Manganese soaps: Human health tier II assessment

08 March 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Octadecanoic acid, manganese(2+) salt	3353-05-7
Manganese tallate	8030-70-4
Octanoic acid, manganese salt	6535-19-9
Hexanoic acid, 2-ethyl-, manganese(2+) salt	13434-24-7
Hexanoic acid, 2-ethyl-, manganese salt	15956-58-8
Neodecanoic acid, manganese salt	27253-32-3
Isooctanoic acid, manganese(2+) salt	37449-19-7
Fatty acids, tall oil, manganese salts, basic	68648-07-7

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 consists of manganese soaps, which are manganese salts of fatty acids. They are grouped together due to their expected similarity in physico-chemical properties, and related end uses.

Import, Manufacture and Use

Australian

According to industry information, the chemicals manganese(2+) ethylhexanoate (CAS No. 13434-24-7) and manganese ethylhexanoate (CAS No. 15956-58-8) have reported domestic and commercial uses in paints, at a concentration of 0.05–0.2 %.

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

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the United States (US) Environmental Protection Agency (EPA) ChemView database; the US EPA Chemistry Dashboard; the US National Library of Medicine's Household Products Database; and the Kirk-Othmer Encyclopedia of Chemical Technology (Pisarczyk, 1995).

The chemicals have reported domestic and commercial uses, including:

- as paint or varnish driers (CAS Nos 3353-05-7, 8030-70-4, 6535-19-9, 13434-24-7, 15956-58-8, 27253-32-3, 68648-07-7); and
- in lubricants (manganese tallate only, CAS No. 8030-70-4).

The chemicals have reported site-limited uses, including:

- as a catalyst in chemicals used in producing personal care and food contact products (manganese stearate only, CAS No. 3353-05-7);
- in formulations, mixtures or reaction products used to produce building materials, floor coverings, electrical and electronic products, plastic and rubber products, toys, playground and sporting equipment (manganese tallate only, CAS No. 8030-70-4).
- in ink or paint manufacturing (CAS Nos 8030-70-4, 13434-24-7, 15956-58-8, 27253-32-3);
- in metal, machine and electrical manufacturing (manganese 2-ethylhexanoate only, CAS No. 15956-58-8)

No specific international use, importation, or manufacturing information has been identified for the chemical manganese isooctanoate (CAS No. 37449-19-7).

Restrictions

Australian

No known restrictions have been identified.

International

No known international restrictions have been identified for the specific chemicals in this group.

Manganese compounds are limited to 60 mg/kg (as Mn) as polymerisation aids for plastics intended to come into contact with food (Council of Europe Resolution AP (92) 2) (Galleria Chemica).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

The following exposure standard is identified for manganese compounds (Safe Work Australia) and considered relevant to the chemical:

- manganese, dust and compounds (as Mn) have an exposure standard of 1 mg/m^3 time weighted average (TWA).

International

The following exposure standards are identified for manganese compounds (Galleria Chemica) and considered relevant to the chemicals:

- TWA values of 0.02–5 mg/m^3; and
- short-term exposure limit (STEL) values of 0.6–3 mg/m^3.

Health Hazard Information

Only limited data are available for one of the chemicals in this group (manganese 2-ethylhexanoate, CAS No. 15956-58-8). The toxicity of manganese compounds, including the chemicals in this assessment, is considered due to the presence of the manganese component (cation). The various fatty acid components (anions) of these manganese soaps are considered to be chemicals of low concern to human health, with the exception of the 2-ethylhexanoic acid (2-EHA) anion which is toxicologically distinct and hazardous as a standalone chemical.

When data for the chemicals being assessed are not available, health hazard information for soluble manganese compounds has been included in this report to cover exposure to the manganese component of the metal soaps. The assessed soluble manganese compounds are classified for acute oral toxicity, eye irritation, and neurotoxicity following repeated oral and inhalation exposure (NICNASa). For the acute and local effects of manganese soaps, bioaccessibility data was used to better represent the bioavailability of manganese (see **Toxicokinetics** section). Bioaccessibility is an in vitro estimation of in vivo bioavailability, allowing for uptake and systemic toxicity of metals to be more accurately assessed. Should specific bioaccessibility and/or bioavailability data become available, the extent to which the classification for soluble manganese compounds has been applied to this group of chemicals could be re-examined.

