Cadmium salts of selected fatty acids: Human health tier II assessment

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Octadecanoic acid, barium cadmium salt (4:1:1)	1191-79-3
Octanoic acid, cadmium salt	2191-10-8
Octadecanoic acid, cadmium salt	2223-93-0
Hexanoic acid, 2-ethyl-, cadmium salt	2420-98-6
Dodecanoic acid, cadmium salt	2605-44-9
Decanoic acid, cadmium salt	2847-16-7
Nonanoic acid, cadmium salt	5112-16-3
Hexadecanoic acid, cadmium salt	6427-86-7
Tetradecanoic acid, cadmium salt	10196-67-5
9-Octadecenoic acid, cadmium salt, (Z)-	10468-30-1

Chemical Name in the Inventory	CAS Number
9-Octadecenoic acid, 12-hydroxy-, cadmium salt (2:1), [R-(Z)]-	13832-25-2
Eicosanoic acid, cadmium salt	14923-81-0
Dodecanoic acid, barium cadmium salt	15337-60-7
Isooctanoic acid, cadmium salt	30304-32-6
Docosanoic acid, cadmium salt	34303-23-6
Neodecanoic acid, cadmium salt	61951-96-0
Isooctadecanoic acid, cadmium salt	84878-36-4
Nonanoic acid, branched, cadmium salt	93686-40-9
Fatty acids, tallow, hydrogenated, cadmium salts	68953-39-9
Resin acids and rosin acids, cadmium salts	68956-81-0
Octadecanoic acid, 12-hydroxy-, cadmium salt (2:1)	69121-20-6
Hexanoic acid, 2-ethyl-, cadmium salt, basic	90411-62-4
Fatty acids, castor oil, hydrogenated, cadmium salts	91697-35-7
Isodecanoic acid, cadmium salt	93965-24-3
Isoundecanoic acid, cadmium salt	93965-30-1
Dodecanoic acid, cadmium salt, basic	101012-89-9
Octadecanoic acid, cadmium salt, basic	101012-93-5
Octadecanoic acid, 12-hydroxy-, cadmium salt, basic	101012-94-6

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

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

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

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

This group of 28 chemical compounds consists of cadmium salts of selected fatty acids. These compounds have been included in this group due to the expectation that the physico-chemical properties will not vary greatly, leading to the compounds within this group having related end uses. The toxicity is considered to result entirely from the presence of the cadmium component (cation). In addition, information outlined in the Organisation for Economic Co-operation and Development (OECD) guideline on Grouping of Chemicals (OECD, 2007) provides guidance on grouping chemicals based on physico-chemical or toxicological criteria.

Import, Manufacture and Use

Australian

Of the compounds in this group, no specific Australian use, import, or manufacture information has been reported under previous mandatory and/or voluntary calls for information, except in the following case:

9-Octadecenoic acid, cadmium salt, (Z)- (CAS No. 10468-30-1)

Reported site-limited use including:

- as a stabiliser.

International

Of the compounds in this group, no specific international use, import, or manufacture information has been reported for:

- Decanoic acid, cadmium salt (CAS No. 2847-16-7)
- Nonanoic acid, cadmium salt (CAS No. 5112-16-3)
- Eicosanoic acid, cadmium salt (CAS No. 14923-81-0)
- Isooctanoic acid, cadmium salt (CAS No. 30304-32-6)
- Docosanoic acid, cadmium salt (CAS No. 34303-23-6)
- Isooctadecanoic acid, cadmium salt (CAS No. 84878-36-4)
- Nonanoic acid, branched, cadmium salt (CAS No. 93686-40-9)
- Fatty acids, tallow, hydrogenated, cadmium salts (CAS No. 68953-39-9)
- Hexanoic acid, 2-ethyl-, cadmium salt, basic (CAS No. 90411-62-4)
- Fatty acids, castor oil, hydrogenated, cadmium salts (CAS No. 91697-35-7)
- Isodecanoic acid, cadmium salt (CAS No. 93965-24-3)
- Isoundecanoic acid, cadmium salt (CAS No. 93965-30-1)
- Dodecanoic acid, cadmium salt, basic (CAS No. 101012-89-9)
- Octadecanoic acid, cadmium salt, basic (CAS No. 101012-93-5)
- Octadecanoic acid, 12-hydroxy-, cadmium salt, basic (CAS No. 101012-94-6)

The remaining cadmium fatty acid compounds have one or more of the following reported uses, which have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; EU Risk Assessment Reports (EU RAR); Substances and Preparations in the Nordic countries (SPIN) database; the International Agency for Research on Cancer (IARC) report; the United States (US) National Toxicology Program's Report on Carcinogens (NTP RoC); Galleria Chemica and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB):

Reported commercial use including:

- as lubricants in plastics; and
- as paint driers.

Reported site-limited use including:

- as light and heat stabilisers in plastics (polyvinyl chloride and copolymers);
- in preparing metallic soaps for vinyl stabilisers; and

- as intermediates.

Restrictions

Australian

Cadmium and cadmium compounds are listed in the *Poisons Standard* (the Standard for the Uniform Scheduling of Medicines and Poisons – SUSMP (SUSMP, 2012)) under the following Schedules:

Appendix I, The Uniform Paint Standard

The following applies to paints containing cadmium or cadmium compounds at >0.1 % (the proportion of a substance for the purposes of this Schedule is calculated as a percentage of the element present in the non-volatile content of the paint).

'A person must not manufacture, sell, supply or use a paint containing >0.1% of cadmium or cadmium compounds for application to:

- a roof or any surface to be used for the collection or storage of potable water; or
- furniture; or
- any fence, wall, post, gate or building (interior or exterior) other than a building which is used exclusively for industrial purposes or mining or any oil terminal; or
- any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.' (SUSMP, 2012)

Additionally, 'a person must not manufacture, sell, supply or use a paint for application to toys unless the paint complies with the specification for coating materials contained in Australian/New Zealand Standard AS/NZS ISO 8124.3:2012 entitled *Safety of toys Part 3: Migration of certain elements* (ISO 8124-03:2010, MOD).' (SUSMP, 2012)

'Schedule 6 except when:

(a) included in Schedule 4; or

(b) in paints or tinters containing 0.1 per cent or less of cadmium calculated on the non-volatile content of the paint or tinter.' (SUSMP, 2012)

Schedule 6 substances are considered to have 'moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.' (SUSMP, 2012)

Cadmium and its compounds are also listed as restricted hazardous chemicals in the Australia Work Health and Safety Regulations, 2011 for 'use in abrasive blasting at a concentration of greater than 0.1% as cadmium.' (SafeWork Australia)

International

Cadmium and cadmium compounds are listed on the following (Galleria Chemica):

- EU Cosmetic Directive 76/768/EEC Annex II: List of substances which must not form part of the composition of cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain; and
- Health Canada list of prohibited and restricted cosmetic ingredients (The "Hotlist").

Cadmium and its compounds are also restricted in the EU under Annex XVII of the European Chemicals Agency (ECHA) REACH Regulation, including in:

- plastic materials;
- paints;
- metal plating; and
- brazing (soldering/welding) fillers.

Existing Worker Health and Safety Controls

Hazard Classification

The members of this group are not individually listed in Hazardous Substances Information System (HSIS). Therefore, by default, they are covered by the generic 'cadmium compounds' classification as hazardous with the following risk phrases for human health (Safe Work Australia):

Xn; R20/21/22 (Harmful by inhalation, in contact with skin and if swallowed)

Exposure Standards

Australian

Cadmium and cadmium compounds have an exposure standard of 0.01 mg/m^3 time weighted average (TWA).

International

For cadmium and cadmium compounds the following exposure limits were identified (Galleria Chemica).

An exposure limit (TWA) of 0.01 - 0.2 mg/m^3 in different countries such as Canada, USA, Latvia and Switzerland.

