Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

Compounds of dibutyltin

Evaluation statement

30 June 2022

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AICIS evaluation statement

Subject of the evaluation

Compounds of dibutyltin

Chemicals in this evaluation

Name	CAS registry number
6H-1,3,2-Oxathiastannin-6-one, 2,2-dibutyldihydro-	78-06-8
Stannane, dibutyldifluoro-	563-25-7
Stannane, dibutylbis(dodecylthio)-	1185-81-5
Stannane, dibutylthioxo-	4253-22-9
3,8,10-Trioxa-9-stannatetradeca-5,12-dien-14-oic acid, 9,9-dibutyl-4,7,11-trioxo-, ethyl ester, (Z,Z)-	13173-04-1
2,7,9-Trioxa-8-stannatrideca-4,11-dien-13-oic acid, 8,8-dibutyl-3,6,10-trioxo-, methyl ester, (Z,Z)-	15546-11-9
5,7,12-Trioxa-6-stannaoctadeca-2,9-dienoic acid, 6,6-dibutyl-14-ethyl-4,8,11-trioxo-, 2-ethylhexyl ester	15546-12-0
5,7,12-Trioxa-6-stannahexadeca-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, butyl ester, (Z,Z)-	15546-16-4
5,7,12-Trioxa-6-stannaoctacosa-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, hexadecyl ester, (Z,Z)-	19706-58-2
Tin, dibutylbis(2,4-pentanedionato-O,O')-, (OC-6-11)-	22673-19-4
2-Butenoic acid, 4,4'-[(dibutylstannylene)bis(oxy)]bis[4-oxo-, diisooctyl ester, (Z,Z)-	25168-21-2
Tin, dibutylbis(octyl mercaptoacetato-O',S)-	32011-18-0
10-Oxa-4,6-dithia-5-stannahexadecanoic acid, 5,5-dibutyl-12-ethyl-9-oxo-, 2-ethylhexyl ester	53202-61-2
5,7,12-Trioxa-6-stannatriaconta-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, octadecyl ester, (Z,Z)-	61813-52-3
9-Octadecenoic acid, (Z)-, (dibutylstannylene)bis(thio-2,1-ethanediyl) ester	67361-77-7
Propanoic acid, 3,3'-[(dibutylstannylene)bis(thio)]bis-, diisooctyl ester, reaction products with dibutyloxostannane	68412-50-0
Stannane, dibutylbis(butylmercaptomethoxy-1-oxopropoxy)-	69039-26-5
Silicic acid (H4SiO4), tetraethyl ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane	70750-24-2
10-Oxa-4,6-dithia-5-stannatricosanoic acid, 5,5-dibutyl-9-oxo-, tridecyl ester	70942-47-1
Propanoic acid, 3,3'-[(dibutylstannylene)bis(thio)]bis-, diisotridecyl ester	84896-44-6

Name	CAS registry number
3,5,7,9-Tetraoxa-4,8-disila-6-stannaundecane, 6,6-dibutyl-4,4,8,8-tetraethoxy-	87735-26-0
Silicic acid (H4SiO4), diethyl bis(2-methoxyethyl) ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane	93925-40-7
Silicic acid (H4SiO4), diethyl bis(2-methoxyethyl) ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane and silicic acid (H4SiO4) tetrakis(2-methoxyethyl) ester	93925-41-8
Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dibutylstannane	93925-42-9
Silicic acid (H4SiO4), tetrakis(2-methoxyethyl)ester, reaction products with bis(acetyloxy)dibutylstannane	93925-44-1
Silicic acid (H4SiO4), tetrapropyl ester, reaction products with bis(acetyloxy)dibutylstannane	93925-45-2
Tin, dibutylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4)-	149715-03-7
Silicic acid (H4SiO4), tetraethyl ester, reaction products with dibutyloxostannane	185630-89-1
Fatty acids, C16-18 and C18-unsatd., reaction products with dibutyloxostannane, ethylene glycol, hydrotreated heavy petroleum naphtha, isophthalic acid, maleic anhydride-styrene polymer, (2-methoxymethylethoxy)propanol, (1-methylethyl)benzene, terephthalic acid, trimellitic anhydride and trimethylolpropane	256422-04-5
2-Butenedioic acid (2Z)-, monobutyl ester, polymer with butyl 2-propenoate, 1,4-diethenylbenzene, ethenylbenzene and 2,5-furandione, reaction products with 2,2-dibutyl-4-hydroxy-1,3,2,4-dioxastannaboretane	375844-86-3

Reason for the evaluation

Evaluation Selection Analysis indicated a potential human health risk.

Parameters of evaluation

The chemicals are a group of dibutyltin compounds listed on the Australian Inventory of Industrial Chemicals (the Inventory). Two of the chemicals are polymers. This evaluation is a human health risk assessment for all identified industrial uses of these chemicals.

These chemicals have been assessed as a group because the toxicity of organotin compounds depends largely on the organotin moiety, and these chemicals are structurally similar in that they are expected to metabolise to simple dibutyltin compounds. Based on a review of the available information, dibutyltin compounds have been reported to be genotoxic and cause reproductive and immune system toxicity. Neurotoxic effects may occur at high doses. These human health effects are likely to be the main drivers of any risk management recommendations for this group of chemicals.

Although data for systemic acute effects and local effects are presented for chemicals where available, this evaluation will not provide conclusions on these endpoints where data are not available.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific information about the introduction, use and end use of these chemicals in Australia. Data on emissions and sources of emissions for organotin compounds in Australia indicate site limited use in polymer product manufacturing.

Based on international information for twelve chemicals in this group, these chemicals are used as a catalyst, process regulator, additive, plasticiser, or heat stabiliser in the manufacture of plastic and other products used in a wide range of commercial applications. Three of the chemicals have reported domestic uses in adhesives, sealants, and other household products. No information is available for the rest of the chemicals in this group, but they are expected to have site limited uses similar to other dibutyltin compounds (see **Supporting information** section).

Public consultation provided data that identified commercially active, most likely active, and inactive chemicals for ten chemicals in this group (see **Supporting Information – Introduction and use: International** section).

Human health

Summary of health hazards

There is limited toxicological information for 9 chemicals in this group. The main driver for the toxicity of dibutyltin compounds is expected to be the dibutyltin moiety. Therefore, available data for other dibutyltin compounds, including dibutyltin dichloride, dibutyltin dilaurate, dibutyltin alkyl mercaptoacetates, dibutyltin diacetate and dibutyltin oxide, are used to draw conclusions regarding the systemic effects of chemicals in this group. These dibutyltin compounds were assessed previously and their respective reports should be read in conjunction with this evaluation statement (NICNAS 2016a; NICNAS 2016b; NICNAS 2019a; NICNAS 2019b; NICNAS 2019c).

Based on read across, critical health effects for risk characterisation include:

- reproductive and developmental toxicity
- immunotoxicity
- genotoxicity.

Based on read across data, the chemicals are expected to cause serious systemic health effects following repeated exposure. The thymus was consistently the target organ in studies with dibutyltin dichloride, dibutyltin alkyl mercaptoacetates and dibutyltin dilaurate. Effects included reduced thymus weights, thymus atrophy, reduced cellularity in the thymus and lymphoid depletion.

