Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

Lead soaps

Evaluation statement

14 January 2022

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AICIS evaluation statement

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Lead soaps

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Reason for the evaluation

The Evaluation Selection Analysis indicated a potential risk to the environment.

Parameters of evaluation

The chemicals in this group are listed on the Australian Inventory of Industrial Chemicals (the Inventory). The chemicals have been assessed for their risks to the environment according to the following parameters:

- default domestic introduction of 100 tonnes per annum
- industrial uses listed in the 'Summary of Use' section
- expected release into sewage treatment plants, the water compartment and the soil compartment.

The chemicals have been assessed as a group as they are members of an industrially important class of metal salts known as metallic soaps. They are expected to have similar hazard profiles and use patterns.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific Australian information about the introduction, use and end use of the chemicals in Australia. Based on international use information, these substances are expected to be used as additives in:

- lubricant and grease products
- paint and coating products
- plastic and polymer products

There is no information available on the use volumes of these chemicals in Australia. Data from international jurisdictions indicate that dioxobis(stearato)trilead (CAS No. 12578-12-0) is used in the EU at 0–10 tonnes annually. Negligible use volumes have been reported for other chemicals in this group since 2015.

Environment

Summary of environmental hazard characteristics

The primary environmental effects of the chemicals in this group are expected to be caused by release of ionic lead, which is very toxic to aquatic organisms and which bioaccumulates in most organisms. The environmental hazards of ionic lead was previously assessed under the IMAP framework (NICNAS, 2020).

The chemicals in this group are lead salts of organic acids. A PBT hazard categorisation was not performed for the organic acid components of these chemicals, as they or their analogues were previously assessed under the IMAP framework and the findings are published elsewhere (NICNAS, 2014a; 2014b; 2014c; 2018a; 2018b). These organic acids are generally of low environmental concern.

Environmental hazard classification

The chemicals satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for environmental hazards as follows. This does not consider classification of physical hazards and health hazards.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 1	H400: Very toxic to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

The principal environmental concern for the chemicals in this group is their potential to release bioavailable forms of ionic lead into the environment. This poses a concern because bioavailable forms of ionic lead are very toxic to aquatic organisms.

The lead soaps in this group are mainly used as stabilisers in polyvinyl chloride (PVC) and drying agents in paints. These uses may result in emissions of ionic lead to water and terrestrial compartments.

Available information from domestic and international sources indicates that the use of lead soaps in PVC has been largely phased out, and that the chemicals in these group are not currently used in paints in Australia. The quantity of lead released from any PVC articles containing lead-based stabilisers is expected to be small relative to total anthropogenic lead emissions. The chemicals are, therefore, not expected to pose a high risk to the environment for the industrial uses identified in this evaluation.

Conclusions

The conclusions of this evaluation are based on the information described in this statement. Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

The Executive Director is satisfied that the identified environment 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.

Supporting information

Rationale

This evaluation considers the environmental risks associated with the industrial uses of twenty lead salts of carboxylic acids classed as metallic soaps. This is an industrially important class of metal salts and they are primarily salts of fatty acids (Nora and Koenen, 2012).

The risk assessment of these chemicals has been conducted as a group because all twenty substances are expected to have generally similar environmental fate and ecotoxicity profiles due to similarities in use pattern and properties. They are used in products including paints, polymers and lubricants. As these salts are soluble in water, they can all potentially release ionic lead upon dissolution, which is very toxic to aquatic life.

Environmental risks resulting from the use of other lead soaps in Australia have been previously assessed under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework established by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Environment Tier II assessments are available for 1:2 lead(2+) salts of long-chain carboxylic acids (NICNAS, 2014a), 1:2 lead(2+) salts of medium-chain carboxylic acids (NICNAS, 2014b), Lead(2+) salts of long-chain carboxylic acids (NICNAS, 2014c) and Lead(2+) salts of medium-chain carboxylic acids (NICNAS, 2014d).

