Lead(2+) salts of long-chain carboxylic acids: Environment tier II assessment

18 September 2014

CAS Registry Numbers: 20403-41-2, 19528-55-3, 7428-48-0, 94266-32-7, 3249-61-4, 93966-37-1, 93966-38-2, 94006-20-9, 15347-55-4, 16996-51-3

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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

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Acronyms & Abbreviations

Grouping Rationale

This Tier II assessment considers the environmental risks associated with industrial uses of the lead salts of ten closely related carboxylic acids:

Tetradecanoic acid, lead salt (Lead myristate)
Hexadecanoic acid, lead salt (Lead palmitate)
Octadecanoic acid, lead salt (Lead stearate)
Eicosanoic acid, lead salt (Lead icosanoate)
Docosanoic acid, lead salt (Lead behenate)
Tricosanoic acid, lead salt (Lead tricosanoate)
Tetracosanoic acid, lead salt (Lead lignocerate)
Hexacosanoic acid, lead salt (Lead hexacosanoate)
9-Octadecenoic acid, lead salt, (*Z*)- (Lead oleate)
9,12-Octadecadienoic acid, (*Z*,*Z*)-, lead salt (Lead linoleate)

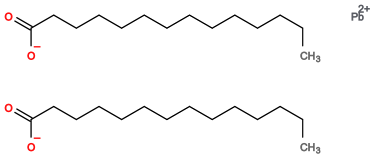
The chemicals in this group are related to the chemicals assessed as part of the 1:2 Lead(2+) Salts of Long-Chain Carboxylic Acids group. Both groups of chemicals are structurally similar, but they may have some minor compositional differences. Although they have been assessed as separate groups, persons interested in the chemicals assessed here should also consider those assessed under the 1:2 Lead(2+) Salts of Long-Chain Carboxylic Acids group assessment. The chemicals previously assessed under the defined stoichiometry group are used as analogue chemicals throughout this assessment.

The parent carboxylic acids for the salts in this group are all long-chain (greater than C_{12}) naturally occurring saturated, mono-unsaturated and di-unsaturated fatty acids. The lead salts of these acids are a subset of a large class of industrially important metal salts of fatty acids collectively identified as metallic soaps. This subset of metallic soaps is of indefinite chemical composition based on their Chemical Abstracts Service chemical names and formulae as listed in the Australian Inventory of Chemical Substances (the Inventory), and they can contain free fatty acids and/or other counter ions in addition to the stoichiometric lead salts.

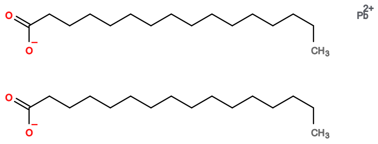
The risk assessment of these chemicals has been conducted as a group because all ten substances are lead(2+) salts of structurally and chemically similar long-chain fatty acids. Although these salts are sparingly soluble in water, they can all potentially release lead(2+) ions which provides a common source of toxicity for each of these substances. Furthermore, the potential environmental exposure pathways for chemicals in this group are similar based on specific industrial uses in the plastics industry and in industrial coatings, such as paints. Based on these considerations, the chemicals in this group are each expected to have generally similar environmental fate and ecotoxicity profiles.

Chemical Identity

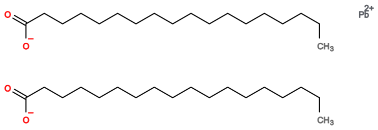
Based on the available chemical composition data for this group of lead soaps (Nora and Koenen, 2012), each salt is composed of lead(2+) ions and carboxylic acid anions in a ratio of approximately 1:2. The chemical identity information provided below for each salt therefore assumes an idealised 1:2 ratio of lead(2+) cations to the respective carboxylate mono-anions. However, it is noted that the chemical composition of lead fatty acid soaps in this group, such as the quantities of free fatty acid present, may vary depending on the manufacturing method employed and the specific requirements of the end-use application.

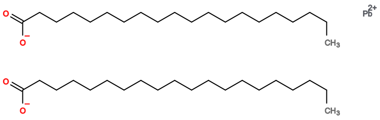
CAS RN	20403-41-2
Chemical Name	Tetradecanoic acid, lead salt
Synonyms	Lead myristate Lead tetradecanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{28}H_{54}O_4Pb$
Representative Molecular Weight (g/mol)	661.93

Representative SMILES	[Pb++].CCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCC(=O)[O-]

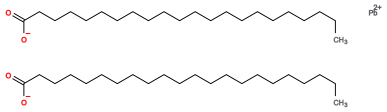
CAS RN	19528-55-3
Chemical Name	Hexadecanoic acid, lead salt
Synonyms	Lead palmitate Lead hexadecanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{32}H_{62}O_4Pb$
Representative Molecular Weight (g/mol)	718.03
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCC(=O)[O-]

CAS RN	7428-48-0
Chemical Name	Octadecanoic acid, lead salt
Synonyms	Lead stearate Lead octadecanoate

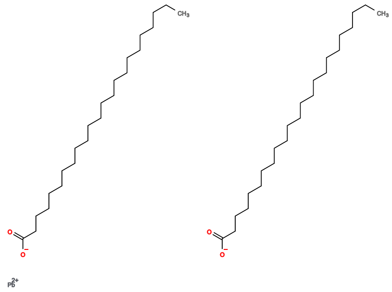
Representative Structural Formula	
Representative Molecular Formula	$C_{36}H_{70}O_4Pb$
Representative Molecular Weight (g/mol)	774.14
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCCCC(=O)[O-]

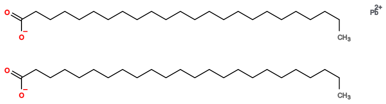
CAS RN	94266-32-7
Chemical Name	Eicosanoic acid, lead salt
Synonyms	Lead icosanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{40}H_{78}O_4Pb$
Representative Molecular Weight (g/mol)	830.24
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCCCC(=O)[O-].