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 dose (EFSA 2004; ATSDR 2005).

Based on read across data, the chemicals are expected to cause specific adverse effects on fertility and development following exposure. The available data on reproductive toxicity for dibutyltin dichloride indicated increased numbers of non-pregnant females, increased pre-implantation loss and increased early resorptions. Data on fertility effects were not available for other dibutyltin compounds. An increased incidence of foetal malformations at low doses was observed in experimental studies with dibutyltin dichloride, dibutyltin dilaurate, dibutyltin diacetate and dibutyltin oxide. These effects were not seen in a single study with a dibutyltin alkyl mercaptoacetate, but effects at higher doses cannot be ruled out.

Based on read across from the available in vivo data for dibutyltin dichloride and dibutyltin dilaurate compounds, the chemicals are expected to be genotoxic. Dibutyltin diacetate was considered not to be 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.

Previously assessed dibutyltin compounds had low to high acute oral toxicity. Acute toxicity studies were available for the chemicals with CAS Nos. 1185-81-5; 15546-11-9; 22673-19-4; 84896-44-6; 93925-42-9. Based on the median lethal dose (LD50) values, CAS 1185-81-5 and 84896-44-6 have low acute oral toxicity and CAS 15546-11-9; 22673-19-4 and 93925-42-9 have moderate acute toxicity. There are minimal data on dermal toxicity but the LD50 values for 1185-81-5 and 93925-42-9) indicate that the chemical has moderate acute dermal toxicity. No data are available on inhalation toxicity.

The majority of dibutyl tin compounds previously assessed were corrosive. Information on skin and eye irritation of varying quality from different types of studies was available for some of the chemicals. Data are sufficient to warrant classification for skin irritation (CAS No. 22673-19-4) and eye irritation (CAS No. 15546-11-9). There are no data on skin sensitisation. Mercaptoacetate alkyl tin compounds are skin sensitisers (NICNAS 2019a). However, read across for this large group of chemicals is not appropriate for local effects.

Health hazard classification

These chemicals satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for hazard classes relevant for work health and safety. This evaluation does not consider classification of physical and environmental hazards. These recommended classifications are based on read across principles (see **Supporting Information – Grouping Rationale** section). If empirical data become available for either member of the group indicating that a lower (or higher) classification is appropriate for a specific chemical, this data may be used to amend the default classification for that chemical.

All chemicals in the group are recommended for classification for repeated dose toxicity, genotoxicity, and reproductive and developmental toxicity.

The acute oral classification applies only to CAS No 15546-11-9; 22673-19-4 and 93925-42-9.

The acute dermal classification applies only to CAS No. 1185-81-5.

The eye damage classification applies only to CAS No. 15546-11-9.

The skin irritation classification applies only to CAS No. 22673-19-4.

Health hazards	Hazard category	Hazard statement
Acute toxicity	Acute Tox. 4	H302: Harmful if swallowed
Acute toxicity	Acute Tox. 4	H312: Harmful in contact with skin
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage
Repeated dose	STOT Rep. Exp. 1	H372: Causes damage to the immune system through prolonged or repeated exposure
Genotoxicity	Muta. 2	H341: Suspected of causing genetic defects
Reproductive and developmental	Repr. 2	H361fd: Suspected of damaging fertility; Suspected of damaging the unborn child

Summary of health risk

Public

There may be exposure of the general public to these chemicals if the chemicals are present in domestic products, specifically do it yourself sealants and adhesives, paints and coatings, and building and construction materials such as fillers, putties, and plasters. These chemicals are currently listed in the *Poisons Standard–the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP), Schedule 7* for tin organic compounds. At concentrations greater than 1%, these chemicals are not available to the general public. A number of warning statements, first aid instructions and safety directions relating to tin organic compounds may apply.

Based on the available use information, the public may be exposed to the chemicals at very low concentrations in articles through their use in the manufacture of plastics and potential use in food contact applications.

Internationally, a tolerable daily intake (TDI) of (0.1 µg/kg bw as Sn) for organotin compounds in foodstuffs, based on systemic effects, has been established for this group (EC 2009).

To reduce the identified risk of organotin compounds transferred from food packaging to foodstuffs, the overall exposure should be lower than the TDI. The dominant contribution to human intake of organotin compounds (mainly tributyltin) is via consumption of fish. Exposure to other organotin compounds, including these chemicals, is expected to be generally low both from food contact and handling plastic articles.

Based on the available use information, there are no identified risks to the public that require further risk management.

Workers

During product formulation and packaging, dermal and inhalation 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 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. Good hygiene practices to minimise incidental oral exposure are expected to be in place.

Given the critical systemic long term health effects, these chemicals could pose a risk to workers. Control measures to minimise dermal exposure and inhalation exposure (if aerosolised) are needed to manage the risk to workers (see **Proposed means for managing any risks** section).

Control measures implemented due to the reproductive toxicity, genotoxicity and repeated dose classifications are expected to be sufficient to protect workers from any potential local and systemic acute health effects.

Proposed means for managing risk

Workers

Recommendation to Safe Work Australia

It is recommended that Safe Work Australia (SWA) update the Hazardous Chemical Information System (HCIS) to include classifications relevant to work health and safety.

Information relating to safe introduction and use

The information in this evaluation statement including recommended hazard classifications, should be used by a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Control measures that could be implemented to manage the risk arising from exposure to these chemicals include, but are not limited to:

- using closed systems or isolating operations
- minimising manual processes and work tasks through automating processes
- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that
- the worker does not come into contact with these chemicals.

Measures required to eliminate or manage risk arising from storing, handling, and using these hazardous chemicals depend on the physical form and how these chemicals are used.

These control measures may need to be supplemented with:

- conducting health monitoring for any worker who is at significant risk of exposure to these chemicals if valid techniques are available to monitor the effect on the worker's health
- conducting air monitoring to ensure control measures in place continue to work effectively.

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.

Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Conclusions

The conclusions of this evaluation are based on the information described in this evaluation statement.

Considering the proposed means of managing risks, the Executive Director is satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory and the proposed means of managing the risks identified during this evaluation are implemented.

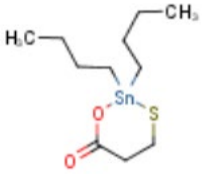
Note: Obligations to report additional information about hazards under *Section 100 of the Industrial Chemicals Act* 2019 apply.

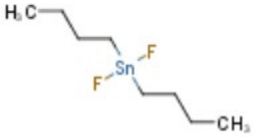
Supporting information

Grouping rationale

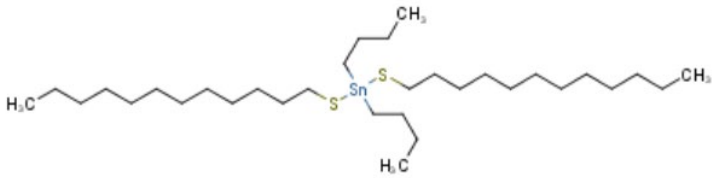
This group of chemicals consists of 30 dibutyl organotin compounds that are expected to release dibutyltin compounds following metabolism. Although toxicokinetic data is limited to one in chemico hydrolysis study, 4 of the chemicals are reported to hydrolyse rapidly following contact with water. Di-substituted 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 and local toxicity. Toxicological data are available for dibultyltin compounds with different X groups including tin compounds coordinated with oxygen, sulfur and halides. Although the levels at which effects are observed may vary for different dibutyltin compounds, similar effects and target organs were seen across the suite of studies, supporting the view that a similar mechanism of toxicity is operating. Because the systemic toxicological properties are sufficiently similar for these compounds, it is appropriate to read across from these chemicals to the chemicals in this evaluation for systemic effects.