Chemical identity

Chemical entities in this grouping are lead salts of carboxylic acids, including lead soaps and basic lead soaps. These have been categorised into three sub-groups based on similarities in chemical composition. The first group comprises basic lead soaps, the second group are UVCB salts of fatty acids and the third are lead salts of fish oils.

Basic lead soaps

Basic lead soaps are described in the literature as containing one or two complexed metal oxides per one molecule of neutral lead soap (Nora and Koenen, 2012). Two of the chemicals in this group have defined stoichiometry, while the remainder are UVCBs (unknown or variable composition, complex reaction products, and biological materials) based on undefined amounts of lead oxide incorporated into the basic lead soap and/or undefined lead oxidation states. Lead soaps are generally assumed to contain lead in the 2+ oxidation state, as this state is the most common (King, et al., 2014). However, lead also exists in the 4+ oxidation state. The stoichiometry of dioxobis(stearato)dilead (CAS No. 56189-09-4) indicates that it contains both lead(2+) and lead(4+), and the soaps with unspecified lead oxidation states may also contain mixed oxidation states:

CAS RN	12578-12-0
Chemical name	Lead, bis(octadecanoato)dioxotri-
Synonyms	Lead, dioxobis(stearato)tri- dioxobis(stearato)trileadbis(octadecanoato)dioxotrilead
Molecular formula	$C_{36}H_{70}O_6Pb_3$

Molecular weight (g/mol)	1220.5

CAS RN	56189-09-4
Chemical name	Lead, bis(octadecanoato)dioxodi-
Synonyms	lead, bis(octadecanoato)dioxodi- dioxobis(stearato)dilead dibasic lead stearate
Molecular formula	$C_{36}H_{70}O_6Pb_2$
Molecular weight (g/mol)	1013.3

CAS RN	68442-95-5
Chemical name	Hexanoic acid, dimethyl-, lead(2+) salt, basic
Synonyms	basic lead dimethylhexanoate lead dimethylhexanoate (basic) lead(II) dimethylhexanoate (basic)
Molecular formula	Unspecified

CAS RN	90342-56-6
Chemical name	Dodecanoic acid, lead salt, basic
Synonyms	basic lead laurate
Molecular formula	Unspecified

CAS RN	90388-09-3
Chemical name	Hexadecanoic acid, lead salt, basic
Synonyms	basic lead palmitate
Molecular formula	Unspecified

CAS RN	90388-15-1
Chemical name	9-Hexadecenoic acid, lead(2+) salt, (Z)-, basic
Synonyms	basic lead palmitoleate
Molecular formula	Unspecified

CAS RN	90459-51-1
Chemical name	Octadecanoic acid, lead salt, basic
Synonyms	basic lead stearate
Molecular formula	Unspecified

CAS RN	90459-88-4
Chemical name	9-Octadecenoic acid, lead salt, basic, (Z)-
Synonyms	basic lead oleate
Molecular formula	Unspecified

CAS RN	90583-65-6
Chemical name	Tetradecanoic acid, lead salt, basic
Synonyms	basic lead myristate
Molecular formula	Unspecified

CAS RN	91671-82-8
Chemical name	Isodecanoic acid, lead(2+) salt, basic
Synonyms	basic lead isodecanoate
Molecular formula	Unspecified

CAS RN	91671-83-9
Chemical name	Isooctanoic acid, lead(2+) salt, basic
Synonyms	basic lead isooctanoate
Molecular formula	Unspecified

CAS RN	91671-84-0
Chemical name	Isoundecanoic acid, lead(2+) salt, basic
Synonyms	basic lead isoundecanoate
Molecular formula	Unspecified

UVCB lead salts of fatty acids

This group comprises salts in which the fatty acids used to generate the salt have unknown or variable composition. Naturally-derived fatty acids are long, unbranched-chain carboxylic acids, almost always with an even number of carbon atoms (Brown, 2000). Three of the substances in this group are described as lead salts of mixtures of fatty acids within a specified range of carbon chain lengths. The other three are lead salts of fatty acids derived from tallow (an animal fat), castor oil (a vegetable oil) and tall oil (a by-product of wood pulping).

