 minutes after exposure through to 48 hours after exposure. At 72 hours to 7 days after exposure, erythema was either absent or very slightly present in the animals. Oedema was not present to very slightly present 60 minutes after exposure, and absent to well defined between 24 and 48 hours after exposure. By day 7 no oedema was observed. A primary dermal irritation index (PDII) score of 1.75 was reported and it was concluded that the chemical was moderately irritating (REACH).

In an in vivo skin irritation study (according to 16 CFR 1500 “Method of testing toxic substances”), NZW rabbits (n = 3/sex) were exposed to 0.5 mL of DMT(2-EHMA):MMT(EHMA) (reported as predominantly DMT) via an occlusive patch on abraded and intact skin for 24 hours. After patch removal the sites were monitored up to 72 hours. Moderate oedema and up to well-defined erythema was noted during the observation period. A PDII score of 2.6 was reported for the 24 hour time point and it was concluded that the chemical was slightly irritating (OECD, 2008a; REACH).

In another in vivo skin irritation study (according to the Appraisal of the Safety of Chemicals in Food, Drugs, and Cosmetics (AFDO)), rabbits (n = 3/sex, Russian breed strain) were exposed to 0.5 mL of DMT(2-EHMA) (purity not reported) via an occlusive test patch on abraded and intact skin for 24 hours. After patch removal the sites were monitored 72 hours after application. Two of the females refused food before dying within 72 hours after application (no further details available), while all animals showed tremors and curved posture after the first 48 hours after treatment. Effects on the exposure sites included mild oedema and slight to moderate erythema, with a 24 hour PDII score of 1.5 (OECD, 2008a; REACH).

In an in vivo skin irritation study (according to the Federal Hazardous Substances Act (FHSA)), rabbits (n = 6, sex and strain not specified) were exposed to 0.5 mL of 95:5 % DMT(IOMA):MMT(IOMA) via an occlusive patch on abraded and intact skin for 24 hours. After patch removal the sites were monitored up to 72 hours. Moderate irritation was noted during the observation period, with a PDII score of 2.36 (scoring key in 191.11 of the Regulations under the FHSA) (OECD, 2008b).

Eye Irritation

Based on the available data, the chemicals are minimal eye irritants. However, deaths (unexplained) were reported in one study.

In an in vivo eye irritation study (OECD TG 405), NZW rabbits (n = 2 males, 1 female) were exposed to 0.1 mL of an unnamed chemical (assumed to be DMT(2-EHMA), 62.8 % purity) placed into one eye, which was subsequently washed after 24 hours. The eyes were monitored at 1, 24, 48 and 72 hours after dosing. No corneal opacity or iritis was noted at any point during the observation period. There was conjunctival irritation at 1 hour in all rabbits, but this was reversed by 24 hours. Average scores over the 24–72 hours time points were 0 for all endpoints (REACH).

In another in vivo eye irritation study (according to 16 CFR 1500 “Method of testing toxic chemicals”), NZW rabbits (n = 3/sex) were administered 0.1 mL of the chemical DMT(2-EHMA):MMT(EHMA) (reported as predominantly DMT) into their right eyes. The eyes were not rinsed and the animals were observed at 24, 48 and 72 hours after application. Slight conjunctival erythema was noted in 3 animals between 24 and 48 hours after application. However, there were no positive irritation scores in any of the animals by the end of the observation period and it was concluded that the chemical was not irritating (OECD, 2008a; REACH).

In an in vivo eye irritation study (according to AFDO), rabbits (n = 3/sex, Russian breed strain) were exposed to 0.1 mL of DMT(2-EHMA) (purity not reported) in one eye for 30 seconds before being rinsed with water. The eyes were monitored at 1, 2, 3, 4 and 7 days after application. Two females refused food and died within 3 days of application (no further details available), and all animals were shaking and hunched after 48 hours. The primary irritation index (PII) scores were 0, 0, and 0.4 for the iris, conjunctivae and cornea, respectively, and it was concluded that the chemical was not irritating (OECD, 2008a; REACH).

