Long chain alkyl esters of 2-ethylhexanoic acid: Human health tier II assessment

28 June 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Hexanoic acid, 2-ethyl-, hexadecyl ester	59130-69-7
Hexanoic acid, 2-ethyl-, octadecyl ester	59130-70-0
Hexanoic acid, 2-ethyl-, tetradecyl ester	72201-45-7
Hexanoic acid, 2-ethyl-, C12-15-alkyl esters	90411-66-8
Hexanoic acid, 2-ethyl-, tridecyl ester	125804-07-1
Hexanoic acid, 2-ethyl-, C16-18-alkyl esters	90411-68-0

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 6 chemicals consists of long chain alkyl esters of 2-ethylhexanoic acid (referred to as alkyl ethylhexanoates). These chemicals have been included in this group due to the expectation that their physico-chemical properties will not vary greatly, leading to these alkyl ethylhexanoates having related end use.

Each chemical in this group is produced through the esterification of 2-ethylhexanoic acid (2-EHA; CAS No. 149-57-5) and its respective long alkyl chain alcohol; therefore, they are expected to hydrolyse to these compounds via chemical or enzymatic processes.

For the purposes of this report, the chemicals in this group will be referred to by the following respective synonyms:

- cetyl ethylhexanoate (CAS No. 59130-69-7);
- stearyl ethylhexanoate (CAS No. 59130-70-0);
- myristyl ethylhexanoate (CAS No. 72201-45-7);
- C12-15-alkyl ethylhexanoate (CAS No. 90411-66-8);
- cetearyl ethylhexanoate (CAS No. 90411-68-0); and

- tridecyl ethylhexanoate (CAS No. 125804-07-1).

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the US Department of Health and Human Services Household Products Database (HPD); the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and Galleria Chemica.

The chemicals in this group are reported to have cosmetic use as emollients and skin conditioners in:

- make-up (lipstick, blush, foundation and concealer) products;
- face creams, hand creams and body lotions; and
- hair care products.

Cetearyl ethylhexanoate and cetyl ethylhexanoate are reported to have domestic uses, including in:

- laundry, washing and cleaning (including carpet cleaning) products;
- inks and toners;
- anti-freeze and de-icing products;
- adhesives and sealants; and
- waxes and polishing products.

Cetearyl ethylhexanoate and cetyl ethylhexanoate are reported to have commercial uses including:

- in lubricants and additives;
- in reprographic agents; and
- as a solvent.

The following non-industrial uses have been identified internationally for cetearyl ethylhexanoate:

- in skin fading/lightener products; and
- in fertiliser and plant protection products.

Restrictions

Australian

The chemicals in this group are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 6 (SUSMP, 2019).

Schedule 6:

'2-ETHYLHEXANOIC ACID and its alkyl esters except in preparations containing 5 per cent or less calculated as 2-ethylhexanoic acid.'

Schedule 6 chemicals are described as 'Substances with a 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'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2019).

Additionally, cetearyl ethylhexanoate (CAS No. 90411-68-0) is listed on the Australian Inventory of Chemical Substances – AICS (the Inventory), with the following annotation regarding conditions of use:

- For cosmetic use only.
- The concentration is not to exceed 5 %.

International

No known restrictions have been identified.

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

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

While limited health hazard information is available for the specific chemicals in this group, each of the chemicals is expected to hydrolyse by chemical or enzymatic process, to produce its respective long chain alkyl alcohol component and 2-EHA (CAS No. 149-57-5). Each of the alcohol components have been assessed by NICNAS and determined to be of low concern in regards to human health (NICNASa) and these are not expected to contribute to the toxicity of the esters in this group (CIR, 2013; Fiume et al., 2015). The common hydrolysis product, 2-EHA, across these esters has been assessed by NICNAS (NICNASb) and, where relevant, available information for 2-EHA has been included in this report.

Toxicokinetics

The chemicals in this group are expected to hydrolyse in the gastrointestinal tract to form 2-EHA and the corresponding alcohol component. These hydrolysis products are then likely to follow their own respective metabolic pathways (Fiume et al., 2015).