In these salts, the lead oxidation state is undefined, and, as with the basic soaps, can be presumed to contain predominately lead(2+), although lead(4+) may also be present:

CAS RN	61788-54-3
Chemical name	Fatty acids, tall oil, lead salts
Synonyms	lead salts of tall oil fatty acids lead tallate
Molecular formula	Unspecified
Chemical description	Tall oil fatty acids are primarily oleic acid (CAS No. 112-80-1) and linoleic acid (CAS No. 60-33-3), with other long-chain fatty acids (C16-C20) as minor components (Gunstone, et al., 2007). This substance can therefore be assumed to predominately comprise lead oleate (CAS No. 15347-55-4) and lead linoleate (CAS No. 16996-51-3).

CAS RN	68131-60-2
Chemical name	Fatty acids, C12-18, lead salts
Synonyms	lead salts of C12-18 fatty acids (C12-18) fatty acids, lead salt
Molecular formula	Unspecified

CAS RN	68605-98-1
Chemical name	Fatty acids, tallow, hydrogenated, lead salts
Synonyms	lead salts of hydrogenated tallow fatty acids tallow acids, hydrogenated, lead salt
Molecular formula	Unspecified
Chemical description	Fatty acids from hydrogenated tallow are primarily palmitic acid (CAS No. 57-10-3) and stearic acid (CAS No. 57-11-4) (Gunstone, et al., 2007). This substance is can therefore be assumed to predominately comprise lead palmitate (CAS No. 19528-55-3) and lead stearate (CAS No. 7428-48-0).

CAS RN	84776-36-3
Chemical name	Fatty acids, C8-18 and C18-unsaturated, lead salts
Synonyms	lead salts of C8-18 and C18-unsaturated fatty acids
Molecular formula	Unspecified

CAS RN	91697-36-8
Chemical name	Fatty acids, castor oil, hydrogenated, lead salts
Synonyms	lead salts of hydrogenated castor oil fatty acids
Molecular formula	Unspecified
Chemical description	Castor oil is composed of 90% ricinoleic acid (CAS No. 141-22-0) (Gunstone, et al., 2007) which, when hydrogenated, forms 12-hydroxy-octadecanoic acid (CAS No. 106-14-9). This substance can therefore be assumed to predominantly comprise 12-hydroxy-octadecanoic acid, lead(2+) salt (2:1) (CAS No. 58405-97-3).

CAS RN	93165-26-5
Chemical name	Fatty acids, C14-26, lead salts
Synonyms	lead salts of C14-26 fatty acids
Molecular formula	Unspecified

Lead salts of fish oils

The two substances in this group are lead salts of fish oils. The composition of fish oils are variable, but can be described by reference to a range of C14-C22 saturated and unsaturated fatty acids (Moffat and McGill, 1993).

In these salts, the lead oxidation state is undefined, and as with the basic soaps, can be presumed to contain predominately lead(2+) but may also contain lead(4+):

CAS No.	68424-76-0
Chemical name	Oils, menhaden, lead salts
Synonyms	fats and glyceridic oils, menhaden, lead salts menhaden oil, lead soap
Molecular formula	Unspecified

CAS No.	68553-63-9
Chemical name	Oils, fish, lead salts
Synonyms	fats and glyceridic oils, fish, lead salts Lead fishate
Molecular formula	Unspecified

Relevant physical and chemical properties

Dibasic lead stearate has been described as a white powder which decomposes above 200°C with no melting point reported (Nora and Koenen, 2012). Dioxobis(stearato)trilead is described as a white powder which decomposes at 290°C with no melting point observed (REACH, 2020b). Limited information is available on the physical properties of other chemicals in this group.

A number of studies of the solubility of various divalent metallic soaps show the lead(2+) soaps typically dissociate in water to release lead(2+) ions and fatty acids in the form of carboxylate mono-anions (Hunter and Liss, 1976; Mauchauffee, et al., 2008). These studies also show that the water solubility of metallic soaps decreases as the length of the fatty acid carbon chain increases.