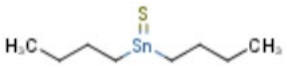
Chemical identity

Chemical name	6H-1,3,2-Oxathiastannin-6-one, 2,2-dibutyldihydro-
CAS No.	78-06-8
Synonyms	dibutyltin mercaptopropionate
Structural formula	
Molecular formula	$C_{11}H_{22}O_2SSn$
Molecular weight (g/mol)	337.1
SMILES	O=C1O[Sn](SCC1)(CCCC)CCCC
Chemical description	Organometallic compound

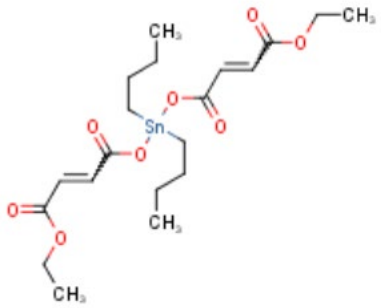
Chemical name	Stannane, dibutyldifluoro-
CAS No.	563-25-7
Synonyms	dibutyltin difluoride
Structural formula	

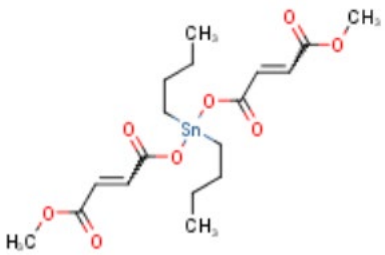
Molecular formula	$C_8H_{18}F_2Sn$
Molecular weight (g/mol)	270.9
SMILES	F[Sn](F)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	Stannane, dibutylbis(dodecylthio)-
CAS No.	1185-81-5
Synonyms	dibutyltin bis(lauryl mercaptide) bis(dodecylthio)dibutyltin
Structural formula	
Molecular formula	$C_{32}H_{68}S_2Sn$
Molecular weight (g/mol)	635.7
SMILES	S(CCCCCCCCCCCC)[Sn](SCCCCCCCCCCCC)(CCCC)CCCC
Chemical description	Organometallic compound

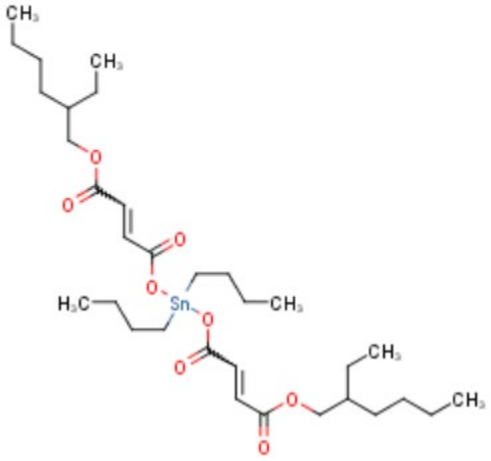
Chemical name	Stannane, dibutylthioxo-
CAS No.	4253-22-9
Synonyms	dibutyltin sulfide
Structural formula	
Molecular formula	$C_8H_{18}SSn$
Molecular weight (g/mol)	265.0
SMILES	S=[Sn](CCCC)CCCC
Chemical description	Organometallic compound

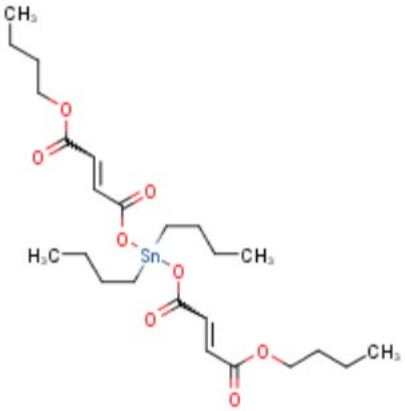
Chemical name	3,8,10-Trioxa-9-stannatetradeca-5,12-dien-14-oic acid, 9,9-dibutyl-4,7,11-trioxo-, ethyl ester, (Z,Z)-
CAS No.	13173-04-1
Synonyms	stannane, dibutylbis[(3-carboxyacryloyl)oxy

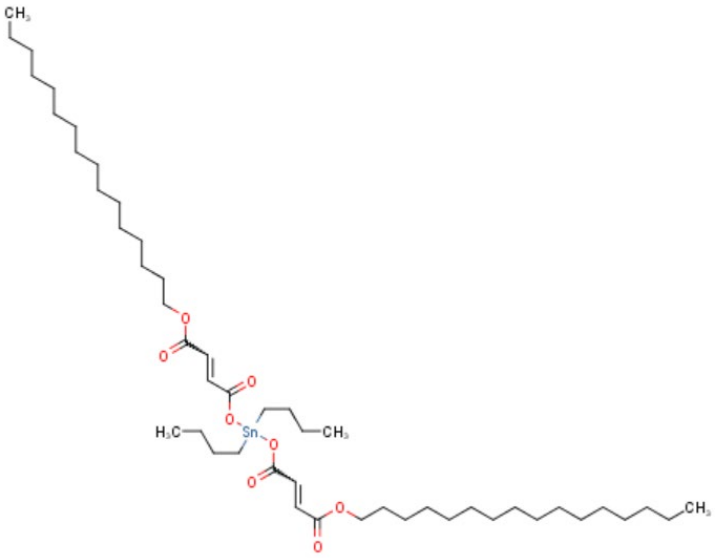
Structural formula	
Molecular formula	$C_{20}H_{32}O_8Sn$
Molecular weight (g/mol)	519.2
SMILES	O=C(OCC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OCC)(CCCC)CCCC
Chemical description	Organometallic compound

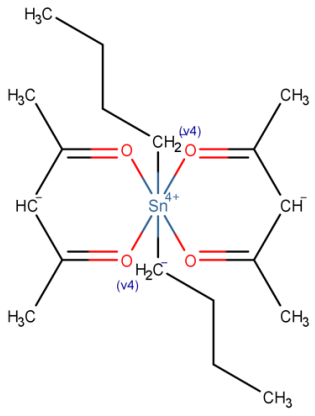
Chemical name	2,7,9-Trioxa-8-stannatrideca-4,11-dien-13-oic acid, 8,8-dibutyl-3,6,10-trioxo-, methyl ester, (Z,Z)-
CAS No.	15546-11-9
Synonyms	di-n-butyltin bis[methyl maleate
Structural formula	
Molecular formula	$C_{18}H_{28}O_8Sn$
Molecular weight (g/mol)	491.1
SMILES	O=C(OC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OC)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	5,7,12-Trioxa-6-stannaoctadeca-2,9-dienoic acid, 6,6-dibutyl-14-ethyl-4,8,11-trioxo-, 2-ethylhexyl ester
CAS No.	15546-12-0
Synonyms	dibutyltin bis(2-ethylhexyl maleate)