Health hazard information for 2-EHA (CAS No. 149-57-5; NICNASb) has also been included in this report, where relevant. The chemical 2-EHA is classified for skin irritation and reproductive/developmental toxicity (NICNASb). The skin irritation effects of 2-EHA are associated with the acidity of this chemical, and are not expected to be manifested by salts of 2-EHA.

The Tier II human health assessment for 'Soluble manganese compounds' is available at: **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1626** and the Tier II human health assessment for 2-EHA is available at:

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=787. These reports should be read in conjunction with this assessment.

Toxicokinetics

The chemicals are considered to be insoluble in water, based on information available for other manganese soaps (e.g. manganese oleate and manganese linoleate) (Lewis & Hawley, 1997). However, manganese is expected to be bioaccessible, or available for release into synthetic biological fluids mimicking physiological conditions, as has been measured for nickel compounds. Bioaccessibility is considered a better measure of in vivo bioavailability than water solubility (Henderson et al., 2012). Nickel and manganese are both transition metals that primarily exist in the 2^+ oxidation state following systemic absorption, and so similar bioaccessibility is expected. Their hazards are related to the bioavailability of the soluble metal 2^+ ions.

For common nickel compounds of varying water solubilities (insoluble, sparingly soluble and water soluble), relative Ni^{2+} bioaccessibility—the proportion of nickel content released in 2 hours from the total available nickel—was measured to be 0–91 % in artificial stomach fluid (pH 1.5). Artificial stomach fluid is a surrogate for measuring systemic availability following oral exposure. Bioaccessibility of water soluble nickel compounds was higher (82–91 %) than that of insoluble or sparingly soluble nickel compounds (0–30 %) after 2 hours, but bioaccessibility increased up to a high of 86 % for the sparingly soluble or insoluble nickel compounds after 72 hours. Bioaccessibility was lower in artificial intestinal fluid (pH 7.4). In vitro bioaccessibility in artificial stomach fluid correlated well (R^2 = 0.91) with the measured in vivo oral median lethal dose (LD50) values available for some of the nickel compounds. Furthermore, by regression analysis, in vitro bioaccessibility could be used to predict oral LD50 classification categories for other nickel compounds (Henderson et al., 2012). Based on these studies, the health effects from exposure to the Ni^{2+} component of nickel soaps (NICNASc) were read-across from studies on soluble nickel compounds (nickel chloride (NICNASd) and nickel sulfate). The spectrum of bioaccessibility observed for nickel compounds of varying water solubilities is expected to be similarly reflected for manganese compounds.

Manganese bioaccessibility has also recently been measured, but only using soil samples and particulate matter (PM_{10}) air fractions. Soils were analysed in artificial gastric (stomach and intestinal) fluids as a surrogate for oral bioavailability following geophagia (deliberate consumption of soil-like substances) in four African countries (Ngole-Jeme et al., 2018), and PM_{10} fractions were analysed in artificial lung fluids (Gamble's solution representing interstitial fluid and artificial lysosomal fluid (ALF) representing the alveolar macrophage environment) as a surrogate for systemic availability following inhalation exposure in urban and industrial areas in Northern Spain (Hernandez-Pellon et al., 2018). The relevance of these studies to the bioaccessibility of manganese soaps is unclear, as the manganese in soil and air is present in metal mixtures.

Acute Toxicity

Oral

No data are available for the chemicals. Soluble manganese compounds are classified as hazardous with hazard category ‘Acute Toxicity – Category 4’ and hazard statement ‘Harmful if swallowed’ (H302) on the HCIS (Safe Work Australia) and the available data for soluble manganese chemicals support this classification (NICNASa).