Water solubility data of dioxobis(stearato)trilead is given in its REACH dossier (REACH, 2020b). No solubility data were identified for the other lead soaps in this group, though water solubility data for lead(2+) stearate (CAS No. 1072-35-1) is sometimes used as a reference value (REACH, 2020a). These values, both derived at 20°C, are given in the table below in milligrams per litre (mg/L), along with the corresponding lead(2+) concentrations in milligrams of lead per litre (mg Pb/L):

Chemical name	Dioxobis(stearato)trilead	Lead(2+) stearate
Water solubility	1.76 mg/L	10.4 mg/L
Dissolved lead(2+) concentration	0.895 mg Pb/L	2.78 mg Pb/L

Dioxobis(stearate)trilead has a higher proportion of lead than dibasic lead stearate or a basic soap containing one equivalent of lead(2+) oxide to lead(2+) stearate. Assuming the same molar solubilities of all three chemicals, dissolution of the latter two chemicals would result in a lead concentration of 0.598 mg Pb/L. For the remaining basic lead soaps, given that the fatty acid anions have equal or shorter chain lengths than the stearate anion (C18), these compounds are conservatively assumed to have solubilities resulting in lead concentrations of greater than or equal to 0.598 mg Pb/L.

For the UVCB lead salts of fatty acids, these mixtures all contain stearate salts or salts with other C18 fatty acids, usually as the main or longest-chain component, with lead likely to be predominately in the 2+ oxidation state. These substances can therefore be conservatively assumed to have at least the same molar solubilities as lead(2+) stearate, resulting in lead concentrations greater than or equal to 2.78 mg Pb/L.

No solubility data applicable to lead salts of fish oils were identified.

Introduction and use

Australia

No specific Australian use, import or manufacturing data have been identified for the chemicals in this group.

Available information suggests that the use of lead compounds in PVC products has been decreasing in Australia in the last decades. The Vinyl Council of Australia has reported that their PVC Stewardship Program has committed to elimination of lead stabiliser use, which has been reportedly achieved by 47 signatory companies (Vinyl Council of Australia, 2019). This is compared to a reported 1200 tonnes (by metal content) used by program signatories in 2002. This phase out is voluntary and driven by industry, rather than regulatory requirements. Lead stabilisers, including dibasic lead stearate, have previously been used in PVC pipes for household sewage and stormwater drainage (Tjandraatmadja and Diaper, 2006). These are now substituted with less toxic metal salts, with most PVC pipes in Australia no longer being made with lead stabilisers.

International

The chemicals in this group have mainly been used internationally as stabilisers in polymers and drying agents in paints. Although some countries report use volumes of up to 1000 tonnes per year, these volume bands are from older sources and are likely outdated given a decrease in use of these chemicals fuelled by industry phase-outs.

Dioxobis(stearato)trilead has reported use as a stabiliser in PVC (REACH, 2020b) and in textiles (Swedish Chemicals Agency, 2014). There is some indication that dibasic lead stearate may have also been used internationally as a stabiliser for vinyl polymers, as well as in high-pressure lubricants (Galleria Chemica, 2021a). Lead salts of hydrogenated tallow fatty acids has also been reported to be used as a stabiliser in polymer products (SPIN, 2021b). Basic lead dimethylhexanoate has reported use in paints, lacquers and varnishes (SPIN, 2021a), and there is also some indication that lead salts of tall oil fatty acids and basic lead isooctanoate have been used as drying agents in paints (Galleria Chemica, 2021b; 2021c).

In the European Union, the European Stabiliser Producers Association, which represents more than 95% of the PVC stabiliser industry across Europe, states that they phased out all lead-based PVC stabilisers in all formulations sold across the EU by 2015 (ESPA, 2021). However, dioxobis(stearato)trilead is currently registered under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation at volumes of 0–10 tonnes annual use (REACH, 2020b). The REACH dossier for this substance indicates it is used in PVC processing, and is incorporated into plastic materials used in buildings. The ECHA Plastic Additives Initiative indicates that it is used in soft and rigid PVC as a heat stabiliser in concentrations of 2% (ECHA, 2021). The remaining chemicals in this group are not registered under REACH.