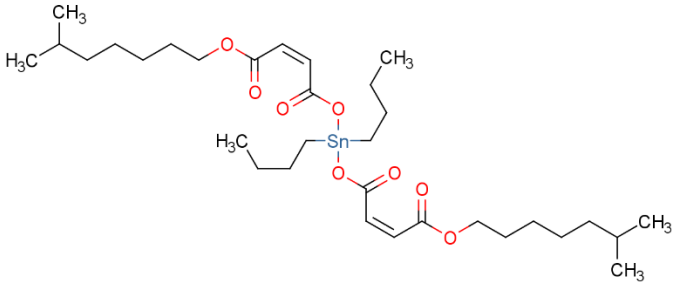
Structural formula	
Molecular formula	$C_{32}H_{56}O_8Sn$
Molecular weight (g/mol)	687.5
SMILES	O=C(OCC(CC)CCCC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OCC(CC)CCCC)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	5,7,12-Trioxa-6-stannahexadeca-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, butyl ester, (Z,Z)-
CAS No.	15546-16-4
Synonyms	stannane, bis[(4-butoxy-1,4-dioxo-2-butenyl)oxy
Structural formula	
Molecular formula	$C_{24}H_{40}O_8Sn$
Molecular weight (g/mol)	575.3
SMILES	O=C(OCCCC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OCCCC)(CCCC)CCCC
Chemical description	Organometallic compound

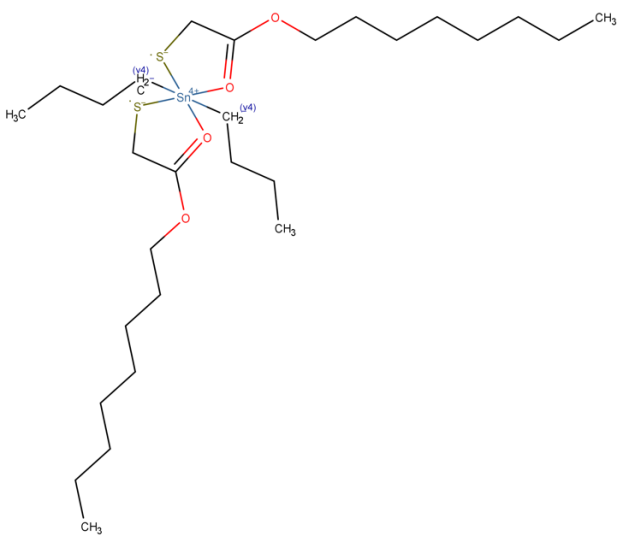
Chemical name	5,7,12-Trioxa-6-stannaoctacosa-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, hexadecyl ester, (Z,Z)-
CAS No.	19706-58-2
Synonyms	-
Structural formula	
Molecular formula	$C_{48}H_{88}O_8Sn$
Molecular weight (g/mol)	911.9
SMILES	O=C(OCCCCCCCCCCCCCCCC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OCCCCCCCCCCCCCCCC)(CCCC)CCCC
Chemical description	Organometallic compound

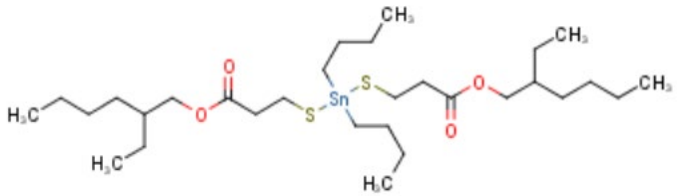
Chemical name	Tin, dibutylbis(2,4-pentanedionato-O,O')-, (OC-6-11)-
CAS No.	22673-19-4
Synonyms	-
Structural formula	
Molecular formula	$C_{18}H_{32}O_4Sn$

Molecular weight (g/mol)	431.2
SMILES	O1=C([CH-]C(=O[Sn+4]12(O=C([CH-]C(=O2)C)C)([CH2-]CCC)[CH2-]CCC)C)C
Chemical description	Organometallic compound

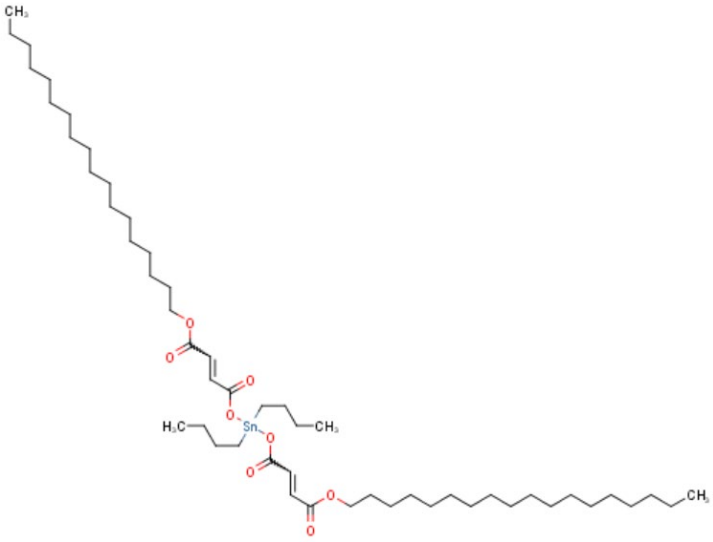
Chemical name	2-Butenoic acid, 4,4'-[(dibutylstannylene)bis(oxy)]bis[4-oxo-, diisooctyl ester, (Z,Z)-
CAS No.	25168-21-2
Synonyms	dibutyltin bis(isooctyl maleate)
Structural formula	
Molecular formula	$C_{32}H_{56}O_8Sn$
Molecular weight (g/mol)	687.5
SMILES	CCCC[Sn](CCCC)(OC(=O)\C=C/C(=O)OCCCCCC(C)C)OC(=O)\C=C/C(=O)OCCCCCC(C)C
Chemical description	Organometallic compound

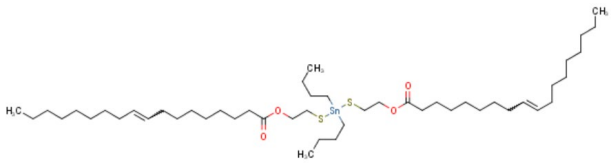
Chemical name	Tin, dibutylbis(octyl mercaptoacetato-O',S)-
CAS No.	32011-18-0
Synonyms	dibutyltin-S,S'-bis(octyl mercaptoacetate) tin, dibutylbis(hydrogen mercaptoacetato)-, dioctyl ester

Structural formula	
Molecular formula	$C_{28}H_{56}O_4S_2Sn$
Molecular weight (g/mol)	639.6
SMILES	O(C1=O[Sn+4]2(O=C(OCCCCCCCC)C[S-]2)([S-]C1)([CH2-]CCC)[CH2-]CCC)CCCCCCCC
Chemical description	Organometallic compound