Assuming that manganese soaps will be orally bioavailable based on the available bioaccessibility data—even if to a lower extent than soluble manganese compounds (see **Toxicokinetics** section), hazard classification is warranted (see **Recommendation** section).

Corrosion / Irritation

Skin Irritation

Based on the available data for manganese 2-ethylhexanoate (CAS No. 15956-58-8), the chemicals are not considered to be irritating to skin. This is also supported by the available data for soluble manganese compounds (NICNASa).

In an in vivo skin irritation study (Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 404), female Himalayan rabbits (n = 3) were exposed (semi-occlusive) to 500 mg of the chemical on shaved skin for 4 hours, and observed for 72 hours following treatment. There were no skin reactions in any rabbit at any observation time point—for all animals, erythema and oedema scores were 0 at 24, 48 and 72 hours (REACH).

Eye Irritation

Based on the available data for manganese 2-ethylhexanoate (CAS No. 15956-58-8), the chemicals are considered to be irritating to eyes, warranting hazard classification (see **Recommendation** section). This is supported by the available data for

soluble manganese compounds (NICNASa). The lower classification for manganese soaps compared with soluble manganese compounds is also supported by the expected comparatively reduced bioavailability (see **Toxicokinetics** section).

In an in vivo eye irritation study (OECD TG 405), male New Zealand White (NZW) rabbits (n = 2) were exposed to 93 mg of the chemical in one eye and observed for 14 days following treatment. Corneal opacity was observed in treated eyes from 24–72 hours in one rabbit and up to 7 days in the other rabbit, but effects were fully reversible by 7 and 14 days, respectively. The average corneal score for 24, 48 and 72 hours was 1/4. Iris effects were observed, but were fully reversible within 14 days—slight inflammation at 1 hour, and slight to moderate or severe discharge from 1 hour to day 7 were reported. The average iris score for 24, 48 and 72 hours was 1/2. There was slight to moderate conjunctival redness (average score for 24, 48 and 72 hours was 1.84/3) and slight to moderate chemosis (average score for 24, 48 and 72 hours was 2.34/4) until day 7, but effects were fully reversible within 14 days (REACH).

In an in vitro eye irritation study (OECD TG 437), corneas from freshly isolated bovine eyes were exposed to a 20 % w/v suspension of the chemical in physiological saline for 240 minutes. The in vitro irritation score (based on opacity and permeability measurements) was calculated to be 0.06 for the chemical, compared with 2.17 for physiological saline (negative control) and 156.46 for 10 % w/v benzalkonium chloride (positive control). The chemical was not considered to be corrosive or severely irritating since it did not reach the threshold score of ≥55.1 (REACH).

Repeated Dose Toxicity

Oral

No data are available for the chemicals. Soluble manganese compounds are classified as hazardous with hazard category 'Specific target organ toxicity (repeated exposure) – Category 1' and hazard statement 'Causes damage to organs through prolonged or repeated exposure if swallowed or inhaled' (H372) on the HCIS (Safe Work Australia). Based on oral bioaccessibility (see **Toxicokinetics** section) and the neurological effects reported in humans following chronic oral and inhalational manganese exposure (see **Other health effects: Neurotoxicity** section), manganese soaps are recommended for classification (see **Recommendation** section).

Genotoxicity

No data are available for the chemicals. Based on the available data for soluble manganese compounds (NICNASa), 2-EHA (NICNASb), and that fatty acids are chemicals of low concern to human health, the chemicals are not considered to be genotoxic.

Carcinogenicity

No data are available for the chemicals. Based on the available data for soluble manganese compounds (NICNASa), limited data for 2-EHA (NICNASb), and that fatty acids are chemicals of low concern to human health, the chemicals are not considered to be carcinogenic.

Reproductive and Developmental Toxicity

No data are available for the chemicals. Soluble manganese compounds are not considered likely to have reproductive and developmental toxicity (NICNASa). The chemical 2-EHA is classified as hazardous with hazard category 'Reproductive toxicity – Category 2' and hazard statement 'Suspected of damaging fertility or the unborn child' (H361) on the HCIS. This is considered relevant for the manganese soaps containing the 2-EHA anion only (CAS No. 13434-24-7 and CAS No. 15956-58-8), warranting hazard classification (see **Recommendation** section).