	CCCCCCCCCCCCCCCCCCCC(=O)[O-]

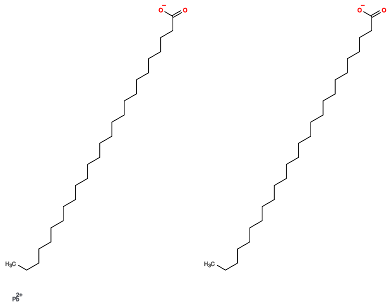
CAS RN	3249-61-4
Chemical Name	Docosanoic acid, lead salt
Synonyms	Lead behenate Lead docosanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{44}H_{86}O_4Pb$
Representative Molecular Weight (g/mol)	886.35
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCCCCCCCC(=O)[O-]

CAS RN	93966-37-1
Chemical Name	Tricosanoic acid, lead salt
Synonyms	Lead tricosanoate
Representative Structural Formula	

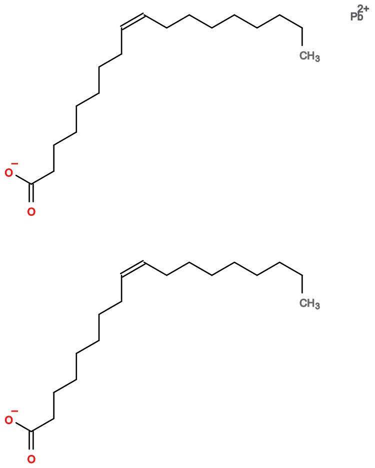
	
Representative Molecular Formula	$C_{46}H_{90}O_4Pb$
Representative Molecular Weight (g/mol)	914.40
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]

CAS RN	93966-38-2
Chemical Name	Tetracosanoic acid, lead salt
Synonyms	Lead lignocerate Lead tetracosanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{48}H_{94}O_4Pb$
Representative Molecular Weight	942.46

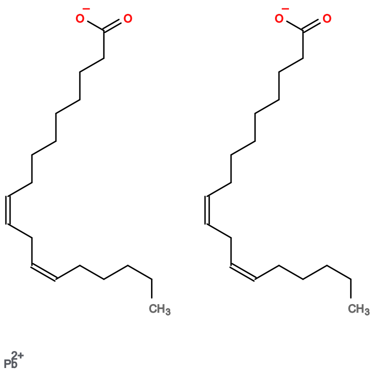
(g/mol)	
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]

CAS RN	94006-20-9
Chemical Name	Hexacosanoic acid, lead salt
Synonyms	Lead cerotate Lead hexacosanoate
Representative Structural Formula	
Representative Molecular Formula	$C_{52}H_{102}O_4Pb$
Representative Molecular Weight (g/mol)	998.56
Representative SMILES	[Pb++].CCCCCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]. CCCCCCCCCCCCCCCCCCCCCCCCCC(=O)[O-]

CAS RN	15347-55-4
Chemical Name	9-Octadecenoic acid, lead salt, (*Z*)-

Synonyms	Lead oleate
Representative Structural Formula	
Representative Molecular Formula	$C_{36}H_{66}O_4Pb$
Representative Molecular Weight (g/mol)	770.11
Representative SMILES	[Pb++].CCCCCCCC/C=C\CCCCCCCC(=O)[O-]. CCCCCCCC/C=C\CCCCCCCC(=O)[O-]

CAS RN	16996-51-3
Chemical Name	9,12-Octadecadienoic acid, (*Z,Z*)-, lead salt
Synonyms	Lead linoleate
Representative Structural Formula	

	
Representative Molecular Formula	$C_{36}H_{62}O_4Pb$
Representative Molecular Weight (g/mol)	766.08
Representative SMILES	[Pb++].CCCCC/C=C\C/C=C\CCCCCCCC(=O)[O-]. CCCCC/C=C\C/C=C\CCCCCCCC(=O)[O-]

Physical and Chemical Properties

There is only limited information available on the physical properties of the chemicals addressed in this group assessment. Lead stearate has been described as a white powder (NJ Health, 2007). The lead salts of other fatty acids in this group are all expected to be solids under ambient conditions based on the typical properties of metallic soaps (Nora and Koenen, 2012). Data available for the analogous 1:2 lead(2+) salts of the fatty acids in this group have been used to characterise the physical and chemical properties of the chemicals considered here.

The metallic soaps of divalent (2+) metal ions are well known to be only sparingly soluble in water (Nora and Koenen, 2012). A number of studies of the solubility of various divalent metallic soaps show the lead(2+) soaps typically dissociate in water to form lead(2+) ions and fatty acids in the form of carboxylate mono-anions. These studies also clearly demonstrate that the water solubility of metallic soaps decreases as the length of the fatty acid carbon chain increases. Additionally, these studies have shown that the lead(2+) salts are typically the least soluble of the divalent metal salts of fatty acids (Hunter and Liss, 1976; Mauchauffee, et al., 2008).

No quantitative water solubility data have been identified for the chemicals in this group. However solubility products (K_{sp}s), which are a quantitative measure of the position of the solubility equilibrium, are available for lead dipalmitate (CAS RN 15773-56-5) and lead distearate (CAS RN 1072-35-1) (Hunter and Liss, 1976). The measurements, obtained at 25°C and an ionic strength of 0.1 M (NaCl), are presented in the following table. The concentrations of lead(2+) ions at saturation were calculated using an activity coefficient of 0.586 M, as used in the original study:

Chemical	Lead dipalmitate	Lead distearate

K_{sp}	6.31×10^{-22}	1.99×10^{-24}
Lead(2+) Concentration at Saturation	20×10^{-3} mg/L	2.84×10^{-3} mg/L

These values are considered to represent the solubility of any 1:2 lead(2+) salts of palmitic acid and stearic acid contained in lead palmitate and lead stearate, respectively. Based on the observed trend in solubility for metallic soaps, any lead(2+) salts of eicosanoic acid (C_{20}), behenic acid (C_{22}), tricosanoic acid (C_{23}), tetracosanoic acid (C_{24}) or hexacosanoic acid (C_{26}) are expected to be less soluble than those of stearic acid (C_{18}). Alternatively, any 1:2 lead(2+) salts of myristic acid (C_{14}) are expected to be more soluble than those of palmitic acid (C_{16}). The presence of impurities in the chemicals in this group may influence their overall solubilities. However, these data are expected to be generally representative of the availability of lead(2+) in water.