Health Hazard Information

The main concern regarding effects on human health is expected to be driven by the cadmium component of these compounds. The majority of the fatty acid components have been assessed by NICNAS as not posing an unreasonable risk to human health (NICNAS). The remaining fatty acid components of the cadmium compounds in this group have been screened by NICNAS and are also not considered to contribute to the final recommendations of this assessment. While there are no data available on these specific chemicals, data sources for determining the hazard of the cadmium cation include animal studies on well characterised cadmium compounds, particularly the soluble cadmium salts: cadmium chloride and cadmium sulfate, and a large amount of literature on observations of cadmium exposure in humans. The toxicity data from cadmium chloride and cadmium sulfate exposure are considered relevant to the cadmium compounds in this group, as the chloride and sulfate components have also been assessed by NICNAS and are not considered to contribute to the final recommendations (NICNAS).

Toxicokinetics

There is a large amount of information on the toxicokinetics of the cadmium ion in humans. This information is mostly related to general cadmium exposure in workers, and is not specific to particular cadmium compounds.

A study reported that octadecanoic acid, cadmium salt (CAS No. 2223-93-0) easily penetrated intact skin of mice, rats, guinea pigs and rabbits. The chemical was detectable in the liver and kidneys, prior to slow excretion (HSDB).

Dermal absorption of cadmium in rabbits following exposure to a cadmium chloride solution was considered to be substantial, resulting in accumulation of up to 0.8 % of the administered dose in the kidney and liver (EU RAR, 2007).

In rodent dietary exposure studies using cadmium oxide, a significant accumulation of cadmium was detected in the liver, kidneys, lungs and spleen. Levels in the liver and kidneys were reported to be dose-dependent. However, no significant increase in bone, blood or urine levels of cadmium was detected. Absorption rates following oral exposure to low doses of the chemical were reported to be much greater than those determined for exposure to higher doses (EU RAR, 2007).

Animal studies have demonstrated that absorption of the chemical following inhalation exposure ranges from 30 % (dusts, size-dependent) to 50 % (fumes). In humans, inhalation absorption of 10-30 % (dusts, size-dependent) is reported (OECD, 2004).

Following long-term low-level exposure, cadmium is reported to be widely distributed in the body and has a biological half-life of 10-20 years. The greatest accumulation occurs in the kidneys and liver, with only 0.005-0.02 % reported to be excreted via urine and faeces per day. Cadmium is also detectable in the placenta, and can cross the placenta, although foetal concentrations are lower than placental concentrations. Concentrations of cadmium in newborn blood were 40-50 % lower than the levels in maternal blood (EU RAR, 2007). Cadmium is reported to be found in human breast milk at <1 µg/L (OECD, 2004). In tissue, cadmium is bound to metallothionein, a low molecular weight metal-binding protein thought to play a key role in the metabolism and detoxification of cadmium (EU RAR, 2007).

Human data available on cadmium indicate that gastro-intestinal absorption rates are low (5-10 %), and vary depending on the source of the cadmium, presence of zinc in the diet, the body’s iron stores (deficiencies linked with increased cadmium absorption) and the person’s age and physiological condition (young or pregnant and lactating animals have shown to absorb more cadmium than non-pregnant adult animals) (EU RAR, 2007; OECD, 2004).

It should be noted that higher levels of cadmium (particularly in the kidney) are detected in smokers compared to non-smokers, as cadmium has been shown to accumulate in tobacco plant leaves (WHO, 2010).

Acute Toxicity

Oral

The compounds in this group are not individually listed in HSIS. Therefore, by default, they are covered by the generic 'cadmium compounds' hazard classification with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). While there are no experimental data available specific to these chemicals, data from other soluble cadmium salts (cadmium chloride and cadmium sulfate) support a recommendation to amend the classification for the compounds in this group.

Cadmium chloride is reported to be acutely toxic in animal tests following oral exposure. The oral median lethal dose (LD50) values in Sprague Dawley (SD) rats range from 107-327 mg/kg bw (EU RAR, 2007, REACH).

Cadmium sulfate is reported to be acutely toxic in rats through oral exposure. The LD50 was reported to be 280 mg/kg bw (HSDB).

Additionally, cadmium chloride and cadmium sulfate are classified as hazardous following acute oral exposure, with the risk phrase 'Toxic if swallowed' (T; R25) in HSIS (Safe Work Australia).

There is sufficient evidence to warrant this classification applying to all compounds in this the group.

Dermal

The compounds in this group are not individually listed in HSIS. Therefore, by default, they are covered by the generic 'cadmium compounds' hazard classification with the risk phrase 'Harmful in contact with skin' (Xn; R21) in HSIS (Safe Work Australia).

While there are no experimental dermal toxicity data available specific to these chemicals, a number of soluble cadmium salts are reported to be absorbed by the skin resulting in detectable levels of cadmium in the liver and kidney (see **Toxicokinetics** section).

In the absence of more comprehensive information, there is insufficient evidence to support a recommendation to amend the classification for this group of chemicals.

Inhalation

The compounds in this group are not individually listed in HSIS. Therefore, by default, they are covered by the generic 'cadmium compounds' hazard classification with the risk phrase 'Harmful if inhaled' (Xn; R20) in HSIS (Safe Work Australia). While there are no experimental data available specific to these chemicals, data from other cadmium compounds support a recommendation to amend the classification for the compounds in this group.

Eight-hour inhalation exposure to cadmium levels of 5 mg/m^3 is reported to be potentially lethal, while 1 mg/m^3 is considered to be immediately dangerous to life (EU RAR, 2008).

Additionally, the soluble cadmium salts, cadmium chloride and cadmium sulfate, are classified as hazardous following acute inhalation exposure, with the risk phrase 'Very toxic by inhalation' (T+; R26) in HSIS (Safe Work Australia).

There is sufficient information about the chemical similarity to warrant this classification applying to all compounds in this group.

Observation in humans

There are many case studies of acute poisoning following inhalation of cadmium oxide fumes, or fumes produced by heating cadmium-containing materials to high temperatures. Documented signs of toxicity include nausea, fever, difficulties in respiration and severe respiratory irritation. Pulmonary oedema, resulting in mortality, was commonly reported following acute exposure (EU RAR, 2007).

Several cases of cadmium poisoning (compound not specified) as a result of ingesting contaminated food or drinks have been documented. Signs and symptoms of toxicity reported include nausea, vomiting, diarrhoea and abdominal cramps.

Corrosion / Irritation

Respiratory Irritation

While no specific data are available for the cadmium compounds in this group, based on inhalation studies in animals and observations in humans (described under **Acute Toxicity**), these compounds are expected to be irritating to the respiratory tract (EU RAR 2007).

Skin Irritation

While no specific data are available for the cadmium compounds in this group, potential skin irritation was reported following exposure to cadmium chloride in humans (refer to **Observation in humans** section).

Eye Irritation

No data are available.

Observation in humans

Eczema patients were patch-tested with 0.06, 0.5, 1 or 2% doses of cadmium chloride in distilled water. At the 2% dose, skin irritation was reported in 25/1502 patients (1.7%), but no vesicular reactions (skin blisters) were observed. A lowest observed

adverse effect level (LOAEL) value of 2 % was reported. No skin irritation was reported at 1 % in patients (EU RAR, 2007; REACH).

Sensitisation

Skin Sensitisation

While no specific data are available for the cadmium compounds in this group, there is evidence of skin sensitisation from human observations following exposure to cadmium chloride (refer to **Observation in humans** section).

In a guinea pig maximisation test, animals (20/dose) were intradermally administered a 0.007 % cadmium chloride solution in water. After an unreported period, a 5 % solution of the chemical (in petrolatum) was topically applied to the animals. When challenged three weeks later with 0.05 % cadmium chloride solution by intradermal injection, and with a 7.5 % topical application, no contact sensitisation was reported at 24 or 48 hours (EU RAR, 2007; REACH).

There is insufficient evidence to classify these chemicals as skin sensitisers.

Observation in humans

Skin patch tests using cadmium chloride and cadmium sulfate tested positive in seven out of approximately 150 patients attending a dermatological department between 1979-1981 (EU RAR, 2007).

Repeated Dose Toxicity

Oral

While there are no data available for these specific chemicals, data from animal studies and observations in humans following exposure to cadmium are provided in the following sections.