Chemical name	10-Oxa-4,6-dithia-5-stannahexadecanoic acid, 5,5-dibutyl-12-ethyl-9-oxo-, 2-ethylhexyl ester
CAS No.	53202-61-2
Synonyms	dibutyltinbis(2-ethylhexyl 3-mercaptopropionate) 2-ethylhexyl 5,5-dibutyl-12-ethyl-9-oxo-10-oxa-4,6-dithia-5-stannahexadecanoate
Structural formula	
Molecular formula	$C_{30}H_{60}O_4S_2Sn$
Molecular weight (g/mol)	667.6
SMILES	O=C(OCC(CC)CCCC)CCS[Sn](SCCC(=O)OCC(CC)CCCC)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	5,7,12-Trioxa-6-stannatriaconta-2,9-dienoic acid, 6,6-dibutyl-4,8,11-trioxo-, octadecyl ester, (Z,Z)-
CAS No.	61813-52-3

Synonyms	dibutyltin bis[stearyl maleate
Structural formula	
Molecular formula	$C_{52}H_{96}O_8Sn$
Molecular weight (g/mol)	968.0
SMILES	O=C(OCCCCCCCCCCCCCCCCCC)C=CC(=O)O[Sn](OC(=O)C=CC(=O)OCCCCCCCCCCCCCCCCCC)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	9-Octadecenoic acid, (Z)-, (dibutylstannylene)bis(thio-2,1-ethanediyl) ester
CAS No.	67361-77-7
Synonyms	dibutyltinbis(2-oleoyloxyethylmercaptide)
Structural formula	
Molecular formula	$C_{48}H_{92}O_4S_2Sn$
Molecular weight (g/mol)	916.1
SMILES	O=C(OCCS[Sn](SCCOC(=O)CCCCCCCC=CCCCCCCCC)(CCCC)CCCC)CCCCCCCC=CCCCCCCCC
Chemical description	Organometallic compound

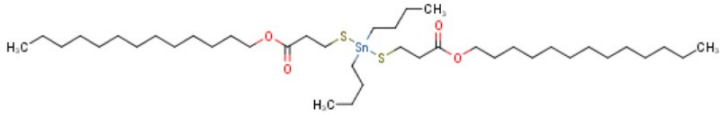
Chemical name	Propanoic acid, 3,3'-[(dibutylstannylene)bis(thio)]bis-, diisooctyl ester, reaction products with dibutyloxostannane
CAS No.	68412-50-0

Synonyms	reaction products of diisooctyl 3,3'-((dibutylstannylene)bis(thio))bispropionate with dibutyltin oxide
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Stannane, dibutylbis(butylmercaptomethoxy-1-oxopropoxy)-
CAS No.	69039-26-5
Synonyms	dibutyltin-S,S'-bis(3-methoxybutylmercaptopropionate)
Structural formula	No structure available
Molecular formula	$C_{24}H_{48}O_6S_2Sn$
Molecular weight (g/mol)	615.5
SMILES	-
Chemical description	Organometallic compound

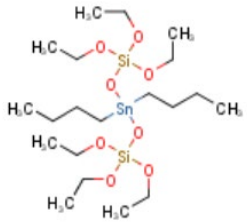
Chemical name	Silicic acid (H4SiO4), tetraethyl ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane
CAS No.	70750-24-2
Synonyms	dibutyltindilaurate, tetraethyl orthosilicate reaction products dodecanoic acid, 1,1'-(dibutylstannylene) ester, reaction products with silicic acid (H4SiO4) tetra-Et ester
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified

Chemical description	Organometallic compound and UVCB

Chemical name	10-Oxa-4,6-dithia-5-stannatricosanoic acid, 5,5-dibutyl-9-oxo-, tridecyl ester
CAS No.	70942-47-1
Synonyms	dibutyltin bis[tridecyl 3-mercaptopropionate
Structural formula	
Molecular formula	$C_{40}H_{80}O_4S_2Sn$
Molecular weight (g/mol)	807.9
SMILES	O=C(OCCCCCCCCCCCCC)CCS[Sn](SCCC(=O)OCCCCCCCCCCCC)(CCCC)CCCC
Chemical description	Organometallic compound

Chemical name	Propanoic acid, 3,3'-[(dibutylstannylene)bis(thio)]bis-, diisotridecyl ester
CAS No.	84896-44-6
Synonyms	diisotridecyl 3,3'-[(dibutylstannylene)bis(thio)]dipropionate
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	3,5,7,9-Tetraoxa-4,8-disila-6-stannaundecane, 6,6-dibutyl-4,4,8,8-tetraethoxy-
CAS No.	87735-26-0
Synonyms	silicic acid (H_4SiO_4), Si,Si'-(dibutylstannylene) Si,Si,Si,Si',Si',Si'-hexaethyl ester

Structural formula	
Molecular formula	$C_{20}H_{48}O_8Si_2Sn$
Molecular weight (g/mol)	591.5
SMILES	O(CC)[Si](OCC)(OCC)O[Sn](O[Si](OCC)(OCC)OCC)(CCCC)CCCC
Chemical description	Organometallic compound

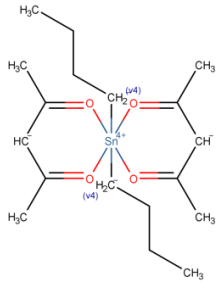
Chemical name	Silicic acid (H_4SiO_4), diethyl bis(2-methoxyethyl) ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane
CAS No.	93925-40-7
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Silicic acid (H_4SiO_4), diethyl bis(2-methoxyethyl) ester, reaction products with dibutylbis[(1-oxododecyl)oxy]stannane and silicic acid (H_4SiO_4) tetrakis(2-methoxyethyl) ester
CAS No.	93925-41-8
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Silicic acid (H_4SiO_4), tetraethyl ester, reaction products with bis(acetyloxy)dibutylstannane
CAS No.	93925-42-9
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic and UVCB

Chemical name	Silicic acid (H_4SiO_4), tetrakis(2-methoxyethyl)ester, reaction products with bis(acetyloxy)dibutylstannane
CAS No.	93925-44-1
Synonyms	silicic acid (H_4SiO_4), tetra-n-propyl ester, bisacetoxydibutylstannane polymer
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Silicic acid (H_4SiO_4), tetrapropyl ester, reaction products with bis(acetyloxy)dibutylstannane
CAS No.	93925-45-2
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Tin, dibutylbis(2,4-pentanedionato-.kappa.O2,.kappa.O4)-
CAS No.	149715-03-7
Synonyms	tin, dibutylbis(2,4-pentanedionato-.kappa.O,.kappaO′)-; tin, dibutylbis(2,4-pentanedionato-O,O′)-
Structural formula	
Molecular formula	$C_{18}H_{32}O_4Sn$
Molecular weight (g/mol)	431.2
SMILES	O1=C([CH-]C(=O[Sn+4]12(O=C([CH-]C(=O2)C)C)([CH2-]CCC)[CH2-]CCC)C)C
Chemical description	Organometallic compound

Chemical name	Silicic acid (H_4SiO_4), tetraethyl ester, reaction products with dibutyloxostannane
CAS No.	185630-89-1
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and UVCB