No quantitative data have been identified for 1:2 lead(2+) salts of unsaturated fatty acids. Based on the measured solubility products for the 1:2 lead(2+) salts of saturated fatty acid analogues, it can be assumed that the 1:2 lead(2+) salts of unsaturated fatty acids are also sparingly soluble in water. The presence of impurities may similarly affect the overall solubility of the salts of unsaturated fatty acids in this group. However, this analysis is again expected to be generally representative of the availability of lead(2+) in water.

Import, Manufacture and Use

Australia

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

International

Limited data suggest that lead stearate has been used internationally in extreme pressure lubricants, as a stabiliser and plasticiser in the plastics industry, as a drier in varnishes, and in cosmetics (NJ Health, 2007).

Lead stearate was reported to be used in Sweden between 1999 and 2011. Here, use volumes have declined from 103 tonnes in 1999 to less than 1 tonne in 2011 (Nordic Council of Ministers, 2013). It is noted that lead stearate – alongside all chemicals in this group – is pre-registered only under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation (ECHA, 2014a). Therefore, it can be assumed that these chemicals are not currently being used at a volume greater than 100 tonnes per annum in the European Union (ECHA, 2014b).

The European Stabiliser Producers Association has reported that all lead-based PVC stabilisers with current commercial relevance have undergone the complete registration process under the REACH legislation (ESPA, 2014). Therefore, it can be assumed that the chemicals in this group are not currently considered to be commercially relevant PVC stabilisers in the European Union. Examples of lead-based PVC stabilisers that are registered include a mixture of C_{16-18}lead carboxylates (CAS RN 91031-62-8) and dibasic lead stearate (CAS RN 12578-12-0) (ECHA, 2014c; 2014d). Nevertheless, use of lead-based PVC stabilisers is declining rapidly in the European Union, with the European PVC industry agreeing to completely phase out use by 2015. As a result of the agreement, lead-based PVC stabiliser use decreased by more than 75% between 2000 and 2010, exceeding the milestone targets that had been set (Vinyl 2010, 2006; 2011).

No additional use data were available for the chemicals in the group. Aside from lead stearate, the chemicals in this group do not appear to be used industrially in Canada and have not been introduced for an industrial use at a volume greater than 100 kg per annum in Sweden since 1993 (Environment Canada, 2013a; KemI, 2014).

Environmental Regulatory Status

Australia

Lead and lead compounds are subject to reporting under the Australian National Pollutant Inventory (NPI). Under the NPI, emissions of lead and lead compounds are required to be reported annually by facilities that use or emit more than 10 tonnes of lead or lead compounds, burn more than 2000 tonnes of fuel, consume more than 60 000 megawatt hours of electricity (excluding lighting and motive purposes), or have an electricity rating of 20 megawatts during a reporting year (Australian Government Department of the Environment, 2013a). Emissions may be intentional, accidental or incidental releases arising through industrial processes. Additionally, emissions of lead and lead compounds from diffuse sources, such as lawn mowers and wood heaters, are also periodically estimated by state environment authorities. Diffuse emissions data are updated much less frequently than facility data (Australian Government Department of the Environment, 2013b).

The *Uniform Paint Standard* of the *Poisons Standard 2013*(Cwlth) 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, 2013).

United Nations

No chemicals in this group are currently identified as a Persistent Organic Pollutant (UNEP, 2001), ozone depleting substance (UNEP, 1985), or hazardous substance for the purpose of international trade (UNEP, 1998).

The United Nations Environment Programme (UNEP), in partnership with the World Health Organization (WHO), have established the Global Alliance to Eliminate Lead Paint. The alliance primarily supports actions in developing nations to phase-out lead use in paints (UNEP, 2011).

OECD

No chemicals in this group have been sponsored for assessment under the Cooperative Chemicals Assessment Programme (CoCAP) (OECD, 2013).

Canada

Lead stearate was categorised as Persistent (P), not Bioaccumulative (not B) and Inherently Toxic to the Environment (iT_E) by Environment Canada during the Categorization of the Domestic Substances List (DSL) (Environment Canada, 2013b). A subsequent screening assessment is yet to be completed (Environment Canada, 2013c).

The remaining chemicals in this group are not currently listed on the DSL (Environment Canada, 2013a).

Lead in most paint products available to consumers in Canada is limited to 90 mg/kg (0.009% w/w) of the non-volatile content under the *Surface Coating Materials Regulations* of the *Canada Consumer Product Safety Act 2010*. Exempted products which contain more than 90 mg/kg lead must be appropriately labelled(Government of Canada, 2005).

European Union

All chemicals in this group have been pre-registered, but have not yet undergone the full registration process, under the REACH legislation (ECHA, 2014f). Therefore, no chemicals in this group are currently identified as a Substance of Very High Concern in the European Union.

Nevertheless, it is noted that all other lead compounds currently registered under the REACH legislation (for example, mixed C_{16-18}lead carboxylates (CAS RN 91031-62-8)) have been identified as Substances of Very High Concern due to their reproductive toxicity, and are currently included on the Candidate List for Eventual Inclusion in Annex XIV (the Authorisation List) to REACH (ECHA, 2013).