A chronic exposure study in male Wistar rats using cadmium chloride reported potential damage to the vertebrae. The animals (10/dose) were orally exposed to cadmium chloride through drinking water for 12 months at 1, 5, 50 mg/L. No treatment related signs were reported at 1 mg/L. At ≥5 mg/L, increased lumbar spine deformities and a decrease in lumbar spine mineralisation (including calcium, magnesium, zinc, copper, iron and phosphate) were reported. A decrease in mechanical strength of the vertebral column at the fourth lumbar vertebra (L4) was reported at 50 mg/L. The L4 was reported to be fractured in 30 % of animals in this group, while 40 % were reported to have L4 deformities. The remaining animals in this group (30 %) had intact L4s. The NOAEL (no observed adverse effect level) and LOAEL (lowest observed adverse effect level) for this study were reported to be 0.2 mg/kg bw/day and 0.5 mg/kg bw/day, respectively (REACH).

In a non-guideline, subchronic repeated dose toxicity study, male and female Wistar rats (20/sex/group) were administered cadmium chloride in their diet at doses of 1, 3, 10, 30 ppm for three months. While cadmium accumulation in the kidneys and liver was reported, no signs of systemic toxicity in the blood, liver or kidney were observed (up to 30 ppm were tolerated by rats over three months). No signs of any alterations were reported after autopsies and histopathology of animals. The NOAEL for this study was reported to be 30 ppm (3 mg/kg bw/day) (REACH).

Additionally, cadmium chloride and cadmium sulfate are classified as hazardous following repeat oral exposure, with the risk phrase 'Toxic: danger of serious damage to health by prolonged exposure if swallowed' (T; R48/R25) in HSIS (Safe Work Australia).

There is sufficient evidence from animal studies and observations in humans to warrant this classification applying to all compounds in this group.

Dermal

No data are available.

Inhalation

While there are no data available for these specific chemicals, data from animal studies and observations in humans following exposure to cadmium are provided in the following sections.

Effects observed in animal studies following repeated-dose exposure to cadmium oxide are reported to be similar to those observed in acute exposure studies including rales (abnormal respiratory sounds characterised by fine crackles), laboured breathing and pneumonia, seen at low doses (EU RAR, 2008).

In a 13-week repeated-dose inhalation study in rats exposed to cadmium oxide, the NOAEL for the chemical was reported to be 0.025 mg/m^3. At higher doses (≥0.05 mg/m^3), treatment-related lesions in the lungs were observed, including inflammation and fibrosis. A dose-related increase in hyperplasia (elevated cell production in lungs) was also reported (EU RAR, 2007).

Additionally, cadmium chloride and cadmium sulfate are classified as hazardous following repeat inhalation exposure, with the risk phrase 'Toxic: danger of serious damage to health by prolonged exposure through inhalation' (T; R48/R23) in HSIS (Safe Work Australia).

There is sufficient evidence from animal studies and observations in humans to warrant this classification applying to all compounds in this group.

Observation in humans

Exposure to low levels of cadmium over a long period of time have been linked to chronic cadmium poisoning. The effects of cadmium on specific target organs following exposure in humans are summarised and provided below.

Respiratory effects

There are number of documented case studies of workers chronically exposed to the chemical fumes (EU RAR, 2007). Effects reported include fatigue, respiratory irritation, shortness of breath, decreased lung function and recurrent bronchitis.

It is suggested that an increase in residual levels of the chemical in lungs may lead to chronic obstructive airway disease, and in some cases mortality, all of which have been documented following exposure (EU RAR, 2007). A LOAEL of 0.0031 mg/L, based on lung effects (increased residual levels of the chemical), was derived from a study on workers exposed to the chemical fumes at <0.5 mg/m^3 over several years.

Renal effects

The kidney is considered to be the main target organ for cadmium toxicity following repeated oral and inhalation exposure (ATSDR, 2012; EU RAR, 2007). Initial signs of kidney effects following cadmium exposure include tubular dysfunction, decreased glomerular filtration rate, and increased proteinuria and enzymuria. Renal dysfunction is considered to occur when renal cortex cadmium concentrations reach 200 ppm (equivalent to 5-10 µg/g creatinine) (EU RAR, 2007).

An increased frequency of kidney stones have also been reported in workers exposed to cadmium (18 %), compared with unexposed workers (3 %) (EU RAR, 2007).

Skeletal effects

Cadmium exposure through the oral route is reported to cause bone disease in humans (EU RAR, 2008). While the underlying mechanism is not clearly understood, it is thought that cadmium-induced kidney damage and resulting hypercalcinuria (elevated levels of calcium in the urine) may promote osteoporotic effects in bone (EU RAR, 2007).

In a case study in Japan, a high incidence of Itai-Itai disease was diagnosed in patients from specific geographical locations. It was found that these areas were irrigated by a river being polluted by cadmium sludge from an upstream mine, and the patients

may have been exposed to cadmium for over 30 years. Samples of rice

taken from those areas were reported to contain cadmium at 0.68 mg/kg, compared with 0.066 mg/kg in other areas (EU RAR, 2007). Itai-Itai disease is characterised by osteomalacia (softening of the bones), osteoporosis, severe renal tubular disease, and is associated with severe pain (WHO, 2011). A limited number of case reports have also documented clinical bone disease in workers exposed to cadmium compounds (EU RAR, 2007).

Genotoxicity

While there are no experimental data available specific to these chemicals, data from other soluble cadmium salts (cadmium chloride and cadmium sulfate) are provided below.

In vitro

Cadmium chloride was reported to not be mutagenic in *Salmonella typhimurium* bacterial strains TA 98, TA100, TA 1535 and TA 1537 with and without metabolic activation (REACH). However, cadmium ions have been shown to induce genotoxic effects in in vitro (reduction in colony-forming ability and DNA strand breaks in *Escherichia coli*) (EU RAR, 2007).

Cadmium chloride and cadmium sulfate were clastogenic in tests using mammalian cells. An increase in sister chromatid exchanges were reported in male and female mouse splenocytes exposed to cadmium chloride, and in human lung fibroblasts exposed to either cadmium chloride or cadmium sulfate; chromosomal aberrations were observed in male and female Swiss mouse splenocytes following exposure to cadmium chloride; and DNA strand breaks and mutations at the K-ras gene were reported in human lung fibroblasts exposed to cadmium sulfate (REACH).

In vivo

Cadmium chloride was reported to be mutagenic in vivo in male albino rats that were injected intraperitoneally (i.p) with a 4 mg/kg bw dose of the chemical. Single strand DNA breaks were observed following exposure, notably in the kidney (EU RAR, 2007).

Cadmium chloride was reported to be mutagenic in vivo in a study where the induction of micronuclei, sister chromatid exchanges in mouse bone marrow and chromosomal aberration were investigated, after a single i.p treatment of the chemical at doses of 1.9, 5.7, 7.6 mg/kg bw.

A dose dependent increase of peripheral erythrocytes with micronuclei were reported, where doses of 5.7 and 7.6 mg/kg bw induced bone marrow toxicity as noted by a significant increase in the percentage of polychromatic erythrocytes when compared to the control. The chemical was also reported to induce chromosomal aberrations (excluding metaphases with chromosome or chromatid gaps). The intensity of effects was dose-dependent, and at a maximum 24 hours post-treatment. A dose-dependent increase in the frequency of sister chromatid exchanges was reported at the two highest doses (EU RAR, 2007).

Additionally, cadmium chloride and cadmium sulfate are classified as hazardous, as Category 2 mutagens, with the risk phrase 'May cause heritable genetic damage' (T; R46) in HSIS (Safe Work Australia).

There is sufficient evidence to warrant this classification applying to all compounds in this group.

Observations in humans

Chromosomal aberrations, increased frequency of micronuclei, and sister chromatid exchanges have been detected in humans environmentally exposed to cadmium (EU RAR, 2007). However, the specific cadmium compounds involved are not identified.

Carcinogenicity

While there are no experimental data available specific to these chemicals, data from other soluble cadmium salts (cadmium chloride and cadmium sulfate) are provided below.

Oral administration of cadmium chloride to Wistar rats increased the incidence of large granular lymphocytes, leukaemia, prostate tumours, and testis tumours. Prostate hyperplasia (increased cell production in prostate) was also reported in Noble

rats orally exposed to the chemical (NTP, 2011; REACH).

A non-guideline inhalation study reported an increase in lung tumours in male and female Wistar rats (20/sex/dose) exposed to aerosolised cadmium chloride, cadmium sulfate, cadmium oxide dusts, cadmium oxide fumes or cadmium sulfide (REACH).