In an in vivo eye irritation study (according to FHSA), albino rabbits (n = 6, sex unspecified) were exposed to 0.1 mL of 95:5 % DMT(IOMA):MMT(IOMA) in the right eye for an unspecified amount of time. The eyes were monitored at 24, 48 and 72 hours following the administration of the chemical. No signs of irritation were observed at any time during the study (OECD, 2008b).

Sensitisation

Skin Sensitisation

The chemical DMT(2-EHMA) is classified as hazardous with hazard category 'Skin sensitisation - Category 1A' and hazard statement 'May cause an allergic skin reaction' (H317) in the HCIS (Safe Work Australia). Based on the available data for the chemicals, and the data for EHMA and IOMA (NICNASb), the classification is warranted for both chemicals in this group (see **Recommendation** section).

In two Maurer optimisation tests the chemicals DMT(2-EHMA) and DMT(IOMA) were tested with the following methodology. Pirbright white guinea pigs (n = 10/sex) were induced intradermally with 0.1 mL of the chemical, twice on two separate sites in the first week. Subcutaneous induction was undertaken in week two and three, using 0.1 mL of the chemical mixed with Freunds complete adjuvant (1:1 ratio), three times per week. After two weeks the animals were administered an intradermal injection of 0.1 mL of 0.1 % of the chemical, in a previously untreated area and assessed 24 hours later. For animals tested with DMT(2-EHMA) a positive sensitisation reaction was observed with 4/10 males and 7/10 females having erythema scores of 1, while in animals tested with DMT(IOMA) positive erythema scores ≤ 1 were noted in males and females in the first 24 hours (OECD, 2008a; OECD, 2008b; CLH, 2012; REACH). In the RAC opinion for the chemical DMT(2-EHMA), it was concluded "that the 55 % incidence of sensitisation in guinea pigs exposed to a 0.1 % intradermal induction dose in the non-standard Maurer optimisation tests was sufficient to meet the criteria for sub-category 1A classification, even though this is usually based on a guinea pig maximisation test (GMPT)" (RAC, 2012).

In a Buehler test, Hartley guinea pigs (n = 10/sex/dose) were induced with a 50 % w/v formulation in acetone occlusively, once a week for three weeks. Two weeks later this was followed by a primary challenge at 1 % w/v in acetone occlusively, once a week for three weeks and animals were monitored for up to 48 hours after the last administration. The incidence of slight to patchy

erythema was similar in the test group and control group, indicating that sensitisation was not induced (OECD, 2006a; CLH, 2012; REACH). The Buehler test is generally considered not as sensitive as the GPMT.

Repeated Dose Toxicity

Oral

The chemical DMT(2-EHMA) is classified as hazardous with hazard category 'Specific target organ toxicity (repeated exposure) - Category 1' and hazard statement 'Causes damage to the nervous system and immune system through prolonged or repeated exposure' (H372) in the HCIS (Safe Work Australia). No data are available for the chemicals. Based on the available data for the gastric metabolite, DMTC (NICNASa), the chemicals are considered to cause serious health effects following repeated oral exposure, which support the hazard classification for both chemicals (see **Recommendation** section).

Exposure to DMTC has been linked to decreased thymus weights and thymus atrophy in males; and increased kidney weights in females, accompanied by histopathological changes. Neurotoxic effects were noted across both sexes with signs including convulsions and tremors, and physiological changes including neuronal necrosis, ventricular dilation, and white matter vacuolisation in the brain and spinal cords (NICNASa).

Genotoxicity

Only limited data are available for DMT(2-EHMA). Based on the available data for the chemicals DMTC, EHMA and IOMA, the chemicals are not considered to be genotoxic (NICNASa; NICNASb).

Negative results were reported for these chemicals in bacterial reverse mutation assays (OECD TG 471 and 472) in *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 and in *Escherichia coli* WP2 uvr A, exposed to DMT(2-EHMA) at 16.7–5000 µg/plate, with and without metabolic activation (OECD, 2008a).

Carcinogenicity

No data are available for the chemical. Carcinogenicity was not observed in long-term studies using mixtures of mono- and dimethyltins (WHO, 2006). The limited data available for EHMA and IOMA do not indicate a concern for carcinogenicity (NICNASb).