United States of America

Select industries in the United States of America (USA), including most mining, utilities and manufacturing facilities, must report emissions of lead and lead compounds to the United States Environmental Protection Agency (US EPA) if the facility manufactures or processes more than 25 000 pounds of lead compounds (approximately 11 tonnes) per annum. Reporting is also required if the facility otherwise uses more than 10 000 pounds (approximately 4.5 tonnes) in a reporting year (US EPA, 2012; 2014a; 2014b).

Most paint products containing lead, as well as toys and furniture painted using such products, are prohibited in the USA if the lead content exceeds 0.009% w/w of the non-volatile paint content under the *Consumer Product Safety Improvement Act 2008*. Exempted products which contain more than 0.009% w/w lead must be appropriately labelled (United States Government, 2008).

Environmental Exposure

Based on the available data, the principal industrial use of lead stearate is as a stabiliser in plastics and as a drier in industrial coatings, such as paints, lacquers and varnishes. These uses are consistent with those of other fatty acid lead salts, which are used in polyvinyl chloride (PVC) and industrial coatings (Bielman, 1993; NICNAS, 2013a; 2013c; Nordic Council of Ministers, 2013; UNEP, 2011). Although international information suggests use in extreme pressure lubricants and cosmetics, these uses are not currently considered relevant in Australia (NICNAS, 2013b; Shugarman, 2003).

Lead salts of long-chain fatty acids are known to be used as stabilisers in the manufacture of PVC articles, at a typical concentration of approximately 0.5% (Smith, 1998). This use pattern has limited potential for direct release of the salt to the environment because the substance is contained within the insoluble polymer matrix of durable articles. However, over time, and depending on the use of the PVC article, there is the potential for release of some of the lead(2+) ions from the stabiliser in the form of soluble ionic lead compounds (Al-Malack, 2001; Koh, et al., 1991; Lasheen, et al., 2008). These soluble lead compounds can be released to the terrestrial compartment or aquatic compartment depending on the situation under which the PVC article is used. However, the major proportion of the salt that is incorporated into a PVC matrix is expected to be retained within the manufactured article and ultimately disposed of to landfill.

Metallic soaps are also known to be used as driers in coatings containing drying oil components, with lead soaps typically used at a concentration of 0.5% w/w lead (non-volatile content) (Australian Government Department of the Environment, 2014; Bielman, 1993). However, the use of these chemicals in industrial coatings in Australia at concentrations resulting in greater than 0.1% w/w lead (non-volatile content) is not allowed under the *Uniform Paint Standard* (Commonwealth of Australia, 2013). Therefore, current industrial use of these chemicals as driers in surface coatings in Australia does not occur. Where used in industrial coating products in the past in Australia, the primary source of environmental exposure is expected to be release of soluble lead(2+) ions from the cured coating. A range of studies have highlighted the potential for lead to be released from intact coatings (Barnes and Davis, 1996; Beauchemin, et al., 2011; Davis and Burns, 1999). Chips and dust from coatings containing lead can also result in environmental exposure of lead compounds. A small proportion may also be released to sewer, surface water or soil during application and disposal of excess product (OECD, 2009).

The extent to which the remaining chemicals in this group are used in Australia is unclear. Based on the use information available for lead stearate and other lead salts of long-chain fatty acids, international data and the chemical similarity of the substance addressed in this group assessment, the remaining chemicals are assumed to also be primarily used as PVC additives and as driers in industrial coatings. Direct releases of these salts to the environment from use as PVC additives are considered unlikely. Further, the restrictions on lead compounds in paints under the *Uniform Paint Standard*, and an increased awareness of the environmental and human health concerns of lead pollution, will preclude current uses of these chemicals in industrial coating products in Australia. Nevertheless, diffuse emissions of lead(2+) ions from previously applied coatings may occur.

Environmental Fate

Dissolution, Speciation and Partitioning

The behaviour of the lead(2+) ion is strongly dependent on the chemistry of the environmental compartment into which it is released.

The metallic soaps are salts of weak acids and dissolution of these substances in water therefore results in hydrolysis. Hydrolysis of the fatty acid conjugate base results in the formation of the corresponding fatty acid. The extent to which this reaction occurs is dependent on the properties of the acid and the pH of the aquatic environment. At neutral pH, fatty acids are predominantly in the conjugate base (anionic) form. Any free fatty acids present in these chemicals will similarly exist as the conjugate base at neutral pH. For the metal ion, hydrolysis is a result of dissociation of hydrogen ions from water molecules coordinated to the metal ion. In the case of lead(2+) ions, coordinated water is only weakly acidic and the predominant form of the dissolved metal ion in pure water at neutral pH is the simple hydrated lead(2+) di-cation (Mauchauffee, et al., 2008).

However, in environmental waters, lead(2+) ions are expected to undergo a range of additional reactions and they can therefore exist as a variety of different chemical species. The speciation chemistry of lead(2+) ions in environmental waters is complex and strongly dependent on water chemistry, especially pH and the presence of complexing anions. For example, at pH levels lower than 7, the simple hydrated lead(2+) di-cation is the dominant species of ionic lead (ANZECC, 2000c). However, at pH levels greater than 7, the speciation of ionic lead is dominated by the formation of carbonate complexes, such as $PbCO_3$ (US EPA, 1999). These carbonate complexes have low solubility and the precipitation of lead(2+) salts becomes important under alkaline conditions. In seawater, lead(2+) is complexed by chloride ions. These complexes account for more than 90% of the speciation of ionic lead in seawater (ANZECC, 2000c).