Other Health Effects

Neurotoxicity

Chronic inhalation and oral exposure to manganese impaired the central nervous system (CNS) function in humans (NICNASa), resulting in a syndrome known as manganism. Classification for neurotoxicity is; therefore, based on the disabling neurological effects observed in humans following chronic manganese exposure.

Risk Characterisation

Critical Health Effects

The critical health effect for risk characterisation is neurotoxicity. Manganese 2-EHA salts (CAS No. 13434-24-7 and CAS No. 15956-58-8 only) can cause reproductive/developmental toxicity. All chemicals can also cause harmful systemic effects following a single oral exposure and eye irritation.

Public Risk Characterisation

The chemicals are potentially used in paints, varnishes and lubricants. The main route of public exposure is expected to be through the skin and inhalation. However, high concentrations are not expected to be present in paints and varnishes, as these chemicals are used as drying agents, and only limited dermal absorption of manganese is expected. Hence, the risk from exposure is not considered unreasonable.

Occupational Risk Characterisation

During product formulation, dermal, inhalation and ocular exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term, systemic acute and local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise exposure 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see **Recommendation** section).

NICNAS Recommendation

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

Regulatory Control

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental

hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

The classification for reproductive and developmental toxicity only applies to the manganese 2-EHA salts (CAS No. 13434-24-7 and CAS No. 15956-58-8 only).

In the absence of specific data on chemicals in this group, data have been read-across from the NICNAS assessments of soluble manganese compounds and 2-EHA (NICNASa; NICNASb). Should empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for the specific chemical, this may be used to amend the default classification for that chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319)
Repeat Dose Toxicity	Not Applicable	Causes damage to nervous system through prolonged or repeated exposure through inhalation and oral routes - Cat. 1 (H372)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging fertility or the unborn child - Cat. 2 (H361fd)

[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 industry

Control measures

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

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;

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

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

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

Obligations under workplace health and safety legislation

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

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

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

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

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

References

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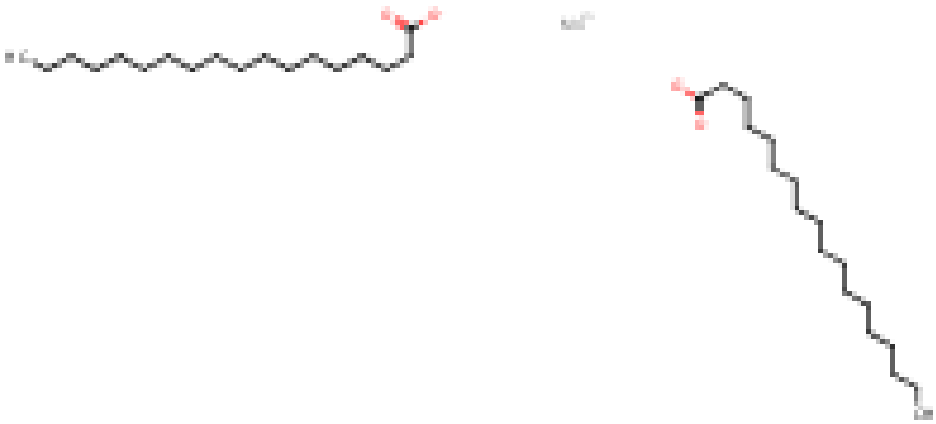
Last Update 08 March 2019