Reproductive and Developmental Toxicity

The chemical DMT(2-EHMA) is classified as hazardous with hazard category 'Reproductive toxicity - Category 2' and hazard statement 'Suspected of damaging the unborn child' (H361d) in the HCIS (Safe Work Australia). No data are available for the chemicals. Based on the available data for DMTC (NICNASa), the chemicals are considered to cause serious health effects following repeated oral exposure, which support the hazard classification for both chemicals (see **Recommendation** section).

The chemicals DMTC and EHMA are classified as hazardous with the hazard category 'Reproductive Toxicity - Category 2' and hazard statement 'Suspected of damaging the unborn child' (H361d) in HCIS (Safe Work Australia).

The available data for DMTC indicated the presence of variations and malformations, and developmental neurotoxicity at low doses in some of the animal studies (NICNASa).

The chemical EHMA was reported to cause developmental effects at maternally toxic levels; however, direct neonatal effects resulting from exposure to maternal milk could not be discounted (NICNASb).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (reproductive and developmental toxicity, neurotoxicity and thymus effects) following oral exposure and local effects (skin sensitisation). The chemicals may also cause systemic acute effects following oral exposure.

Public Risk Characterisation

The chemicals DMT(2-EHMA) and DMT(IOMA) are covered by a listing in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), precluding their use in consumer products in Australia (SUSMP, 2018).

The public could be exposed to the chemicals at low levels based on their use as PVC stabilisers and use in food contact applications. At these levels the acute and local effects are not expected. Internationally, a group tolerable daily intake (TDI) of (0.1 µg/kg bw as Sn) for organotins in foodstuff based on systemic effects has been established (European Commission, 2009). To reduce the identified risk of organotins transferred from food packaging to foodstuffs, the overall exposure should be lower than the TDI. The dominant contribution to human intake of organotins (mainly tributyltin) is via consumption of fish. Exposure to other organotins, including these chemicals is expected to be generally low both from food contact and handling PVC articles. Hence, the public risk from these chemicals is not considered to be unreasonable. If data becomes available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment of these chemicals may be required.

Occupational Risk Characterisation

During product formulation oral and dermal exposure might 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.

Given the critical systemic long-term and acute, and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal and ocular 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 HCIS (Safe Work Australia) (see **Recommendation** section).

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. The chemicals are not available to the public (SUSMP, 2018).

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.

This is the existing classification for DMT(2-EHMA) (CAS No. 57583-35-4).

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]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1A (H317)
Repeat Dose Toxicity	Not Applicable	Causes damage to the nervous system and immune system through prolonged or repeated exposure - Cat. 1 (H372)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging the unborn child - Cat. 2 (H361d)

[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 oral and dermal 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 is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemicals, 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 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

Agency for Toxic Substances and Disease Registry (ATSDR) 2005. Toxicological Profile for Tin and Tin Compounds. Accessed October 2018 at **https://www.atsdr.cdc.gov/toxprofiles/tp55.pdf**