Rats were exposed to cadmium chloride at 0.03 and 0.09 mg/m^3 for 22 hours a day, seven days a week over an 18-month exposure period. The LOAEL for carcinogenicity was reported to be 0.03 mg/m^3 air, as lung bronchioalveolar adenomas (benign glandular tumour of the lung), adenocarcinomas (malignant glandular tumours) and squamous cell carcinomas (cancer of the outer layer of skin or of the lining of the internal organs) were noted at this dose. In male and female rats, a high incidence of lung nodules and lung tumours were reported for 0.03 mg/m^3 exposure (lung nodules in 33/38 rats; primary lung tumours in 28/38 rats). Bronchioalveolar adenomas were observed in 6/38 animals, adenocarcinomas were observed in 19/38 animals and combined squamous cell carcinomas and adenocarcinomas were observed in 3/38 animals.

In another study, rats were exposed to cadmium sulfate at 0.09 mg/m^3 for 22 hours a day, seven days a week over an 18-month exposure period. Lung bronchioalveolar adenomas, adenocarcinomas and squamous cell carcinomas were noted. In another study using cadmium sulfate, a significant incidence of lung tumours was observed following chronic inhalation exposure to 0.09 mg/m^3 over a 29-30 month period (REACH).

Additionally, cadmium chloride and cadmium sulfate are classified as hazardous, as Category 2 carcinogens, with risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia).

There is sufficient evidence to warrant this classification applying to all compounds in this group.

Observations in humans

There are many case studies that explore the link between increased incidences of cancer in workers with exposure to cadmium and cadmium compounds (NTP, 2011; IARC, 2012).

IARC has classified cadmium and cadmium compounds as ‘Carcinogenic to humans (Group 1)’ based on sufficient evidence in humans and experimental animals (IARC, 2012). Additionally, the US NTP has also classified cadmium and cadmium compounds as ‘Known to be human carcinogens’ (NTP, 2011).

Significantly increased mortalities due to lung cancer were reported in workers in cadmium-processing plants, cadmium recovery plants and those who worked in the nickel-cadmium battery production industry (IARC, 2012). An increased risk of lung cancer was identified in workers with long-term employment in high cadmium-exposure jobs.

A limited number of cases of cancer of the prostate, pancreas and kidney have also been reported following exposure to cadmium (either occupational exposure or by contamination).

In some of these cases, workers may have potentially been exposed to other chemicals, including arsenic and nickel. Both IARC and the US NTP concluded that the increase in lung cancers could not be solely due to exposure to other chemicals (NTP, 2011; IARC, 2012). However, the Agency for Toxic Substances and Disease Registry (ATSDR) has concluded that the interpretation of these observations in humans is complicated by co-exposure with other metals, and that there is a 'lack of significant relationship between cadmium exposure and duration' (ASTDR, 2012).

Reproductive and Developmental Toxicity

While there are no experimental data available specific to these chemicals, data from other soluble cadmium salts (cadmium chloride and cadmium sulfate) are provided below.

Reproductive toxicity

In a study in female Wistar rats, animals were exposed to cadmium chloride by oral gavage at 0.04, 0.4, 4 and 40 mg/kg bw/day for 14 weeks. Increased oestrous cycle lengths and decreased body weights compared to controls were reported in rats in the highest dose group (40 mg/kg bw/day) after six weeks of treatment; this was not reported for other dose groups. A reproductive NOAEL of 4 mg/kg bw/day and LOAEL of 40 mg/kg bw/day were reported for this study (REACH; EU RAR, 2007).

Developmental toxicity

Effects of cadmium exposure on maternal and foetal zinc metabolism were reported to be investigated in a non-guideline developmental toxicity study. SD rats were orally exposed to cadmium chloride in drinking water at daily doses of 0, 5, 50 and 100 ppm on gestation days 6-20. Exposure-related reduced maternal weights and weight gains were reported at the highest dose groups at 50 and 100 ppm but not in the 5 ppm group. In the 100 ppm dose group, reduced foetal weights were reported to be a secondary effect to decreased maternal weights (attributed to maternal reduced food and water intake). A significant difference in the foetal weight to maternal weight ratio (as compared to the controls) was only observed in the 50 ppm group.

It was reported at the 50 ppm dose that cadmium-induced zinc retention was the cause for impaired foetal growth as zinc retention in maternal liver and kidney and decreased concentration of zinc in the foetal liver were observed. A maternal and developmental NOAEL of 5 ppm (0.63 mg/kg bw/day) and a maternal and developmental LOAEL of 50 ppm (4.7 mg/kg bw/day) were reported (REACH; EU RAR 2007).

In another study, cadmium chloride was administered intragastrically at 2, 12 and 40 mg/kg bw/day, to pregnant rats. At the two highest dose groups, reduced foetal body weights and reduced skeletal ossification, compared to controls, were reported. However, reduced body weight gains during pregnancy of treated females at all dose levels were also reported. NOAEL or LOAEL estimates were not reported for this study (EU RAR 2007).

Additionally, cadmium chloride and cadmium sulfate are both individually listed in HSIS and are classified as hazardous, as Category 2 reproductive and developmental toxins, with the risk phrases 'May impair fertility' (T; R60) and 'May cause harm to the unborn child' (T; R61) in HSIS (Safe Work Australia).

There is sufficient evidence to warrant this classification applying to all compounds in this group.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity, mutagenicity, reproductive toxicity and developmental toxicity), systemic acute effects (acute toxicity by the oral and inhalation route of exposure), and toxic effects resulting from repeated exposure following ingestion or inhalation. The chemicals are also potential respiratory irritants.

Public Risk Characterisation

Given the uses identified for these chemicals, it is unlikely that the public will be exposed. Hence, the public risk from these chemicals is not considered to be unreasonable.

Occupational Risk Characterisation

Given the critical health effects, the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise exposure to the chemicals are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

NICNAS Recommendation

Assessment of the chemicals is considered to be sufficient, provided that the recommended amendments to the classification are adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

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

Work Health and Safety

The chemicals are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

The classification proposed below is based on read across principles (refer to section on Grouping Rationale). It should be used as a default for all members of the group. If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for the specific chemical, these may be used to amend the default classification for that chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Toxic if swallowed (T; R25) Harmful in contact with skin (Xn; R21)* Very toxic by inhalation (T+; R26)	Toxic if swallowed - Cat. 3 (H301) Harmful in contact with skin - Cat. 4 (H312) Fatal if inhaled - Cat. 1 (H330)
Repeat Dose Toxicity	Toxic: danger of serious damage to health by prolonged exposure through inhalation (T; R48/23) Toxic: Danger of serious damage to health by prolonged exposure if swallowed (T; R48/25)	Causes damage to organs through prolonged or repeated exposure - Cat. 1 (H372)
Genotoxicity	Muta. Cat 2 - May cause heritable genetic damage (T; R46)	May cause genetic defects - Cat. 1B (H340)
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)	May cause cancer - Cat. 1B (H350)
Reproductive and Developmental Toxicity	Repro. Cat 2 - May impair fertility (T; R60) Repro. Cat 2 - May cause harm to the unborn child (T; R61)	May damage fertility or the unborn child - Cat. 1B (H360F) May damage fertility or the unborn child - Cat. 1B (H360D)