Acute Toxicity

Oral

The chemicals in this group are expected to have low acute toxicity in rats following oral exposure. The oral median lethal dose (LD50) for cetyl ethylhexanoate was reported to be >2000 mg/kg bw in rats (REACHa), while the oral LD50 for an unspecified constituent of C12-15-alkyl ethylhexanoate was reported to be >5000 mg/kg bw in rats (REACHb). No documented signs of toxicity are available.

Dermal

Only limited data are available. The dermal LD50 for an unspecified constituent of C12-15-alkyl ethylhexanoate was reported to be >2000 mg/kg bw in rats (REACHb). No documented signs of toxicity are available.

Inhalation

No reliable data are available.

Corrosion / Irritation

Skin Irritation

A Cosmetic Ingredient Review (CIR) of 16 alkyl ethylhexanoates, including the chemicals in group, concluded that there is concern regarding potential irritancy of these chemicals (CIR, 2013; Fiume et al., 2015). This conclusion was based on a number of experimental studies and observations in humans demonstrating that cetyl ethylhexanoate is irritating to the skin. However, it is also reported that formulations containing cetearyl ethylhexanoate generally did not produce skin irritation reactions (CIR, 2013; Fiume et al., 2015).

Eye Irritation

While cetearyl ethylhexanoate was reported to not be an ocular irritant in rabbits (CIR, 2013; Fiume et al., 2015), a study in rabbits using cetyl ethylhexanoate reported conjunctival redness was not reversible in 1 animal for up to 72 hours (REACHc). As this was the maximum observation period of the study, there is insufficient information to determine reversibility of this effect. However, based on the limited available information, there is concern regarding the potential ocular irritancy of these chemicals in rabbits.

Sensitisation

Skin Sensitisation

The CIR assessment of alkyl ethylhexanoates did not come to a conclusion regarding potential skin sensitisation, although it was noted that cetearyl ethylhexanoate was reported to not cause skin sensitisation in humans based on a patch test study using 103 volunteers (CIR, 2013; Fiume et al., 2015).

The chemicals in this group do not contain any functional groups associated with skin sensitisation, which is consistent with the observation that hydrolysis products of each of the chemicals, 2-EHA and the relevant alcohol component, are non-sensitising (NICNAS a; NICNAS b).

Repeated Dose Toxicity

Oral

No specific or reliable data are available for the chemicals in this group.

While experimental data are available for the common hydrolysis product of these chemicals, 2-EHA (NICNASb), the data are limited and insufficient to extrapolate the conclusions to this group of chemicals.

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

While limited data are available for the specific chemicals in this group, they are not expected to be genotoxic.

In an in vitro bacterial reverse mutation assay (AMES test) conducted according to OECD Test Guideline (TG) 471, cetyl ethylhexanoate was reported to not be mutagenic in *Salmonella typhimurium* bacterial strains TA 1535, TA 1537, TA 98, TA 100 and TA 102 at test concentrations of 312.5–5000 µg/plate, with and without metabolic activation (REACHa).

In an in vitro mammalian cell micronucleus test, conducted according to OECD TG 487, it was reported that C12-15-alkyl ethylhexanoate did not induce micronuclei in human lymphoblastoid cells (TK6) at test concentrations up to 750 µg/mL (reported as the limit of solubility) in the absence of metabolic activation, and up to 2000 µg/mL in the presence of metabolic activation (REACHb).

Additionally, the hydrolysis products of each of the chemicals, 2-EHA and the relevant alcohol component, have been assessed by NICNAS and are not considered to be genotoxic (NICNAS a; NICNAS b).

Carcinogenicity

While no specific data are available on the chemicals in this group, the hydrolysis products of each of the chemicals, 2-EHA and the relevant alcohol component, have been assessed by NICNAS and are not considered to be carcinogenic (NICNAS a; NICNAS b).

Reproductive and Developmental Toxicity

Limited data are available for the chemicals in this group.

A developmental toxicity study of cetearyl ethylhexanoate in Wistar rats is available, conducted similar to OECD TG 414 with deviations to the guideline being that the test substance was only administered during organogenesis (days 6–15 of gestation).