Chemical name	Fatty acids, C16-18 and C18-unsatd., reaction products with dibutyloxostannane, ethylene glycol, hydrotreated heavy petroleum naphtha, isophthalic acid, maleic anhydride-styrene polymer, (2-methoxymethylethoxy)propanol, (1-methylethyl)benzene, terephthalic acid, trimellitic anhydride and trimethylolpropane
CAS No.	256422-04-5

Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and polymer

Chemical name	2-Butenedioic acid (2Z)-, monobutyl ester, polymer with butyl 2-propenoate, 1,4-diethenylbenzene, ethenylbenzene and 2,5-furandione, reaction products with 2,2-dibutyl-4-hydroxy-1,3,2,4-dioxastannaboretane
CAS No.	375844-86-3
Synonyms	-
Structural formula	No structure available
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
SMILES	Unspecified
Chemical description	Organometallic compound and polymer

Relevant physical and chemical properties

As this group of chemicals is chemically highly diverse, apart from the potential to hydrolyse to simple dibutyltin compounds, representative physical and chemical properties cannot be provided.

Four of the chemicals (CAS No. 15546-11-9; 22673-19-4; 84896-44-6; 93925-42-9) hydrolyse rapidly in contact with water (REACHb; REACHc; REACHd; REACHe).

Introduction and use

Australia

No specific information is available regarding the introduction, import and use of these chemicals in Australia.

The National Pollutant Inventory (NPI) provides information on emission sources of organotin compounds in Australia. The following site limited sources were identified by the NPI in 2019/2020.

- glass and glass product manufacturing
- polymer product manufacturing.

Information provided through public consultation stated that dioctyltin compounds are not used in glass or glass product manufacturing (unpublished information, 2022).

One chemical (CAS No 22673-19-4) was identified to be present in concentrations up to 7% as part of a hardener component imported for use in industrial paints (unpublished information, 2022).

International

Public consultation provided the following information for ten chemicals in this group:

- Five chemicals (CAS Nos. 1185-81-5; 93925-42-9; 15546-11-9; 22673-19-4; 84896-44-6) were identified as commercially active.
- One chemical, CAS No. 149715-03-7 was not listed on the inventories of any other country apart from Australia (no further information provided).
- Four chemicals (CAS Nos. 13173-04-1; 53202-61-2; 68412-50-0; 70942-47-1) were identified to be commercially inactive in the U.S. chemicals market.

The following international uses for twelve chemicals (CAS No. 78-06-8; 1185-81-5; 4253-22-9; 15546-11-9; 15546-16-4; 22673-19-4; 25168-21-2; 61813-52-3; 67361-77-7; 84896-44-6; 87735-26-0; and 93925-42-9) have been identified through the:

- European Union Registration, Evaluation and Authorisation of Chemicals (REACH)
- Substances in Preparations in Nordic countries (SPIN) database
- Canadian Inventory update activities (2017)
- Galleria Chemica (Chemwatch)
- US Chemical Data Reporting under the Toxic Substances Control Act 2012/2016
- PubChem database (NCBI).

Based on international use information, the chemicals are reported to be primarily used in site limited applications as a catalyst (including for the curing of certain silicone resins), process regulator or aid, additive, plasticiser, and heat stabiliser in the manufacture of plastic products (including soft and rigid PVC) and resins. Typical concentrations for use as heat stabilisers in PVC of 2% were reported for CAS No. 15546-11-9 (ECHA). They are also reported to be used as intermediates in the manufacture of basic organic chemicals and in the manufacture of rubber products, floor coverings, toys, playground and sporting equipment, electrical and electronic equipment, foam seating and bedding, automobile and light-duty motor vehicles.

These chemicals may have a number of commercial applications including:

- in flame retardants and extinguishing agents
- in insulating materials
- in foam seating and bedding
- paints, coatings, lacquers and varnishes
- modelling clay
- adhesives, binding agents and sealants
- floor coverings
- building and construction materials (including fillers, putties and plasters)

- electrical and electronic equipment
- plastics and rubber products
- leather treatment products.

Reported maximum concentrations were typically <1% in commercial uses, although concentrations up to 30% were indicated (US EPA 2012; US EPA 2016).

Some of these commercial uses may also be used in domestic applications. There were no identified products containing these chemicals in North American consumer product databases DeLima Associates). Chemicals with CAS No. 25168-21-2; 22673-19-4 and 93925-42-9 are reported to have domestic uses (REACHc; REACHe; Government of Canada 2017; US EPA 2012).

The chemical with CAS No. 22673-19-4 is prohibited from use in cosmetics under CosIng (EC).

Existing Australian regulatory controls

AICIS

No specific controls are currently available for these chemicals.

Public

Tin organic compounds are listed in the Poisons Standard—SUSMP in Schedule 7 (TGA 2022). 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.' (TGA 2022).

Workers

Tin and its compounds are listed in the Work Health and Safety Regulations (2021 revision) as restricted hazardous chemicals—the restricted use is 'abrasive blasting at a concentration of greater than 0.1% as tin' (SWA 2021).

These chemicals are not specifically listed as hazardous chemicals on the HCIS (SWA).

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) (SWA).

In 2020, Safe Work Australia reviewed and recommended retaining the TWA. The recommended TWA is considered protective for effects on the central nervous system and other systems. A STEL was not recommended due to insufficient data relating to acute exposures (SWA 2020). At the time of publication of this evaluation statement, these workplace exposure standards were yet to be finalised.

International regulatory status

Exposure standards

The following exposure standards were identified for tin, organic compounds (as Sn) (Chemwatch):

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), Denmark, Egypt, Estonia, France, Greece, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Spain, Sweden, Taiwan, the United Kingdom and the United States of American (California, Hawaii, Minnesota, Tennessee, Vermont, Washington).

European Union

Dibutyltin compounds—which includes the chemicals in this assessment—are listed on the following (EC 2010):

- Annex XVII to the REACH— the chemicals cannot be used 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.
- Part 1 of Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals—a severe restriction applies for the industrial chemical for public use.

Tin and tin organic compounds—which includes the chemicals in this assessment—are listed on the following:

- 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 to tin compounds (organic) (COE 1992).
- European 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 liquid or sticky toy material, dry or brittle or powder-like or pliable toy material, and scraped-off toy material, respectfully (COE 2009).
- Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (PMU)—Table 3 Maximum allowed concentrations of impurities in products for tattoos and PMU—a limit of 50 ppm tin (Sn) applies (COE 2008).

The chemical with CAS No. 22673-19-4 is listed on:

- EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products - Annex II - List of Substances Prohibited in Cosmetic Products (EC 2009).
- The candidate list of substances of very high concern (SVHC) for eventual inclusion in Annex XIV (ECHA). The reason for inclusion in the list is the chemical is considered 'toxic for reproduction (Article 57c)'. In the European Union (EU), the inclusion in the Candidate List brings immediate obligations for suppliers of the substance, such as:
    - supplying a safety data sheet
    - communicating on safe use
    - responding to consumer requests within 45 days and
    - notifying European Chemicals Agency (ECHA) if the article they produce contains an SVHC in quantities above one tonne per producer/importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w).