In addition to complexation by simple inorganic anions, lead(2+) is complexed by organic matter in environmental waters. These complexes are of great significance for the environmental fate of lead(2+) because they account for the majority of dissolved lead in natural freshwater at pH values in the range 5 to 9 (ANZECC, 2000c). Further, the partitioning of lead(2+) from the water phase onto clay particles, particulate humic substances, and iron, aluminium and manganese (oxy)hydroxides have all been identified as important mechanisms controlling the concentration of lead in natural waters. In sediments, the speciation of lead will be dominated by complexation by humic substances and the formation of relatively insoluble lead sulfides (ANZECC, 2000c).

The partitioning behaviour of lead in soil has a complex dependence on soil properties, but is mainly determined by pH and clay content. A detailed review of measured partition coefficients for sorption from water onto soil (K_Ds) conducted by the US EPA identified values for lead(2+) in the range of 150 L/kg to 44 580 L/kg. The adsorption of lead on soil generally increases with increasing soil pH (US EPA, 1999). Lead is typically considered relatively immobile in soil (UNEP, 2010).

Biotransformation

The organic components of the salts in this group are expected to be biodegradable both as the lead salts and as the free fatty acids.

No biodegradation data were available for any chemicals in this group. However, a ready biodegradation study on the analogue chemical lead distearate (CAS RN 1072-35-1), conducted in accordance with OECD Test Guideline (TG) 301C, found the chemical to undergo 32.9% degradation in 14 days. The predominant degradation products were lead dipalmitate (di-C_{16}) and lead myristate (C_{14}) (LMC, 2013; NITE, 2014). These findings suggest that the aliphatic chains of the chemicals in this group are available to undergo a degree of biodegradation despite the relatively low solubility of the parent lead salt in water. It should be noted that as the aliphatic chain of these chemicals is shortened, the product lead salts will become relatively more soluble, which could increase the bioavailability of the ionic lead component in the environment.

The fatty acid components of the chemicals in this group are naturally occurring and will undergo relatively rapid biodegradation in the environment. Available experimental data from studies conducted in accordance with OECD TG 301C demonstrate that linoleic acid, oleic acid and palmitic acid are all readily biodegradable (80% degradation in 28 days; 78% degradation in 28 days and 93% degradation in 28 days, respectively) (LMC, 2013). The shorter-chain myristic acid is similarly expected to be readily biodegradable.

The saturated fatty acids with longer aliphatic chains experience less rapid biodegradation in laboratory tests. For example, although 71% of stearic acid degraded in 28 days in a study conducted in accordance with OECD TG 301B, the "10 day window" requirement was not met and the chemical is therefore not classed as readily biodegradable (LMC, 2013). Behenic acid is not readily biodegradable based on a study conducted in accordance with OECD TG 301C (52% degradation in 28 days), but is inherently biodegradable according to a study conducted in accordance with OECD TG 302C (74% degradation in 28 days) (LMC, 2013). Eicosanoic acid (C_{20}), which has a structure intermediate between that of stearic acid (C_{18}) and behenic acid (C_{22}), is expected to undergo biodegradation in the environment at a rate between that of the two structural end members of this series. Tricosanoic acid, tetracosanoic acid and hexacosanoic acid are also expected to be capable of undergoing biodegradation in the environment by standard fatty acid oxidation pathways (Nelson and Cox, 2008; Poirier, et al., 2006). Despite the slower rate of biodegradation implied by these study results, all of the fatty acids in this group are expected to undergo relatively rapid and ultimate biodegradation in the environment.

Bioaccumulation

Chemicals in this group will release lead ions, which bioaccumulate in most organisms.

The lead(2+) ions released from these chemicals may pose a bioaccumulation hazard depending on the bioavailability of the metal ion under the prevailing exposure conditions. Conventional measures of bioaccumulation are not appropriate for metal ions. These measures do not consider the potential for metals to accumulate in specific tissues, the physiological mechanisms available to organisms to regulate internal metal concentrations, and the influence of environmental factors (US EPA, 2007). Nevertheless, lead and lead compounds are globally acknowledged to pose a significant bioaccumulation concern (UNEP, 2010; 2014).

The fatty acid components of the chemicals in this group are not expected to pose a bioaccumulation hazard. They are fatty acids which are naturally ubiquitous in the environment and organisms and can be metabolised to yield energy. Their storage in body tissues is an essential biological process which is regulated by homeostatic controls (Nelson and Cox, 2008; NRC, 2005; Poirier, et al., 2006).

Transport

The chemicals in this group and their ionic components have a low potential for long-range transport.

The lead salts of fatty acids are ionic solids that do not partition to the atmospheric compartment, where long-range transport typically occurs. The fatty acid constituents of these salts are rapidly biodegradable and therefore not subject to long-range transport. The ionic lead components of the salts may have some limited mobility in water due to complexation by dissolved organic matter, but lead released into water and onto soil will eventually become bound to sediment or soil particles (UNEP, 2010).

Predicted Environmental Concentration (PEC)

A PEC was not calculated for the chemicals or their ionic components addressed under this assessment.

Diffuse emissions of soluble lead(2+) from PVC articles can occur. Studies which have focused on the implications of this for drinking water supplies have highlighted the potential for lead to be released from PVC pipes to water (Al-Malack, 2001; Koh, et al., 1991; Lasheen, et al., 2008). However, other studies have concluded that extraction of lead from PVC pipes by running water rapidly declines shortly after initial use and that lead released by this process makes a relatively small contribution to total lead emissions to the environment (Smith, 1998). The majority of fatty acid lead salts which are used industrially in PVC are expected to enter landfills incorporated into PVC articles disposed of at the end of their useful life. A number of studies have examined the release of lead from PVC articles in landfills and they conclude that most of the lead contained in PVC is expected to remain bound within the polymer matrix. Furthermore, a study conducted in the European Union found that the lead from lead compounds used in PVC pipes and cables represents approximately 3% of total lead content in municipal solid waste (ARGUS, et al., 2000). It is noted that this value may also include other lead-based compounds that are used in PVC but are not addressed under this assessment. A similar Australian review concluded that the amount of lead (in all forms) released to the environment due to use of lead compounds in PVC was relatively small compared to lead contributions from other sources (Smith, 1998).