In Canada, dioxobis(stearato)trilead and lead salts of tall oil fatty acids have been reported to have import or manufacture volumes of 0–1 tonnes annually and lead salts of C12-18 fatty acids were reported at 1–1000 tonnes annually (OECD, 2006). These volumes have not been updated since 2006.

In Japan, dioxobis(stearato)trilead and dibasic lead stearate were reported to be manufactured and/or imported in quantities of 1–1000 tonnes annually from 2012–2015 but have not been reported since then (NITE, 2021). Lead salts of C12-18 fatty acids are included in the group "Aliphatic monocarboxylic acid (C=6-28) salt (Pb, Cu, Mn, Zn, Zr, Ce, Cd, Sn, Sr, Co)" with a reported volume band of 10 000–20 000 tonnes annually from 2012–2019, and it is assumed that this reflects the combined volume of the 282 chemicals in this group. Based on relevant international information, the contribution of these lead salts to this volume band is likely to be minimal.

In the Nordic countries, basic lead dimethylhexanoate and lead salts of hydrogenated tallow fatty acids were each reported to have 0 tonnes annual use as of 2019 and 2009, respectively (SPIN, 2021a; 2021b).

Dioxobis(stearato)trilead is on the OECD List of High Production Volume (HPV) chemicals, indicating that at least one member country of the OECD produced or imported this chemical at a volume greater than 1000 tonnes annually (OECD, 2021a). This list appears to have been last updated in 2007 (OECD, 2021b), and the available international use volumes currently reported for this chemical are below this volume.

Six chemicals in this group are listed as 'active' on the United States Environmental Protection Agency (US EPA) Chemical Substance Inventory, established under the Toxic Substances Control Act 1976 (US EPA, 2020).

No international use data were identified for the remaining chemicals in this group.

Existing Australian regulatory controls

Environment

Lead and lead compounds are subject to reporting under the Australian National Pollutant Inventory (NPI) (NPI, 2019).

The *Poisons Standard June 2021* restricts lead and lead compounds to a maximum of 0.1% of the non-volatile content of all paints manufactured and sold in Australia (measured as elemental lead) (Commonwealth of Australia, 2021). As of 1 October 2021, this will be amended to reduce the permissible level to 0.009% in all paints other than anti-fouling or anti-corrosive paint (TGA, 2021).

Default guideline values have been published for lead in the Australian and New Zealand Guidelines for Fresh and Marine Water Quality (ANZG, 2000; 2018). Contaminant guidelines for lead are further discussed in the IMAP Environment Tier II assessment of water soluble lead(2+) salts (NICNAS, 2020).

International regulatory status

The regulatory status of lead in paints and painted products are discussed in previous assessments of lead soaps (NICNAS, 2014a; 2014b; 2014c; 2014d). This section will therefore only cover the international regulatory status of the specific chemicals in this evaluation.

United Nations

The chemicals in this group are not currently identified as Persistent Organic Pollutants (UNEP, 2001), ozone depleting substances (UNEP, 1987), or hazardous substances for the purpose of international trade (UNEP & FAO, 1998).

Environmental exposure

Based on the available data, chemicals in this group are used primarily as PVC stabilisers and drying agents in paints. Dioxobis(stearato)trilead has reported use in PVC at concentrations of 2% (ECHA, 2021). Some sources also indicate potential use of dibasic lead stearate in high pressure lubricants.

Studies focussing on leaching of lead to water from PVC pipes have shown that lead stabilisers are held within the PVC matrix, and that emissions from the surface will rapidly decrease to trace levels over time (Smith, 1998; Tjandraatmadja and Diaper, 2006). However, environmental factors such as exposure to UV radiation, low pH and the presence of certain anions can increase the release of lead (Al-Malack, 2001; Lasheen, et al., 2008). These soluble lead compounds can be released to the terrestrial or aquatic compartment depending on the conditions under which the PVC article is used. In particular, lead stabilisers used in PVC pipes are expected to be released to wastewater and sewage treatment plants. However, contributions of lead-based PVC stabilisers to lead levels in the environment are considered minor compared to other sources such as fuel and coal combustion, mining, metal manufacturing, and dumped lead-acid batteries (NPI, 2021; Smith, 1998; Tjandraatmadja and Diaper, 2006). Furthermore, as discussed above in Introduction and Use, the use of lead-based stabilisers in PVC in Australia has been declining in the last decades due to voluntary phase-out by the vinyl industry.