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

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

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

Advice for consumers

Products containing the chemicals should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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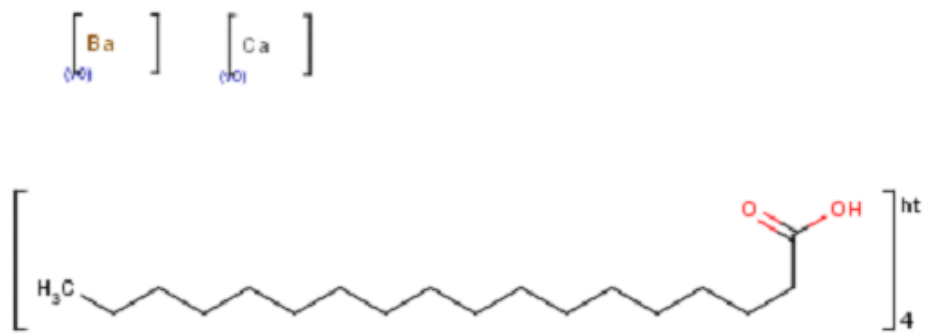
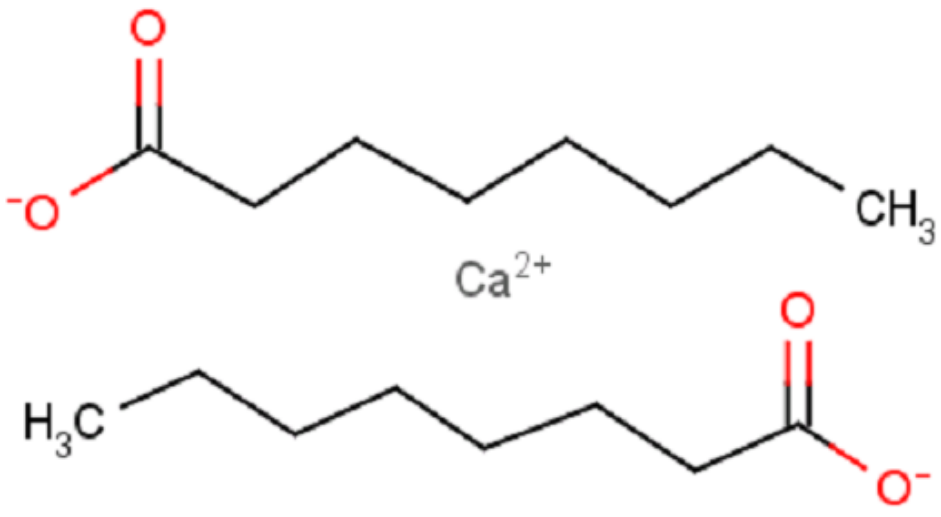
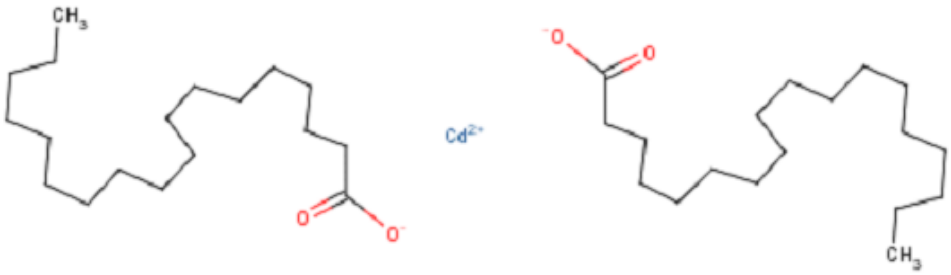
Last Update 22 November 2013

Chemical Identities

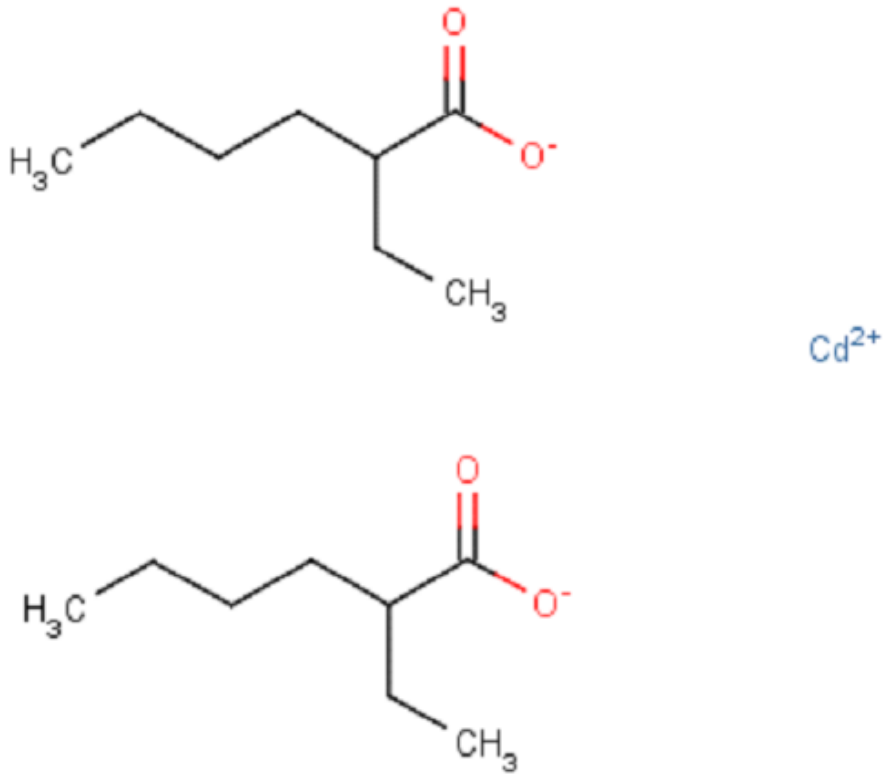
Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, barium cadmium salt (4:1:1)** Barium cadmium stearate Stearic acid, barium cadmium salt (4:1:1) Barium cadmium tetrastearate Cadmium barium stearate
CAS Number	1191-79-3
Structural Formula	
Molecular Formula	C18H36O2.1/4Ba.1/4Cd
Molecular Weight	1315.33

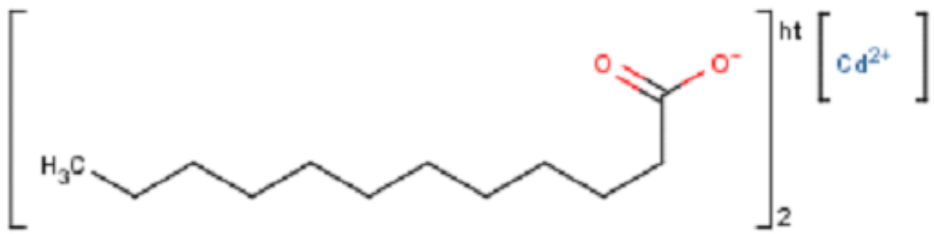
Chemical Name in the Inventory and Synonyms	**Octanoic acid, cadmium salt** Cadmium octoate Cadmium caprylate Cadmium octanoate
CAS Number	2191-10-8
Structural Formula	
Molecular Formula	C8H16O2.1/2Cd

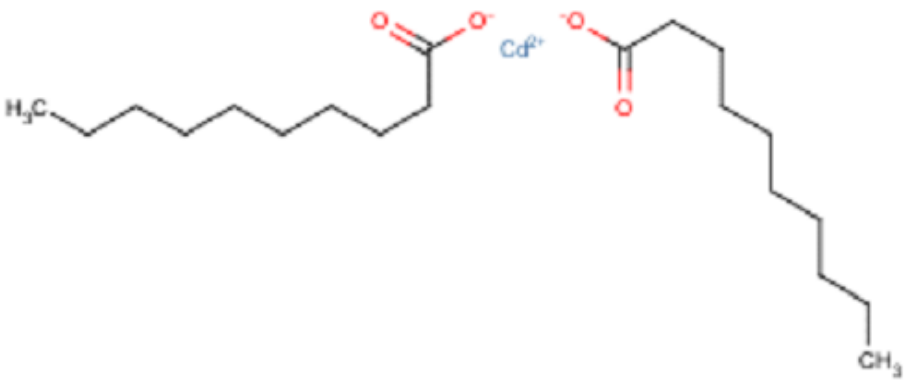
Molecular Weight	326.49

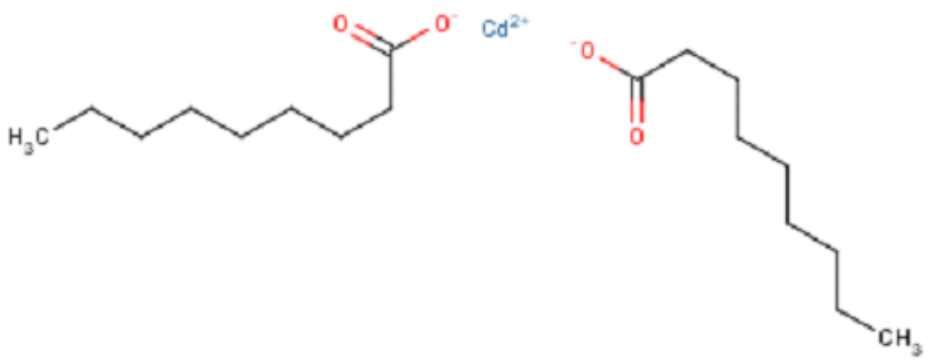
Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, cadmium salt** Cadmium stearate Alaixol 11 Stabilizer SCD Cadmium octadecanoate Stearic acid, cadmium salt
CAS Number	2223-93-0
Structural Formula	
Molecular Formula	C18H36O2.1/2Cd
Molecular Weight	679.36