Historically, lead compounds in paint have been a significant source of lead in the environment. Further, surfaces previously coated with preparations containing high concentrations of lead compounds continue to release lead to the environment (Davis and Burns, 1999; UNEP, 2011). However, the release of lead compounds from current industrial use of the chemicals in this group is not expected due to restrictions of lead compounds in coating products used in Australia. The most significant source of potential environmental emissions of lead compounds from paint is expected to be associated with the release of lead during the lifetime, and end-of-life disposal, of coated articles. Studies which have considered the release of lead from outdoor surfaces have found water runoff from surfaces painted between 1994 and 1999 to contain an average of 8.4 micrograms per litre (µg/L) of lead (Davis and Burns, 1999). While some runoff water may pass into sewers, a proportion can be expected to be released directly to surface waters or soil. At the end of their useful life, coated articles are expected to be disposed to landfill. This should not be expected to result in significant environmental exposure due to the immobility of lead in soil.

Environmental Effects

No ecotoxicity data specific to the chemicals addressed under this assessment are available. However, it is expected that the environmental effects of sparingly soluble lead salts of fatty acids will be determined principally by the release of lead(2+) ions into the environment. Lead is recognised to be a highly toxic environmental contaminant (UNEP, 2010; 2014). The effects assessment of the chemicals in this group has therefore primarily focused on the extensive body of information regarding the ecotoxicity of lead and inorganic lead compounds.

Effects on Aquatic Life

Bioavailable forms of lead(2+) are very toxic to aquatic life in short and long term exposures.

Toxicity of lead(2+)

The speciation of lead(2+) is strongly dependent on water chemistry, which can have a dramatic effect on the bioavailability and therefore toxicity of lead. For example, lead(2+) is more toxic to freshwater species in soft water than hard water. Toxicity is also higher in acidic freshwater when compared to alkaline freshwater. However, toxicity is lower to marine species than for freshwater species (ANZECC, 2000c). These factors and their effects should be noted when evaluating the toxicity of lead(2+) salts.

The following acute median lethal concentration (LC50s) and median effective concentration (EC50) values for model organisms across three trophic levels for the lead cation were reported in the Registration Dossier for the chemical under the European Union REACH legislation for lead metal ((CAS RN 7439-92-1)) (ECHA, 2014e). All studies were conducted on freshwater species using soluble salts of lead(2+):

Taxon	Endpoint	Method
Fish	96 h LC50 = 108 µg Pb/L	Experimental *Pimephales promelas* (Fathead minnow) ASTM Method; Flow through $CaCO_3$ = 43.9 mg/L, pH = 7.4

Taxon	Endpoint	Method
Invertebrates	48 h LC50 = 73.6 µg Pb/L	Experimental *Ceriodaphnia dubia* (Water flea) US EPA Method; Semi-static $CaCO_3$ = 16.4 mg/L, pH = 5.7
Algae	48 h EC50 = 23.1 µg Pb/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201; Static $CaCO_3$ = 24 mg/L, pH = 7.3 Reduced growth rate observed

The chronic toxicity of lead(2+) to freshwater and marine species was critically evaluated for the compilation of water quality trigger values for environmental contaminants in the Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Only studies that considered the complex relationship between water chemistry and toxicity were considered, and no-observed effect concentration (NOEC) equivalent values were derived (ANZECC, 2000c). The equivalent NOEC values available for sensitive freshwater fish and invertebrate species are reported below, along with an effective concentration for 10% of the test population (EC10) value for algae as reported in the Registration Dossier for lead under the European Union REACH legislation (ANZECC, 2000c; ECHA, 2014e):

Taxon	Endpoint	Method
Fish	NOEC = 5.65 µg Pb/L	Experimental *Lepidomeda vittatus* (Little Colorado spinedace) $CaCO_3$ = 30 mg/L
Invertebrates	NOEC = 19.5 µg Pb/L	Experimental *Daphnia magna* (Water flea) $CaCO_3$ = 30 mg/L
Algae	48 h EC10 = 4.5 µg Pb/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201; Static $CaCO_3$ = 24 mg/L, pH = 7.3 Reduced growth rate observed

Toxicity of long-chain fatty acids

The long-chain fatty acid constituents of these chemicals have only moderate toxicity to aquatic life in short and long term exposures.

The following acute LC50 value and EC50 values for model freshwater organisms across three trophic levels for (a) oleic acid (CAS RN 112-80-1) and (b) docosanoic acid (CAS RN 112-85-6) were reported in the databases included in the OECD QSAR Toolbox (LMC, 2013). Additional available toxicity values similarly reflect moderate to low ecotoxicity for these long-chain fatty acids (LMC, 2013; NITE, 2014):

Taxon	Endpoint	Method
Fish	(a) 96 h LC50 = 205 mg/L	Experimental *Pimephales promelas* (Fathead minnow)
Invertebrates	(b) 48 h EC50 = 5 mg/L	Experimental *Daphnia magna* (Water flea) OECD TG 202 Immobilisation observed
Algae	(b) 72 h EC50 = 5 mg/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) Reduced growth rate observed

The following chronic NOEC values for model organisms across two trophic levels for (a) oleic acid, (b) docosanoic acid, (c) palmitic acid (CAS RN 57-10-3) and (d) myristic acid (CAS RN 544-63-8) were reported in the databases included in the OECD QSAR Toolbox (LMC, 2013):

Taxon	Endpoint	Method
Invertebrates	(a) 21 d NOEC = 0.32 mg/L (d) 21 d NOEC = 1.3 mg/L	Experimental *Daphnia magna* (Water flea) OECD TG 211 Reproductive toxicity observed

Taxon	Endpoint	Method
Algae	(a) 72 h NOEC = 2.6 mg/L (b) 72 h NOEC = 4.1 mg/L (c) 72 h NOEC = 0.6 mg/L (d) 72 h NOEC = 2.1 mg/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201 Reduced growth rate observed

Effects on Sediment-Dwelling Life

Bioavailable forms of lead(2+) are toxic to sediment-dwelling organisms.