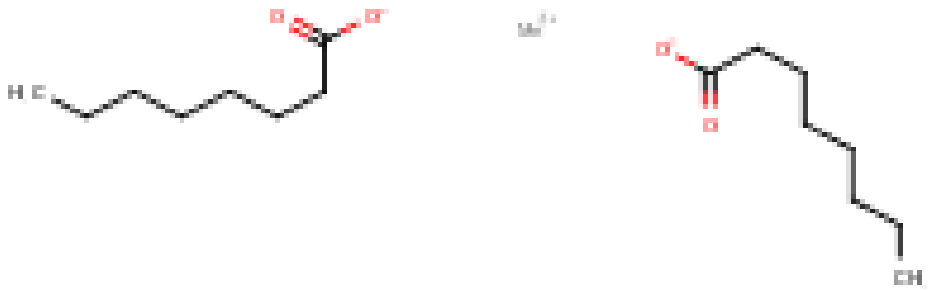
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Octadecanoic acid, manganese(2+) salt** manganese(2+) dioctadecanoate manganese stearate manganese distearate stearic acid manganese(2+) salt
CAS Number	3353-05-7
Structural Formula	

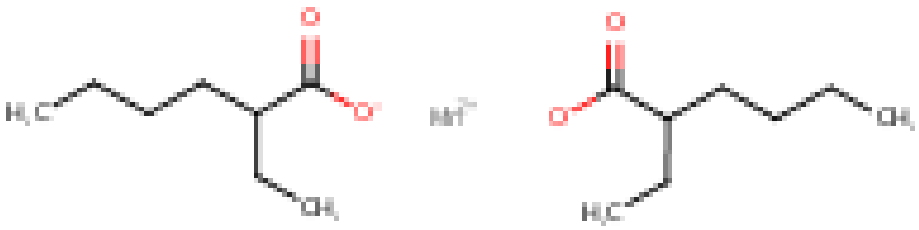
	
Molecular Formula	C18H36O2.1/2Mn
Molecular Weight	621.88

Chemical Name in the Inventory and Synonyms	**Manganese tallate** fatty acid, tall oil, manganese(2+) salt fatty acids, tall-oil, manganese salts tall oil, manganese salts
CAS Number	8030-70-4
Structural Formula	**No Structural Diagram Available**

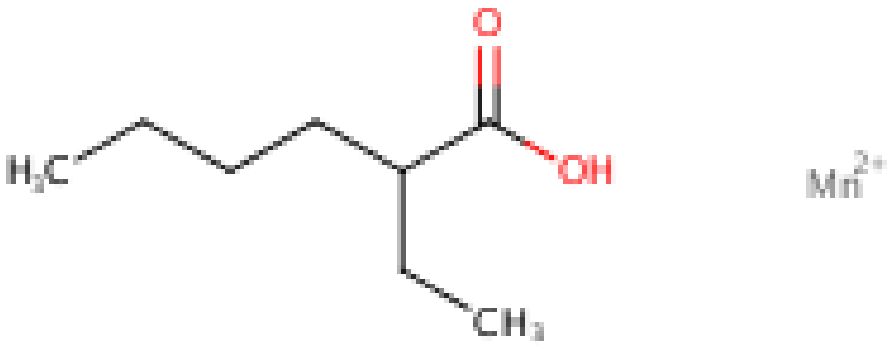
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	**Octanoic acid, manganese salt** manganese octoate manganese(2+) octanoate dioctanoic acid manganese(II) salt manganese caprylate
CAS Number	6535-19-9
Structural Formula	
Molecular Formula	C8H16O2.xMn
Molecular Weight	341.35