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, cadmium salt** Cadmium 2-ethylhexanoate Cadmium bis(2-ethylhexanoate) Cadmium ethylhexanoate Cadmium octanoate Cadmium di-2-ethylhexylate
CAS Number	2420-98-6
Structural Formula	

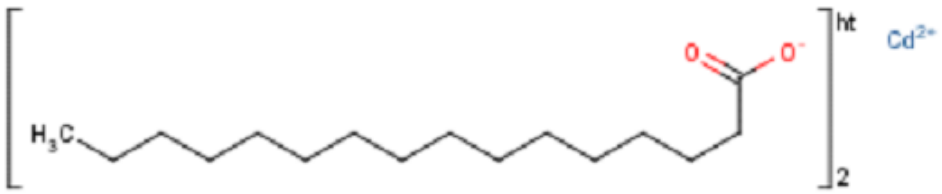
	
Molecular Formula	C8H16O2.1/2Cd
Molecular Weight	398.82

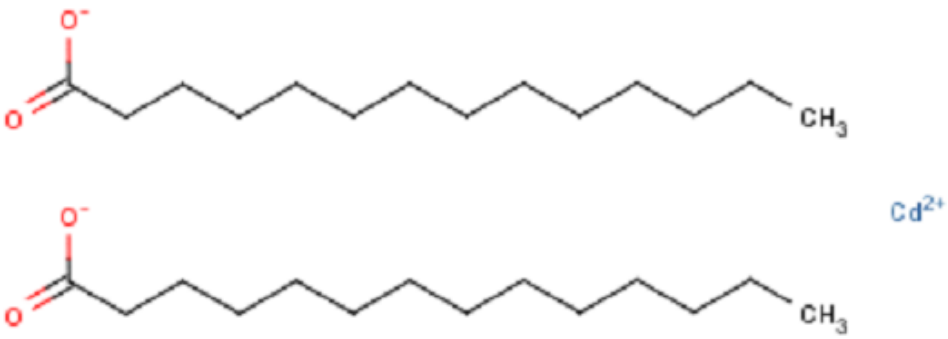
Chemical Name in the Inventory and Synonyms	**Dodecanoic acid, cadmium salt** Cadmium dilaurate Lauric acid, cadmium salt (2:1) Cadmium dodecanoate Dodecanoic acid, cadmium salt (2:1) Cadmium laurate
CAS Number	2605-44-9
Structural Formula	
Molecular Formula	C12H24O2.1/2Cd
Molecular Weight	511.03

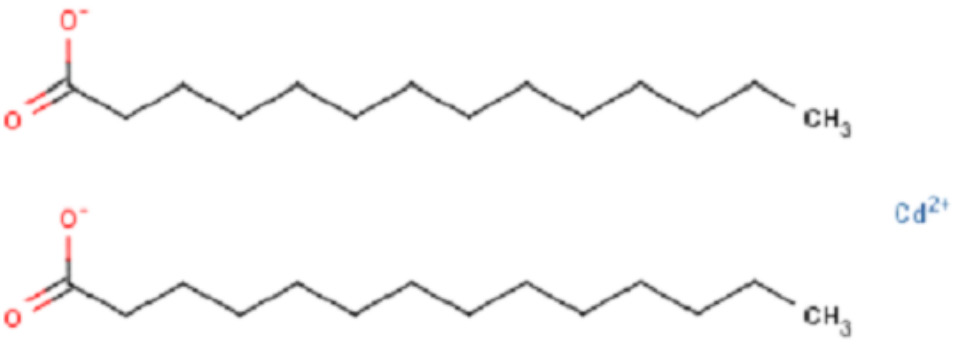
Chemical Name in the Inventory and Synonyms	**Decanoic acid, cadmium salt** Cadmium decanoate Cadmium didecanoate Decanoic acid, cadmium salt (2:1)
CAS Number	2847-16-7
Structural Formula	
Molecular Formula	C10H20O2.1/2Cd
Molecular Weight	454.93

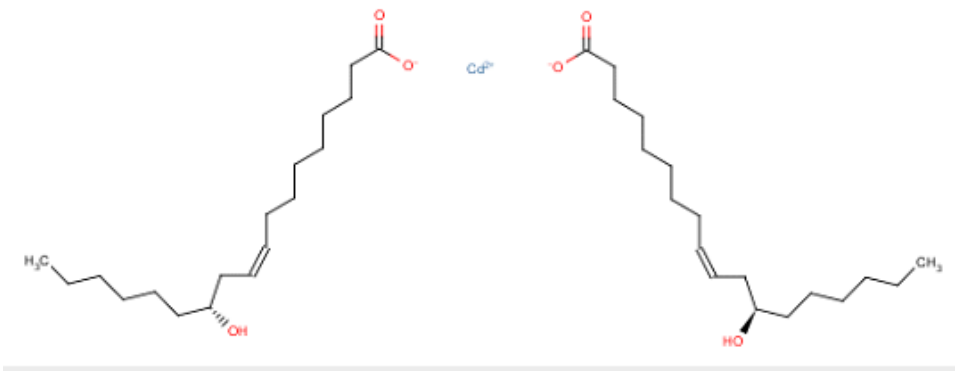
Chemical Name in the Inventory and Synonyms	**Nonanoic acid, cadmium salt** Cadmium pelargonate Cadmium nonan-1-oate Cadmium nonanoate Nonanoic acid, cadmium salt (2:1)
CAS Number	5112-16-3
Structural Formula	
Molecular Formula	C9H18O2.1/2Cd

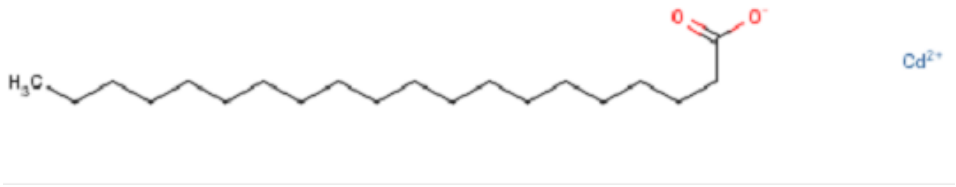
Molecular Weight	426.87

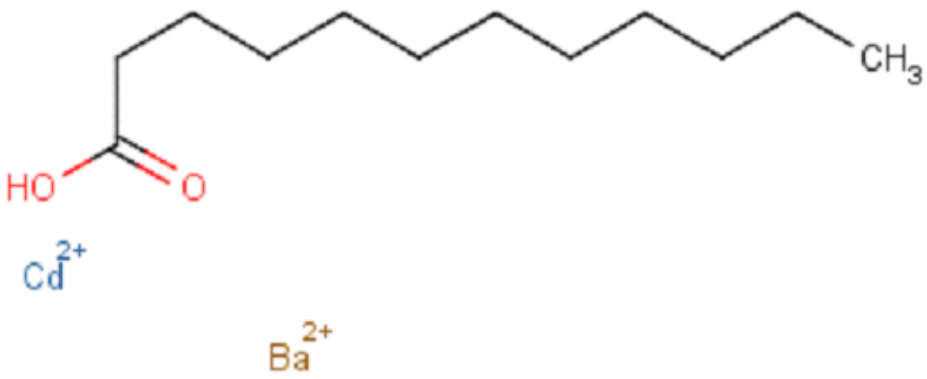
Chemical Name in the Inventory and Synonyms	**Hexadecanoic acid, cadmium salt** Cadmium hexadecanoate Cadmium dipalmitate Hexadecanoic acid, cadmium salt (2:1) Cadmium palmitate
CAS Number	6427-86-7
Structural Formula	
Molecular Formula	C16H32O2.1/2Cd
Molecular Weight	623.25