Toxicity of lead(2+)

The toxicity of lead to sediment-dwelling organisms has been summarised in the rationale and background information to the Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Exposure to sediment contaminants for benthic organisms is assumed to principally involve pore waters (ANZECC, 2000b). The available NOEC value equivalents for select sediment-dwelling organisms (corrected to a $CaCO_3$concentration of 30 mg/L) include a NOEC of 5.1 micrograms of lead per litre (µg Pb/L) for the amphipod *Gammarus pseudolimnaeus* and a NOEC of 28 µg Pb/L for the midge *Tanytarsus dissimilis* (ANZECC, 2000c). However, toxicity is highly dependent on sediment chemistry, which is complex and depends on a range of variable environmental parameters such as dissolved oxygen, pH and the geochemistry of sediment particles (ANZECC, 2000b). In particular, the presence of natural organic matter and the formation of sulfides will affect lead bioavailability. These factors must also be considered when determining the toxicity of lead(2+) to sediment-dwelling species.

Toxicity of long-chain fatty acids

No suitable data were available to evaluate the effects of the fatty acid constituents of these chemicals on sediment-dwelling organisms. However, the release of lead(2+) ions to the sediment compartment is expected to dominate ecotoxicity concerns for these salts.

Effects on Terrestrial Life

Bioavailable forms of lead(2+) ions are very toxic to terrestrial organisms.

Toxicity of lead(2+)

The toxicity of lead to terrestrial organisms has been summarised in Schedule B5c of the *National Environment Protection (Assessment of Site Contamination) Measure 1999*(Cwlth). Lead is strongly adsorbed to organic matter in soil and therefore bioavailability is typically limited. Mean NOEC values for terrestrial invertebrates range from 129 milligrams of lead per kilogram of soil (mg Pb/kg soil) for the earthworm *Dendrobaena rubida* to 1797 mg Pb/kg soil for the springtail *Fautrix candida*. Plants are also susceptible to lead toxicity, with mean NOEC values in a range from 50 mg Pb/kg soil for barley (*Hordeum vulgare*) to 546 mg Pb/kg soil for the Loblolly pine (*Pinus taeda*). Reproductive toxicity and impaired growth are listed as the most common toxic effects (Commonwealth of Australia, 1999).

Toxicity of long-chain fatty acids

No suitable data were available to evaluate the effects of the fatty acid constituents of these chemicals on terrestrial organisms. However, release of lead(2+) ions to the terrestrial compartment is again expected to dominate ecotoxicity concerns for these salts.

Predicted No-Effect Concentration (PNEC)

The primary environmental effects of the chemicals in this group are expected to be caused by the release of lead(2+) ions.

In place of the PNECs for aquatic and sediment compartments for this ionic component, the trigger values published for lead in the Australian and New Zealand Guidelines for Fresh and Marine Water Quality have been used. These values represent thresholds above which further assessment of potential toxicity may be required to ensure environmental quality. Although they were not developed for risk assessment purposes, they nevertheless provide important reference values for evaluating the risks posed by anthropogenic emissions of lead to the Australian environment. For freshwater ecosystems with low water hardness (30 mg/L $CaCO_3$), a high reliability trigger value for protection of 95% of species has been determined to be 3.4 µg Pb/L. The equivalent value for protection of marine species is 4.4 µg Pb/L. For the sediment compartment, the trigger value is 50 mg Pb/kg, dry weight (ANZECC, 2000a).

In place of a PNEC for the soil compartment for lead(2+), the added contaminant limit published for lead in the *National Environment Protection (Assessment of Site Contamination) Measure 1999* (Cwlth) has been used. This value represents the level above which further investigation or evaluation is required after considering naturally occurring background levels. For soil where the contaminant has been present for less than two years, the contaminant limit for protection of 99% of species is 110 mg added Pb/kg soil (Commonwealth of Australia, 1999).

Categorisation of Environmental Hazard

It is not currently possible to categorise the environmental hazards of metals and other inorganic chemicals according to standard persistence, bioaccumulation and toxicity (PBT) hazard criteria. These criteria were developed for organic chemicals and do not take into account the unique properties of inorganic substances and their behaviour in the environment and biota (UNECE, 2007; US EPA, 2007). Therefore, environmental hazard categorisation according to domestic PBT criteria has only been performed for the organic components of the chemicals in the Lead Salts of Long Chain Carboxylic Acids group, as presented below:

Persistence

Not Persistent (Not P). Based on results obtained from various biodegradation studies which indicate rapid and ultimate biodegradation of long-chain fatty acids, the organic components of all chemicals in this group are categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the essential biological functions of long-chain fatty acids as dietary fats and the associated homeostatic controls, the organic components of all chemicals in this group are categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available acute ecotoxicity values greater than 1 mg/L, and chronic ecotoxicity values greater than 0.1 mg/L, the organic components of all chemicals in this group are categorised as Not Toxic.

Summary

The organic components of tetradecanoic acid, lead salt; hexadecanoic acid, lead salt; octadecanoic acid, lead salt; eicosanoic acid, lead salt; docosanoic acid, lead salt; tricosanoic acid, lead salt; tetracosanoic acid, lead salt; hexacosanoic acid, lead salt; 9-octadecenoic acid, lead salt, (*Z*)-; and 9,12-octadecadienoic acid, (*Z*,*Z*)-, lead salt are all categorised as:

- Not P
- Not B
- Not T

An environmental hazard categorisation for the inorganic lead component of the chemicals in this group has not been assigned for the reasons discussed above. Nevertheless, there is an international consensus that bioavailable forms of lead are highly toxic to the environment and that lead bioaccumulates in most organisms (UNEP, 2010; 2014).