Health hazard information

Toxicokinetics

Studies have shown that in general, sulfur or carboxylate-based ligands of organotin compounds are easily displaced under mild physiological conditions (OECD 2006). Abiotic hydrolysis of the chemical with CAS No. 84896-44-6 has been studied. However, no data are available regarding the in vivo metabolism of these chemicals.

The hydrolysis of CAS No. 84896-44-6 was studied using Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 111 at pH 1.2, 4, 7 and 9 using NMR spectroscopy. The chemical was reported to be hydrolytically stable at pH 4, 7 and 9. After 5 days of hydrolysis at 50 °C, less than 10% of the test material was hydrolysed (half-life at 25 °C >1 year). At simulated gastric conditions (0.1 M HCl/pH 1.2 at 37 °C/5 days) the chemical was hydrolysed to its monochloro ester, suggesting that this might be the only metabolite formed in the simulated mammalian gastric environment (REACHd).

Acute toxicity

Oral

Limited data are available. The following LD50s were reported, indicating low to moderate toxicity:

- >2000 mg/kg bw in Sprague Dawley (SD) rats, 3/sex/dose, OECD TG 423 conducted with good laboratory practice (GLP) (CAS No. 1185-81-5) (REACHa)
- 419 (females) and 526 (males) mg/kg bw in SD rats, 10/sex/dose, OECD TG 401, sub-lethal signs of toxicity included lethargy, motor incoordination, nose bleeding and body weight retardation (CAS No. 15546-11-9) (REACHb)
- 1864 mg/kg bw in SD rats, 5 females/dose plus 5 males at the highest dose (2000 mg/kg bw), OECD TG 401 conducted with GLP, sub-lethal signs included ataxia, lethargy, laboured respiration. Pathological observations included haemorrhagic lungs, haemorrhage of the small and large intestines and sloughing of the non-glandular epithelium of the stomach (CAS No. 22673-19-4) (REACHc)
- >2000 mg/kg bw in Wistar rats 1 female at 300 mg/kg bw and 5 females at 2000 mg/kg bw, OECD TG 423 conducted with GLP (CAS No. 84896-44-6) (REACHd)

- 1000 mg/kg bw in 6 females/dose, OECD TG 423 with GLP, sub-lethal signs of toxicity included reduced spontaneous activity, weight reduction and half eyelid closure (CAS No. 93925-42-9) (REACHe).

The following LD50 values in rats were reported, indicating high toxicity (no study details):

- 62 mg/kg bw (CAS No. 15546-11-9 (CCOHS 2021b)
- 284 mg/kg bw (CAS No. 15546-12-0) (CCOHS 2021c)
- 120 mg/kg bw (CAS No. 15546-16-4) (CCOHS 2021d)
- 145 mg/kg bw (CAS No. 4253-22-9) (CCOHS 2021a).

Other dibutyltin compounds have low to high acute oral toxicity (NICNAS 2016a; NICNAS 2016b; NICNAS 2019a; NICNAS 2019b; NICNAS 2019c).

Dermal

Limited data are available. The following LD50 values were reported, indicating low to moderate toxicity:

- >1000 and <2000 mg/kg bw in New Zealand White (NZW) rabbits, 3 females/dose, OECD TG 402 conducted with GLP (CAS No. 1185-81-5) (REACHa)
- approximately 5000 mg/kg bw in Tif:RAlf rats, 5/sex/dose, OECD TG 402, (CAS No. 15546-11-9) (REACHb)
- >2000 mg/kg bw in Wistar rats, 1/sex/dose, OECD TG 402 with GLP, no signs of systemic toxicity (CAS No. 22673-19-4) (REACHc)
- >2000 mg/kg bw in Wistar rats 1 female at 300 mg/kg bw and 5 females at 2000 mg/kg bw, OECD TG 420 with GLP (CAS No. 84896-44-6) (REACHd)
- 1000 mg/kg bw in 6 females/dose, OECD TG 423 with GLP (CAS No. 93925-42-9) (REACHe).

Other dibutyltin compounds have low to moderate acute dermal toxicity (NICNAS 2016a; NICNAS 2016b; NICNAS 2019a; NICNAS 2019b; NICNAS 2019c).

Inhalation

There are no specific data for this endpoint.

Dibutyltin alkyl mercaptoacetate compounds have moderate acute inhalation toxicity (NICNAS 2019a). Dibutyltin dichloride and dibutyltin dilaurate have very high inhalation toxicity (NICNAS 2016a; NICNAS 2016b).

Corrosion/Irritation

Information on skin and eye irritation of varying quality from different types of studies was available for some of the chemicals. Several studies reported skin corrosion associated with extended exposures (24 hours), particularly under occlusive conditions. However, due to the severe conditions used in these studies, no conclusions can be drawn regarding the skin irritation potential of these chemicals under standard conditions. Data are sufficient to warrant classification for skin irritation for one of the chemicals (CAS No. 22673-19-4).

Information on eye irritation was available for 5 of the chemicals. Reactions ranged from slight irritant effects to severe corneal damage. Data are sufficient to warrant classification for

one of the chemicals (CAS No. 15546-11-9). One chemical had such strong adhesive properties that data requirements were waived.

The majority of dibutyltin compounds previously assessed were corrosive (NICNAS 2016a; NICNAS 2016b; NICNAS 2019a; NICNAS 2019b).

Skin irritation

In a GLP compliant in vitro skin corrosion study conducted in accordance with OECD TG 435 (in vitro membrane barrier test method for skin corrosion), the chemical with CAS No. 1185-81-5 was applied to the membrane barrier in 4 replicate tests. The mean time to break through the membrane and subsequently activate the underlying chemical detection system (CDS) was >120.0 min. Based on the criteria of the assay, the chemical was determined to be non-corrosive to skin. In an acute dermal toxicity test conducted in accordance with OECD TG 402, NZW rabbits were exposed to the same chemical for 24 hours under occlusive conditions (5/sex/dose). Treated skin abnormalities and localised areas of alopecia were observed (REACHa).

In a skin irritation study conducted similarly to OECD TG 404, intact and abraded skin of NZW rabbits (3/sex) were treated with the chemical (CAS No. 15546-11-9) for 24 hours under occlusive conditions. The test was terminated after 48 hours for humane reasons. The mean scores for 24 and 48 hours respectively were 3.3/4, 3.5/4 for erythema and 3/4 and 3/4 for oedema (individual scores were not reported). In an acute dermal toxicity test conducted in accordance with OECD TG 402, Tif:Ralf rats were exposed to the same chemical for 24 hours under occlusive conditions (5/sex/dose). The experiment was terminated following signs of necrosis and the sloughing off of whole skin leaving muscles exposed to the air (REACHb). Due to the severe conditions in the studies using this chemical, no conclusions can be drawn about its irritancy under standard conditions.

In a standard Draize test with little information, the chemical with CAS No. 15546-12-0 (500 mg) caused a ‘mild’ reaction following application to rabbit skin for 24 hours (CCOHS 2021c).