Chemical Name in the Inventory and Synonyms	**Tetradecanoic acid, cadmium salt** Cadmium tetradecanoate Cadmium myristate Tetradecanoic acid, cadmium salt (2:1)
CAS Number	10196-67-5
Structural Formula	
Molecular Formula	C14H28O2.1/2Cd
Molecular Weight	567.14

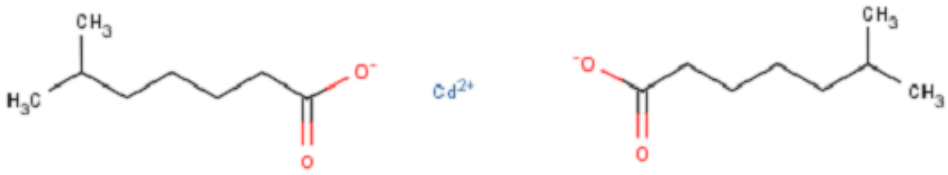
Chemical Name in the Inventory and Synonyms	**9-Octadecenoic acid, cadmium salt, (Z)-** Cadmium oleate 9-Octadecenoic acid (9Z)-, cadmium salt 9-Octadecenoic acid (9Z)-, cadmium salt (2:1) 9-Octadecenoic acid (Z)-, cadmium salt
CAS Number	10468-30-1
Structural Formula	
Molecular Formula	C18H34O2.1/2Cd
Molecular Weight	675.32

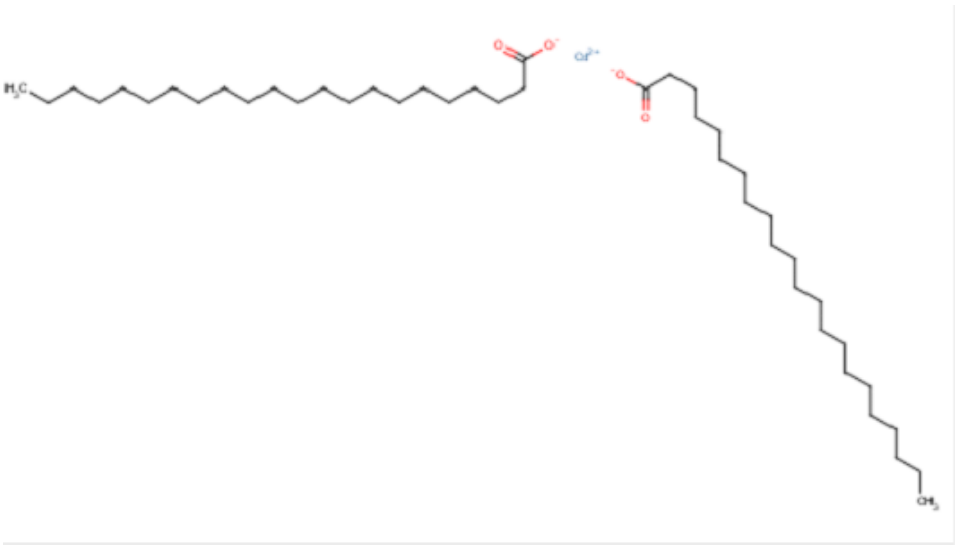
Chemical Name in the Inventory and Synonyms	**9-Octadecenoic acid, 12-hydroxy-, cadmium salt (2:1), [R-(Z)]-** Cadmium ricinoleate Cadmium diricinoleate
CAS Number	13832-25-2
Structural Formula	
Molecular Formula	C18H34O3.1/2Cd
Molecular Weight	707.32

Chemical Name in the Inventory and Synonyms	**Eicosanoic acid, cadmium salt** Cadmium diicosanoate Cadmium eicosanoate Arachidic acid, cadmium salt Cadmium arachidate
CAS Number	14923-81-0
Structural Formula	
Molecular Formula	C20H40O2.1/2Cd
Molecular Weight	423.94

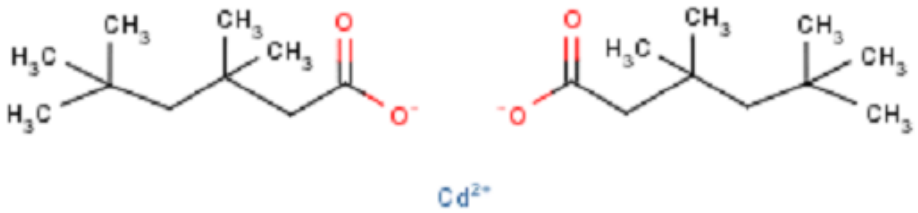
Chemical Name in the Inventory and Synonyms	**Dodecanoic acid, barium cadmium salt** Advastab BC 26 Barium cadmium laurate Lauric acid, barium cadmium salt Dodecanoic acid, barium cadmium salt (1:?:?)
CAS Number	15337-60-7
Structural Formula	
Molecular Formula	C12H24O2.xBa.xCd
Molecular Weight	450.06

Chemical Name in the Inventory and Synonyms	**Isooctanoic acid, cadmium salt** Cadmium isooctanoate Cadmium isoctanoate

CAS Number	30304-32-6
Structural Formula	
Molecular Formula	C8H16O2.1/2Cd
Molecular Weight	398.82

Chemical Name in the Inventory and Synonyms	**Docosanoic acid, cadmium salt** Cadmium behenate Cadmium didocosanoate Docosanoic acid, cadmium salt (2:1)
CAS Number	34303-23-6
Structural Formula	
Molecular Formula	C22H44O2.1/2Cd
Molecular Weight	791.57

Chemical Name in the Inventory and Synonyms	**Neodecanoic acid, cadmium salt** Cadmium neodecanoate

	Neodecanoic acid, cadmium salt (2:1)
CAS Number	61951-96-0
Structural Formula	
Molecular Formula	C10H20O2.1/2Cd
Molecular Weight	454.93

Chemical Name in the Inventory and Synonyms	**Isooctadecanoic acid, cadmium salt** Cadmium isooctadecanoate
CAS Number	84878-36-4
Structural Formula	**No Structural Diagram Available**
Molecular Formula	C18H36O2.1/2Cd
Molecular Weight	