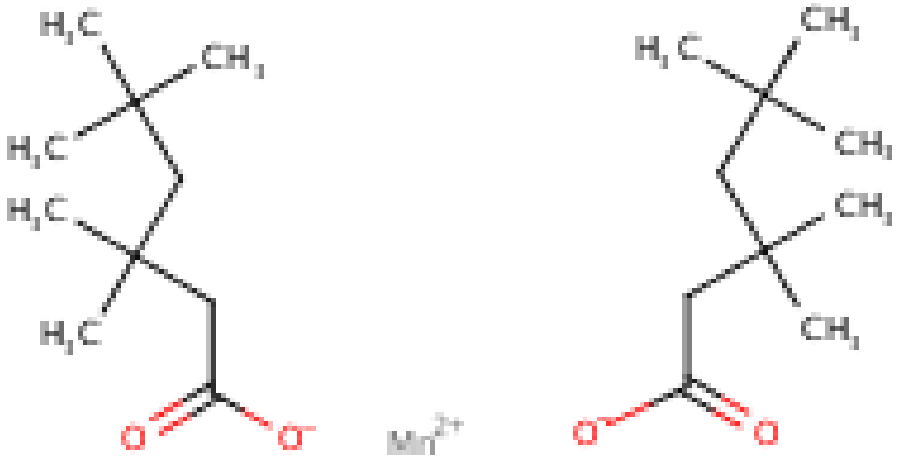
Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, manganese(2+) salt** 2-ethylhexanoate, manganese(2+) manganese bis(2-ethylhexanoate)

CAS Number	13434-24-7
Structural Formula	
Molecular Formula	C8H16O2.1/2Mn
Molecular Weight	341.35

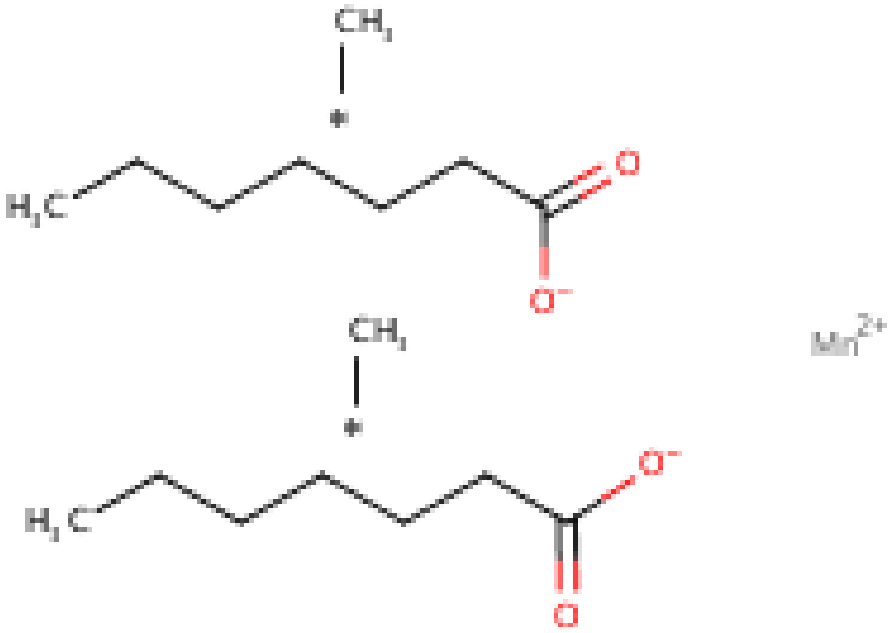
Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, manganese salt** manganese 2-ethylhexanoate manganese 2-ethylhexoate manganese soap of 2-ethylhexoic acid manganese octoate
CAS Number	15956-58-8
Structural Formula	

	
Molecular Formula	C8H16O2.xMn
Molecular Weight	199.15

Chemical Name in the Inventory and Synonyms	**Neodecanoic acid, manganese salt** manganese neodecanoate manganese(2+) 3,3,5,5-tetramethylhexanoate
CAS Number	27253-32-3
Structural Formula	

	
Molecular Formula	C10H20O2.xMn
Molecular Weight	397.45

Chemical Name in the Inventory and Synonyms	**Isooctanoic acid, manganese(2+) salt** manganese isooctanoate manganese(II) isooctanoate manganese(2+) bis(6-methylheptanoate)
CAS Number	37449-19-7
Structural Formula	

	
Molecular Formula	C8H16O2.1/2Mn
Molecular Weight	343.36

Chemical Name in the Inventory and Synonyms	**Fatty acids, tall oil, manganese salts, basic** tall oil acids, basic manganese salt tall oil fatty acids, manganese salts, basic
CAS Number	68648-07-7
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	Unspecified

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