Risk Characterisation

Risk quotients (RQs) have not been calculated for these chemicals.

The chemicals in this group contain lead(2+) ions, which can be released into the environment from industrial applications. Anthropogenic emissions of lead to the environment are acknowledged to be of concern, both domestically and internationally, due to the bioaccumulation properties and high toxicity of bioavailable forms of lead. Environmental contamination by lead is of particular concern because high exposure to lead compounds can cause neurological defects and reproductive toxicity across a range of organisms, including humans, plants and animals (UNEP, 2010; 2014).

However, the release of lead to the environment in Australia from industrial uses of chemicals in this group is expected to be limited in volume and diffuse in nature. Available research and use data suggest that the contribution of lead from lead salts of long-chain fatty acids currently used in PVC and industrial coatings to total environmental lead loads is comparatively small. Furthermore, changes in the industrial manufacture of PVC resins and domestic restrictions on the lead content in surface coatings, as well as international trends to reduce lead content in paint, have dramatically reduced the consumption of these lead salts for their main industrial uses. The risks from lead released from PVC articles and articles to which lead-containing industrial coating products have been applied is expected to decline further as lead salts of long-chain fatty acids are finally phased out of use.

Key Findings

The main industrial use of chemicals in the Lead Salts of Long-Chain Carboxylic Acids group is expected to be as stabilisers in the manufacture of PVC articles and as driers in industrial coatings. However, available information from domestic and international sources indicates that the use of lead salts of long-chain fatty acids for these applications has largely been phased out.

The principal environmental concern for industrial uses of lead salts of long-chain fatty acids is the potential for release of soluble forms of ionic lead from manufactured PVC articles and articles on which industrial coatings have been used. This poses a concern because lead and lead compounds are considered to be highly significant environmental contaminants. 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. Further, the potential for lead to be released to the environment due to the use of the chemicals in this group in paints and other coating products is expected to be greatly reduced compared to historic emissions.

The chemicals in this group are considered to pose a low and declining risk to the environment based on the expected limited contribution to total anthropogenic lead emissions from lead-based stabilisers and current uses of industrial coating products containing lead based driers. Both of these main uses have been phased out. No further assessment of the environmental risks of these chemicals is currently required.

The organic components of the chemicals in the Lead Salts of Long Chain Carboxylic Acids group are not PBT substances according to domestic environmental hazard criteria.

Recommendations

The ten chemicals in the Lead Salts of Long-Chain Carboxylic Acids group are not prioritised for further assessment under the IMAP framework.

Environmental Hazard Classification

In addition to the categorisation of environmental hazards according to domestic environmental thresholds presented above, the classification of the environmental hazards of tetradecanoic acid, lead salt; hexadecanoic acid, lead salt; octadecanoic acid, lead salt; eicosanoic acid, lead salt; docosanoic acid, lead salt; tricosanoic acid, lead salt; tetracosanoic acid, lead salt; hexacosanoic acid, lead salt; 9-octadecenoic acid, lead salt, (*Z*)-; and 9,12-octadecadienoic acid, (*Z*,*Z*)-, lead salt according to the third edition of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is presented below (UNECE, 2009):

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Category 1 (H400)	Very toxic to aquatic life
Chronic Aquatic	Category 1 (H410)	Very toxic to aquatic life with long lasting effects

The classification of octadecanoic acid, lead salt (lead stearate) was conducted based on the data available from a study conducted in accordance with the OECD Transformation and Dissolution Protocol for the 1:2 lead(2+) salt of octadecanoic acid and the ecotoxicological data identified in this assessment (ECHA, 2014c; 2014e; LMC, 2013). The chemical is classified as Acute Aquatic Category 1 as the dissolved metal concentration obtained from the lowest loading level after seven days for the lead(2+) salt (27.2 µg Pb/L) exceeds the acute toxicity endpoint available for the algae *Pseudokirchneriella subcapitata.* Similarly, the dissolved metal concentration obtained from the lowest loading level after 28 days for the lead(2+) salt (41.2 µg Pb/L) exceeds all chronic toxicity endpoints listed above for aquatic species. Hence, this salt is categorised as Chronic Aquatic Category 1 according the GHS classification strategy for metals and metal compounds (UNECE, 2007). While lead stearate is expected to contain components beside the lead(2+) salt, the values obtained for the 1:2 lead(2+) salt are considered appropriate for read-across to determine the potential for lead stearate to release lead(2+) ions to the environment.

Based on the available K_{sp} values, and the observed trend in solubility for metallic soaps, hexadecanoic acid, lead salt and tetradecanoic acid, lead salt are considered more soluble than lead stearate. Therefore, these chemicals will be considered more toxic than lead stearate under the GHS. However, lead stearate has been classified under the highest environmental hazard categories available. Therefore, these more soluble chemicals have been classified under the same aquatic hazard categories as lead stearate.

There are insufficient solubility data available for the remaining chemicals in this group to classify their aquatic toxicity hazards according to the procedure outlined above. In accordance with the classification guidance provided for metals and metal compounds in Annex 9 of the GHS, these chemicals are assumed to be sufficiently soluble to release lead(2+) ions at concentrations which exceed the relevant ecotoxicological endpoints (UNECE, 2007). Therefore, these remaining chemicals are all 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 the findings of a study conducted in accordance with the OECD Transformation and Dissolution protocol (UNECE, 2007). Therefore, should a study conducted in accordance with this protocol suggest a lower hazard classification is warranted, these chemicals may be reclassified as appropriate.

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Last update 18 September 2014

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