Most of the lead soaps that are incorporated into a PVC matrix are expected to be retained within the article when it is disposed of. Studies have indicated that leaching of lead-based stabilisers from PVC does not significantly contribute to the amounts of heavy metals in landfill bodies (ARGUS, et al., 2000). However, recycling of PVC products containing lead-based additives may spread these to new products (GBCA, 2010). The environmental risk arising from recycling of PVC articles is beyond the scope of this evaluation.

Uses of lead soaps in surface coatings may result in release to the environment through flaking, chipping and weathering (OECD, 2009). However, in all paints manufactured and sold in Australia, the incorporation of lead and lead compounds is restricted to a maximum of 0.1% of the non-volatile content by the *Poisons Standard June 2021* (Commonwealth of Australia, 2021), soon to be reduced to 0.009% for most paints (TGA, 2021). The chemicals in this group were not identified as being used in paints in a survey conducted by the Australian Paint Manufacturers' Federation Inc. and NICNAS in 2007 (NICNAS, 2007).

Depending on the use of a lubricant, release of additives to the environment can occur as the result of spills, leakage and, in the case of automotive lubricants, exhaust emissions (OECD, 2004). However, the evidence that chemicals in this group are used in high pressure lubricants is limited.

Environmental fate and effects

The chemicals in this group are expected to be released into the terrestrial and aquatic environment, where they will dissociate into the corresponding acids and ionic lead.

For the basic lead soaps and UVCB salts of fatty acids, the relevant carboxylate anions are octanoate, isooctanoate, dimethylhexanoate, isodecanoate, isoundecanoate, dodecanoate (laurate), tetradecanoate (myristate) hexadecanoate (palmitate), (Z)-9-hexadecenoate (palmitoleate), octadecanoate (stearate), (Z)-9-octadecenoate (oleate), (Z,Z)-9,12-octadecadienoate (linoleate), 12-hydroxyoctadecanoate, eicosanate, docosanoate, tetracosanoate and hexacosanoate. The environmental fate and effects of the conjugate acids of all these carboxylate anions, except for dimethylhexanoate, have been considered by previous lead soap assessments and found to be of low environmental concern (NICNAS, 2014a; 2014b; 2014c). Dimethylhexanoate is the only anion that has not been previously assessed, but considering this is an isomer of both the octanoate and isooctanoate anions, it is expected to have a similar hazard profile and also be of low environmental concern.

For the lead salts of fish oils, it has been found that as fish oils (CAS No. 8016-13-5) and menhaden oils (CAS No. 8002-50-4) are composed of a complex mixture of degradable organic substances extracted from animal products, the natural breakdown products of these substances are unlikely to cause harm in the environment (NICNAS, 2018a; 2018b).

While both lead(2+) and lead(4+) oxidation states are present in these chemicals, lead(4+) species are only stable in aqueous solution under strongly alkaline conditions (Powell, et al., 2009). It is therefore expected that these chemicals will ultimately form lead(2+) ions in the environment.

A detailed account of the environmental fate and effects of ionic lead is available in the IMAP Environment Tier II assessment of water soluble lead(2+) salts (NICNAS, 2020). In summary, the behaviour of lead(2+) ions is strongly dependent on the chemistry of the environmental compartment into which it is released, and they will bioaccumulate in most organisms. Bioavailable forms of lead(2+) are very toxic to aquatic life, sediment-dwelling organisms and toxic to terrestrial organisms. The toxicity of ionic lead to aquatic organisms is strongly influenced by water chemistry, and lead is expected to be most toxic in waters with low water hardness, acidic to neutral pH and low dissolved organic carbon (DOC). The toxicity of lead to sediment-dwelling organisms depends on environmental parameters such as dissolved oxygen, pH and the geochemistry of sediment particles. While bioavailable forms of lead are toxic to terrestrial organisms, lead is strongly adsorbed to organic matter in soil and therefore bioavailability is typically limited.