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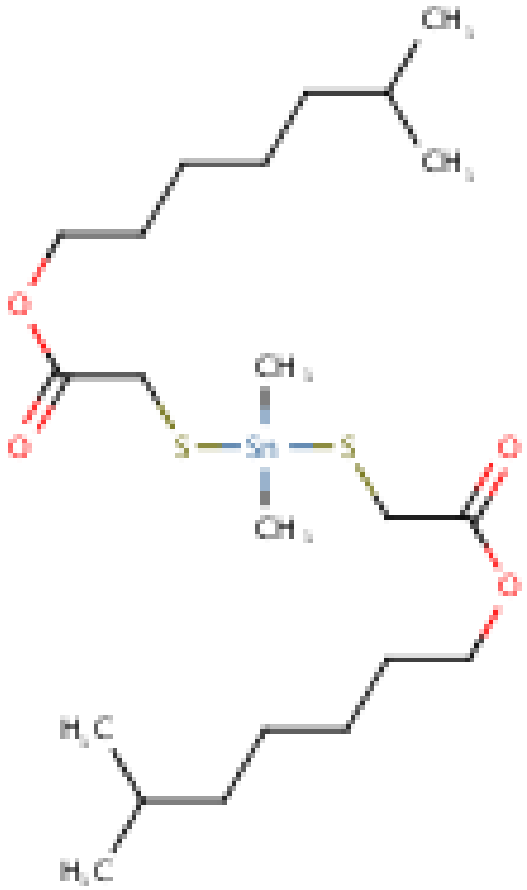
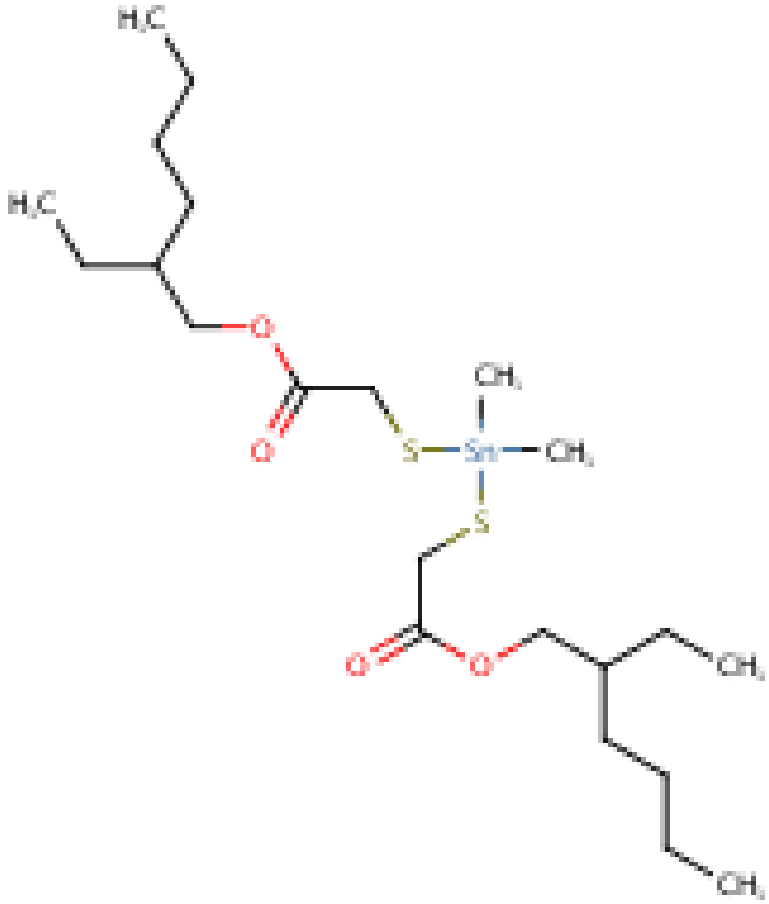
Last Update 26 October 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Acetic acid, 2,2'-[(dimethylstannylene)bis(thio)]bis-, diisooctyl ester** stannane, dimethylbis[(carboxymethyl)thio dimethyltin-bis(isooctylthioglycolate) DMT(IOMA) dimethyltin bis(isooctyl mercaptoacetate) diisooctyl ((dimethylstannylene)dithio)diacetate
CAS Number	26636-01-1
Structural Formula	

	
Molecular Formula	C22H44O4S2Sn
Molecular Weight	555.43

Chemical Name in the Inventory and Synonyms	**8-Oxa-3,5-dithia-4-stannatetradecanoic acid, 10-ethyl-4,4-dimethyl-7-oxo-, 2-ethylhexyl ester** dimethyltin bis[2-ethylhexyl mercaptoacetate] DMT(2-EHMA) dimethyltin bis(2-ethylhexyl thioglycolate) 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate 8-oxa-3,5-dithia-4-stannatetradecanoic acid, 10-ethyl-4,4-dimethyl-7-oxo-, 2-ethylhexyl ester
CAS Number	57583-35-4
Structural Formula	

	
Molecular Formula	C22H44O4S2Sn
Molecular Weight	555.43

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