In this study cetearyl ethylhexanoate was administered by oral gavage to pregnant females (25 animals per group), at 600, 1000 or 1500 mg/kg bw/day from gestation day (GD) 6 through to GD 15 (REACHc). While no clinical signs of maternal toxicity were observed in this study, a statistically significant increase in the total rate of foetuses with skeletal malformations (particularly bipartite sternebra or sternebrae, with dislocated ossification centres) was reported in the 1000 mg/kg bw/day maternal dose group compared with the vehicle control group. Statistically significant increased occurrences of just 1 skeletal retardation (incomplete ossification of thoracic vertebral body or bodies) in foetuses from the 600 and 1500 mg/kg bw/day maternal dose groups were also reported. The study authors reported that these effects were within the historical control range.

2-EHA, the common hydrolysis product for all the esters in this group, is classified as hazardous with the hazard category 'Toxic to reproduction' (Category 2), with the hazard statement ‘Suspected of damaging fertility or the unborn child’ (H361) in the HCIS (Safe Work Australia).

The hydrolysis product, 2-EHA, was reported in several studies to cause developmental toxicity in rats following treatment via the oral route (NICNASb). These effects, including foetal skeletal variations, malformations, reduced foetal body weights and early foetal deaths, were noted in the absence of signs of maternal toxicity. The lowest observed adverse effect level (LOAEL) for developmental toxicity was reported to be 100 mg/kg bw/day. Effects on the male reproductive system (reduction in sperm motility) and fertility were also observed at 100 mg/kg bw/day.

Based on the proportion of 2-EHA formed on hydrolysis of the smallest (C12-alkyl) and the largest (C18-alkyl) esters in this group, equivalent doses of the esters required to reach the level of toxicity reported for 2-EHA (LOAEL of 100 mg/kg bw/day), range from 217–275 mg/kg bw/day.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation relate to the uncertainty associated with developmental effects as a result of metabolism to 2-EHA. The chemicals in this group may also cause skin and eye irritation.

Public Risk Characterisation

Although use of the chemicals in cosmetic or domestic products in Australia is not known, the majority of chemicals in this group are reported to be used in cosmetic and domestic products overseas, that are potentially available for consumer use in Australia.

In a 2018 Canadian quantitative risk assessment, the developmental LOEAL of 100 mg/kg bw/day for 2-EHA was used as the critical effect level in determining risk to human health from use of cosmetic products containing the 2-EHA ester, 2-ethylhexyl 2-ethylhexanoate (Government of Canada, 2018). Based on the level of 2-EHA available on hydrolysis, the Canadian report considered the margin of exposure for reported cosmetic products to be 'potentially inadequate to account for uncertainties in the health effects and exposure databases. In particular, the health effects endpoint (i.e. developmental toxicity) is severe, and the LOAEL of 100 mg/kg-bw/day was the lowest dose tested, indicating a potentially lower critical effect level' (Government of Canada, 2018).

Considering the range of domestic, cosmetic and personal care products that may contain these chemicals, the main route of public exposure is expected to be through the skin, with some of the chemicals in this group predominantly reported to be used in leave-on cosmetic products overseas at the following maximum use concentrations (CIR, 2013; Fiume et al., 2015):

- 52 % for cetyl ethylhexanoate;
- 35 % for cetearyl ethylhexanoate;
- 22 % for C12-15 alkyl ethylhexanoate; and
- 10 % for stearyl ethylhexanoate.

The CIR Panel concluded in their 2013 report (CIR, 2013), which was subsequently published in 2015 (Fiume et al., 2015) that the alkyl ethylhexanoates, which includes the chemicals in this group, are 'safe in the present practices of use and concentration described', so as long as the product is formulated to be non-irritating. However, based on the relative molecular weight of the chemicals in this group, all except for stearyl ethylhexanoate (at 10 %) would result in formation of 2-EHA at proportions of >5 % on hydrolysis of each of the esters at their respective reported maximum use concentrations. Products at these concentrations would need to be labelled according to the Poisons Standard in Australia (SUSMP, 2019).