Predicted environmental concentration (PEC)

Contributions to environmental lead loads arising from use of lead soaps in PVC articles and paints have been discussed in previous assessments (NICNAS, 2014a; 2014b; 2014c; 2014d). It was concluded that significant release to the environment is not expected from these sources in Australia.

GHS classification of environmental hazard

The classification of the lead soaps in this evaluation are based on the available acute ecotoxicity values for the lead(2+) ion as identified in the IMAP Environment Tier II assessments of water soluble lead(2+) salts (NICNAS, 2020), in accordance with the classification procedure for metals and metal compounds under the GHS (UNECE, 2017).

The aquatic hazards associated with the chemicals in this group are dependent on their capacity to release ionic lead at concentrations that exceed identified acute toxicity thresholds. The basic lead soaps and UVCB lead salts of fatty acids are classified as Acute Aquatic Category 1, as their estimated minimum lead concentration at saturation, based on read-across from dioxobis(stearato)trilead and lead(2+) stearate, exceed the most sensitive acute toxicity values for ionic lead. They are also classified as Chronic Aquatic Category 1 as lead(2+) bioaccumulates in aquatic organisms.

For the lead salts of fish oils, there are insufficient solubility data available to classify their aquatic toxicity hazards according to the procedure outlined above. Accordingly, these chemicals are cautiously assumed to be sufficiently soluble to release lead(2+) ions at concentrations which exceed the relevant ecotoxicological endpoints. Therefore, these chemicals are classified as Acute Aquatic Category 1 and Chronic Aquatic Category 1 based on the available toxicity data for lead.

It is preferable to classify the hazard posed by metals and metal compounds using available solubility data or the findings of a study conducted in accordance with the OECD Transformation and Dissolution protocol (UNECE, 2017). Therefore, should solubility data or a study conducted in accordance with this protocol suggest a lower hazard classification is warranted, these chemicals may be reclassified as appropriate.

Environmental risk characterisation

The chemicals in this group contain lead ions, which can be released to the environment from their main industrial uses as PVC stabilisers and drying agents in paints. However, available information from domestic and international sources indicates that the use of lead soaps in

PVC has been largely phased out, and that the chemicals in this group are not currently used in paints in Australia.

The principal environmental concern for industrial uses of these lead soaps is the potential for release of soluble forms of ionic lead from manufactured PVC articles. This poses a concern due to the toxicity of bioavailable forms of lead. However, an analysis of the risks arising from the industrial use of these chemicals indicates that the quantity of lead released from PVC articles containing lead-based stabilisers makes a relatively small contribution to total anthropogenic lead emissions.

There is no reported use data for the chemicals in this group in Australia. Furthermore, available information indicates that the global volumes of use of these chemicals are relatively low. Dioxobis(stearato)trilead is currently used in the EU as a PVC stabiliser in low volumes (0–10 tonnes per year), while minimal use volumes have been directly reported for the other chemicals in this group in the last five years. It is therefore very likely that the default assumed introduction volume of 100 tonnes per annum of each chemical in this group into Australia is an overestimate.

Therefore, it is unlikely that the use of the lead soaps considered in this evaluation pose a high risk to the Australian environment.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in scope. Some relatively common data limitations can be addressed through use of conservative assumptions (OECD, 2019) or quantitative adjustments such as assessment factors (OECD, 1995). Others must be addressed qualitatively, or on a case-by-case basis (OECD, 2019).

The most consequential areas of uncertainty for this evaluation are:

- No Australian volume of use data are available for the chemicals in this group. Should information become available to indicate that the chemicals in this group are used in high volumes or they are released directly to the environment, the outcome of this evaluation may change.

References

Al-Malack MH (2001). Migration of lead from unplasticized polyvinyl chloride pipes. *Journal of Hazardous Materials,* **82**(3), pp 263-274.

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