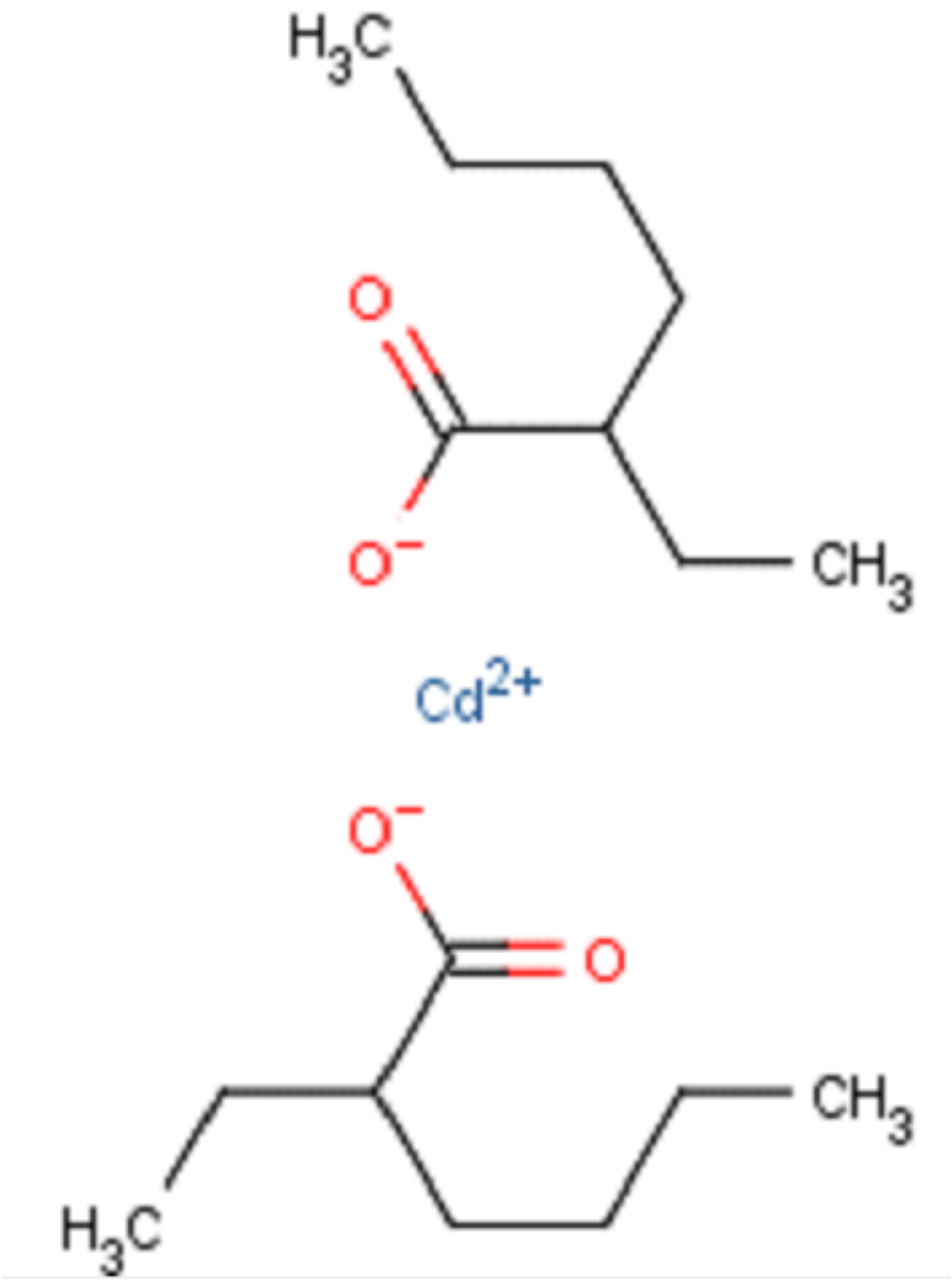
Chemical Name in the Inventory and Synonyms	**Nonanoic acid, branched, cadmium salt**

CAS Number	93686-40-9
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

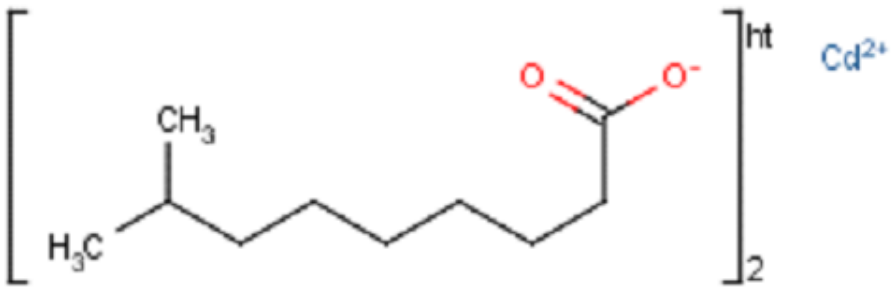
Chemical Name in the Inventory and Synonyms	**Fatty acids, tallow, hydrogenated, cadmium salts** Hydrogenated tallow fatty acids, cadmium salt
CAS Number	68953-39-9
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

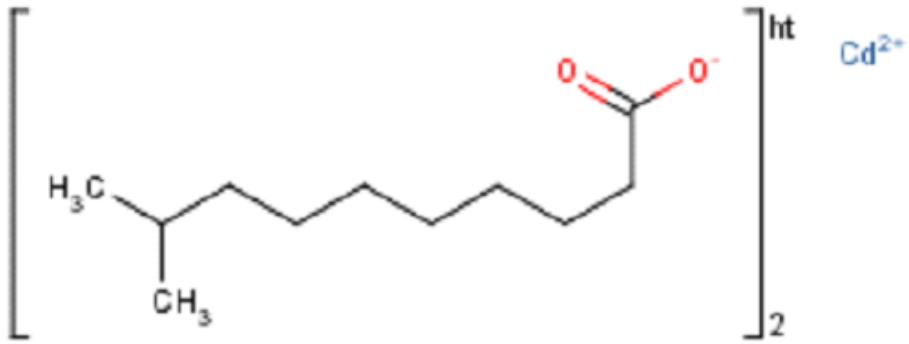
Chemical Name in the Inventory and Synonyms	**Resin acids and rosin acids, cadmium salts** Cadmium rosinate Resin acid cadmium salts Cadmium resinate
CAS Number	68956-81-0
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

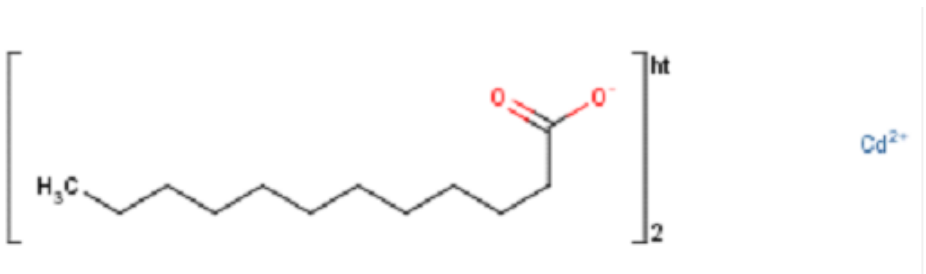
Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, 12-hydroxy-, cadmium salt (2:1)** Cadmium 12-hydroxyoctadecanoate Cadmium(2+) 12-hydroxyoctadecanoate
CAS Number	69121-20-6
Structural Formula	**No Structural Diagram Available**
Molecular Formula	C18H36O3.1/2Cd
Molecular Weight	411.88

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, cadmium salt, basic**
CAS Number	90411-62-4
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	398.82

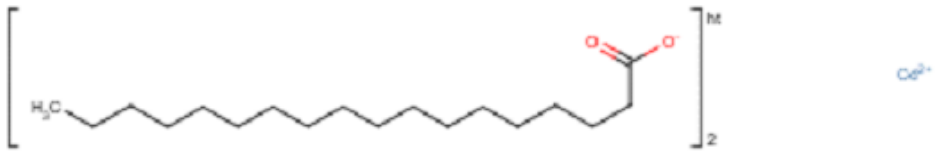
Chemical Name in the Inventory and Synonyms	**Fatty acids, castor oil, hydrogenated, cadmium salts**
CAS Number	91697-35-7
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

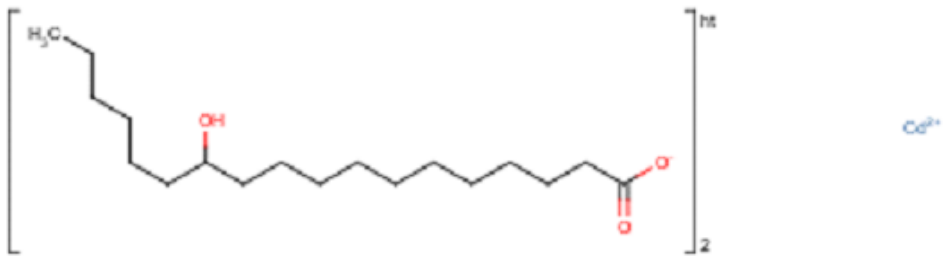
Chemical Name in the Inventory and Synonyms	**Isodecanoic acid, cadmium salt** Cadmium isodecanoate
CAS Number	93965-24-3
Structural Formula	
Molecular Formula	C10H20O2.1/2Cd
Molecular Weight	454.93

Chemical Name in the Inventory and Synonyms	**Isoundecanoic acid, cadmium salt** Cadmium bis(isoundecanoate)
CAS Number	93965-30-1
Structural Formula	
Molecular Formula	C11H22O2.1/2Cd
Molecular Weight	482.98

Chemical Name in the Inventory and Synonyms	**Dodecanoic acid, cadmium salt, basic** Basic cadmium laurate
CAS Number	101012-89-9
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	511.03

Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, cadmium salt, basic** Basic cadmium stearate

CAS Number	101012-93-5
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	679.36

Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, 12-hydroxy-, cadmium salt, basic**
CAS Number	101012-94-6
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	711.35

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