As the chemicals in this group are all esters of 2-EHA, they are currently covered by the listing of 2-EHA on Schedule 6 of the Poisons Standard (SUSMP, 2019) for preparations containing >5 % of 2-EHA (see **Restrictions** section). Additionally, a number of warning statements, first aid instructions and safety directions relating to use of these chemicals at any concentration, apply.

In relation to cetearyl ethylhexanaoate, use of this chemical in products other than cosmetics, or at greater than 5 %, is not covered by the existing AICS entry (see **Restrictions** section), and as such, would be deemed to be a new industrial chemical under the definition given in Section 5 of the Industrial Chemicals (Notification and Assessment) Act 1989.

Occupational Risk Characterisation

During product formulation, exposure to these chemicals may 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.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory. At this stage no further assessment is required under the IMAP framework.

Regulatory Control

Public Health

Products containing the chemicals in this group should be labelled in accordance with state and territory legislation (SUSMP, 2019). It should also be noted that products containing the chemicals at concentrations greater than the equivalent of 5 % 2-EHA may not be used in Australia unless labelled as required by the SUSMP.

Work Health and Safety

Whilst there is uncertainty associated with developmental effects as a result of metabolism to 2-EHA, the chemicals are unlikely to pose a risk to workers. Information in this report can be used by a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) to determine the appropriate controls.

Advice for consumers

Products containing the chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal or 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:

- 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;
- 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.

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NICNAS b. NICNAS IMAP Human Health Tier II Assessment for Hexanoic acid, 2-ethyl- (149-57-5). Available at **http://www.nicnas.gov.au**

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REACH b. REACH Dossier for Hexanoic acid, 2-ethyl-, C12-15-alkyl esters (CAS RN 90411-66-8). Accessed April 2019 at **http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances**

REACH c. REACH Dossier for Hexanoic acid, 2-ethyl-, C16-18-alkyl esters (CAS RN 90411-68-0). Accessed April 2019 at **http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances**

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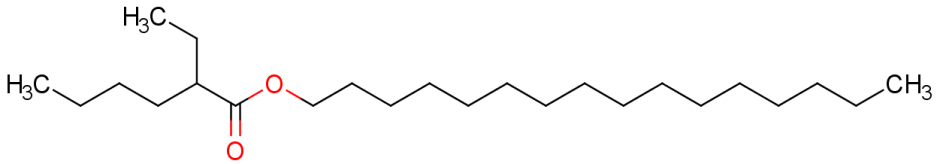
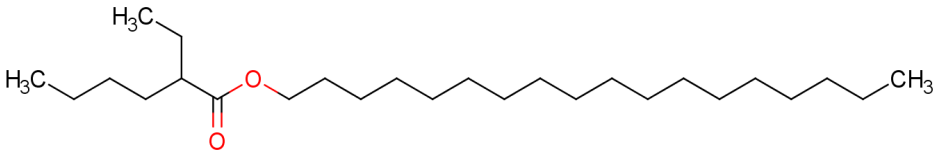
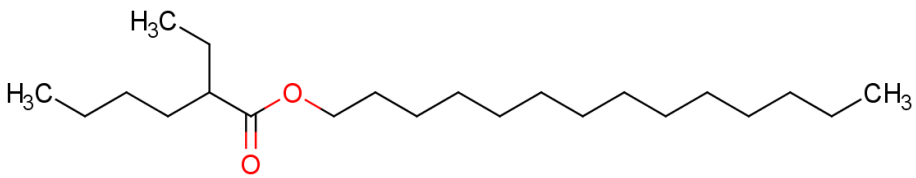
Last Update 28 June 2019