In a GLP compliant study in vitro skin corrosion test assay conducted in accordance with OECD TG 431, the chemical with CAS No. 22673-19-4 was applied to reconstructed human epidermis (EpiSkin) for 3, 6 and 240 minutes. The mean tissue viability was 172.3%, 197.0% and 170.3% respectively. Substances that do not reduce viability to less than 35% after 240 minutes using this skin model are considered to be unlikely to have the potential to cause corrosion in vivo following application. In a GLP compliant in vitro skin irritation study considered to be similar to OECD TG 439 using reconstructed human epidermis (RHE), the chemical was applied in triplicate tests to RHE for 15 minutes followed by an incubation period of 42 hours. A relative mean viability of 20.7% was reported for the chemical in this study, and it was determined to be irritating. In a GLP compliant acute dermal toxicity study conducted similarly to OECD TG 402, 2 Wistar rats were treated with a single dose of 2000 mg/kg bw of the chemical under semi-occlusive conditions for 24 hours. Observations included well-defined erythema, very slight oedema, loss of skin elasticity, hardened dark brown/black coloured scabs, scab lifting at the edges to reveal dried blood and scar tissue, indicating dermal corrosion (REACHc). As the animals were exposed to the test material for 24 hours it is not possible to classify the chemical as corrosive based on this study, although based on the in vitro data it can be deemed to be a skin irritant warranting classification.

In a standard Draize test with little information, the chemical with CAS No. 4253-22-9 (500 mL) caused a severe reaction following application to rabbit skin for 24 hours (CCOHS 2021a).

In a GLP compliant study conducted in accordance with OECD TG 406, no signs of skin irritation were observed in 10 Dunkin-Hartley guinea pigs exposed to the chemical with CAS No. 93925-42-9 under occlusive conditions for 48 hours and observed for 72 hours (REACHe).

Eye irritation

In a GLP compliant eye irritation study conducted similarly to OECD TG 405, the chemical with CAS No. 1185-81-5 (0.1 mL) was instilled into the eye of one NZW rabbit. There was no corneal opacity or iritis noted at any observation period and conjunctival irritation was reversible by day 14. In an eye irritation study conducted similarly to OECD TG 405 and prior to the introduction of GLP, the chemical was instilled into one eye each of 3 NZW rabbits and scored at 1, 24, 48 and 72 hours, 7 and 14 days. There were no signs of corneal opacity, iritis or chemosis. Conjunctival redness was observed in all animals and was fully reversed by 14 days. Mean scores for all animals were 2/3 for conjunctival redness at 24 hours, 1.33/3 at 48 hours and 1/3 at 72 hours (REACHa). Both studies indicate the chemical is at most slightly irritating to eyes.

In an eye irritation study conducted similarly to OECD TG 405 and prior to the introduction of GLP, the chemical with CAS No. 15546-11-9 was instilled into one eye each of 6 NZW rabbits. The eyes of 3 rabbits were rinsed after 30 seconds of exposure and the eyes of the other 3 rabbits were left unrinsed. The chemical caused extreme irritation and the study was terminated at 48 hours for humane reasons. Conjunctival irritation was maximal in all animals at 24 and 48 hours and corneal damage could not be assessed in more than half of the cases due to extreme chemosis (REACHb).

In standard Draize tests with little information, the following chemicals caused ‘moderate’ reactions when 100 mg was administered to the eye of a rabbit for 24 hours:

- CAS No. 15546-12-0 (CCOHS 2021c)
- CAS No. 19706-58-2 (CCOHS 2021e).

In a non-guideline study compliant with GLP, the chemical with CAS No. 22673-19-4 was applied evenly to the cornea of 3 enucleated rabbit eyes for 10 seconds then washed off. Corneal cloudiness was assessed before enucleating the eyes, after equilibration and approximately 60, 120, 180 and 240 minutes after treatment. Two additional eyes remained untreated for control purposes. The corneas were assessed for opacity, thickness, condition and fluorescein uptake. Moderate loss of transparency in the cornea was noted 240 minutes after treatment. Corneal swelling increased at each of the assessments (REACHc). It is not possible to compare these results with classification criteria.

The chemical with CAS No. 93925-42-9 was found to be highly adhesive, thereby justifying data waiving for animal testing. Two drops of the chemical mixed with a drop of water was applied to a 0.5 cm strip of cloth and was able to hold a weight greater than 30 g (REACHe).

Sensitisation

No data are available.

Mercaptoacetate alkyltin compounds are skin sensitisers based on animal studies for one chemical (NICNAS 2019a) and dibutyltin hydrogen borate is classified as a skin sensitiser but there are no data to evaluate this classification (NICNAS 2016a). However, read across for this large group of chemicals is not appropriate for local effects.

Repeat dose toxicity

No data are available.

Based on read across data from previously assessed dibutyltin compounds, the chemicals are expected to cause serious systemic health effects following repeated exposure. The thymus was consistently observed as the target organ in studies with dibutyltin dichloride, dibutyltin alkyl mercaptoacetates and dibutyltin dilaurate. Effects included reduced thymus weights, thymus atrophy, reduced cellularity in the thymus and lymphoid depletion. Hepatotoxicity and evidence of neurotoxicity have also been reported (NICNAS 2016a; NICNAS 2016b).

Genotoxicity

Very little data are available. In the absence of data, hazard classification consistent with the classification for dibutyltin dichloride and dibutyltin dilaurate compounds is warranted.

Based on read across information from the following positive in vivo studies, the chemicals are expected to be genotoxic:

- dibutyltin dichloride – increased incidence of micronucleated polychromatic cells in a GLP compliant mouse micronucleus test
- dibutyltin dilaurate – dose dependent increase in DNA damage in a single cell gel electrophoresis assay focussing on cerebral cortical cells (NICNAS 2016a; NICNAS 2016b).

Genotoxicity information was only available for one of the chemicals (CAS No. 1185-81-5). Negative results were reported in a GLP compliant bacterial reverse mutation assay (OECD TG 471) in *Salmonella typhimurium* TA 1535, 1537, 98 and 100 and *Escherichia coli* WP2 *uvr*A with and without metabolic activation at concentrations up to 5000 µg/plate (REACHa).

This is consistent with the overall negative in vitro genotoxicity results for dibutyltin dichloride, dibutyltin oxide and the dilaurate, dialkyl mercaptoacetate and diacetate derivatives of dibutyltin (NICNAS 2016a; NICNAS 2016b; NICNAS 2019a; NICNAS 2019b; NICNAS 2019c).

Carcinogenicity

No data are available. 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.

Reproductive and development toxicity

No data are available.

Based on read across data, the chemicals are expected to cause specific adverse effects on fertility and development following exposure. The available data on reproductive toxicity for dibutyltin dichloride indicated increased numbers of non-pregnant females, increased pre-implantation loss and increased early resorptions. Data on fertility effects were not available for other dibutyltin compounds. An increased incidence of foetal malformations including

ankyloglossia, schistoglossia, cleft mandibles/lower lips and fused ribs was observed at low doses in experimental studies with dibutyltin dichloride, dibutyltin dilaurate, dibutyltin diacetate and dibutyltin oxide. These effects were not seen in a single study with a dibutyltin alkyl mercaptoacetate, but effects at higher doses cannot be ruled out.

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).

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