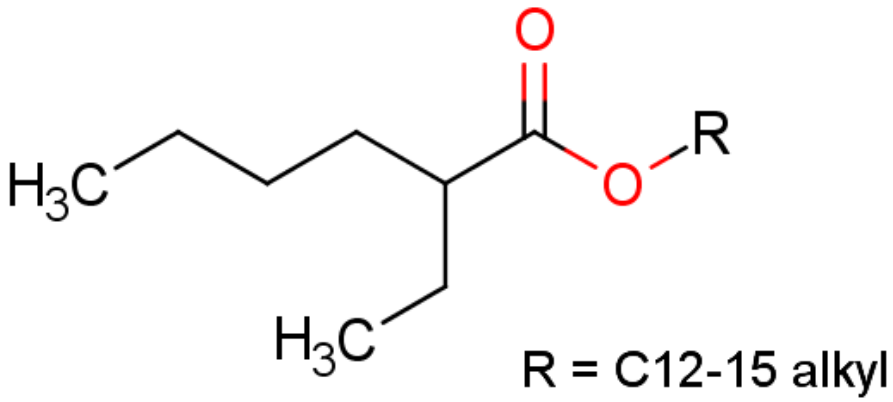
Chemical Identities

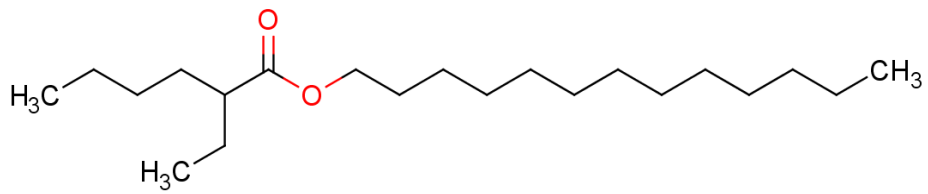
Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, hexadecyl ester** 2-ethylhexanoic acid, hexadecyl ester hexadecyl 2-ethylhexanoate cetyl 2-ethylhexanoate cetyl octanoate
CAS Number	59130-69-7
Structural Formula	

	
Molecular Formula	C24H48O2
Molecular Weight	368.64

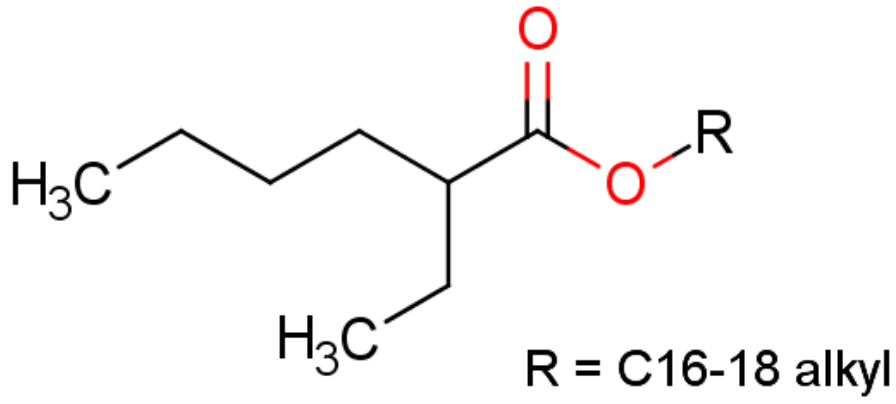
Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, octadecyl ester** 2-ethylhexanoic acid, octadecyl ester octadecyl 2-ethylhexanoate stearyl 2-ethylhexanoate stearyl octanoate
CAS Number	59130-70-0
Structural Formula	
Molecular Formula	C26H52O2
Molecular Weight	396.69

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, tetradecyl ester** 2-ethylhexanoic acid, tetradecyl ester tetradecyl 2-ethylhexanoate myristyl ethylhexanoate
CAS Number	72201-45-7
Structural Formula	
Molecular Formula	C22H44O2
Molecular Weight	340.58

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, C12-15-alkyl esters** 2-ethylhexanoic acid, C12-15 alkyl esters C12-15-alkyl ethylhexanoate (C12-15) Alcohols, octanoate
CAS Number	90411-66-8
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, tridecyl ester** 2-ethylhexanoic acid, tridecyl ester tridecyl 2-ethylhexanoate tridecyl ethylhexanoate
CAS Number	125804-07-1
Structural Formula	
Molecular Formula	Not specified
Molecular Weight	326.55

Chemical Name in the Inventory and Synonyms	**Hexanoic acid, 2-ethyl-, C16-18-alkyl esters** 2-ethylhexanoic acid, C16-18 alkyl esters cetearyl ethylhexanoate

	cetearyl octanoate
CAS Number	90411-68-0
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	

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