



6:2 Fluorotelomer siloxanes and silicones: Human health tier II assessment

21 April 2016

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Silane, triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-	51851-37-7
Silane, dichloromethyl(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-	73609-36-6
Silane, trichloro(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-	78560-45-9
Silane, trimethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-	85857-16-5
Silane, dimethoxymethyl(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-	85857-17-6
2-Butanone, O,O',O''-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silyldiyne]oxime	94158-20-0
Siloxanes and silicones, dimethyl, methyl 3-(1,1,2,2-tetrafluoroethoxy)propyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl-	104780-70-3

Chemical Name in the Inventory	CAS Number
Siloxanes and silicones, dimethyl, methyl 3-(1,1,2,2-tetrafluoroethoxy)propyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated	115340-94-8
Siloxanes and silicones, dimethyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl	115340-95-9
Siloxanes and silicones, dimethyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated	115340-96-0
Siloxanes and silicones, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated	115341-00-9

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are structurally related substances with a chain of perfluorinated carbons linked to a silicon atom by two non-fluorinated carbon atoms. The perfluorinated carbon chain in all chemicals is part of a 6:2 fluorotelomer. These chemicals may degrade to perfluorocarboxylic acids (PFCAs) (OECD, 2007).

NICNAS has developed an action plan to assess and manage chemicals which may degrade to PFCAs, perfluoroalkane sulfonates (PFASs) or similar chemicals. The primary assumption outlined in the action plan is that chemicals with a perfluorinated chain terminated with an alkyl or aryl group will degrade to form a mix of PFCAs with both the original chain length and with one less perfluorinated carbon atom (for more information, see Appendix G of the NICNAS Handbook for Notifiers (NICNASa)).

In cases where the 6:2 fluorotelomer in the chemicals is hydrolysed to 6:2 fluorotelomer alcohol, the biotic and abiotic degradation is well understood (Danish EPA, 2015) and is expected to primarily result in the loss of one fluorinated carbon atom leading to the formation of perfluorohexanoic acid (PFHxA) as the degradation product (Nielsen, 2012; Ruan et al., 2014). However, as the fluorotelomer in these chemicals is directly bonded to electropositive silicon atom, the mechanism of degradation is unclear and therefore a greater proportion of the original perfluorinated carbon chain may be retained, resulting in the formation of perfluorinated heptanoic acid (PFHpA).

The chemical PFHxA is considered a short-chain perfluorinated carboxylate (containing five or less perfluorinated carbon atoms) with potentially better human health outcomes and bioaccumulation than chemicals with longer perfluorinated carbon chain (NICNASb). On the other hand, the chemical PFHpA is structurally intermediate between the long-chained perfluorinated carboxylates (seven or more perfluorinated carbon atoms, including perfluorooctanoic acid (PFOA)), and the short-chain perfluorinated carboxylates. It is not currently clear whether the hazards for the intermediate chain-length acids are comparable to the homologous long-chain or short-chain PFCAs (NICNASc). Therefore, due to this uncertainty, PFOA hazard information was used, as a worst case scenario, to estimate the hazard of PFHpA. The chemical PFOA and its direct precursors have been previously assessed by NICNAS (NICNASd).

The degradation of PFCAs is very slow compared with their rate of formation from breakdown of parent chemicals (precursors). Since PFCAs will be the final degradants from multiple precursors, the amount of PFCAs in the environment (general or local) or in the body is expected to be higher than that of any of the precursors. It will therefore be assumed, for the purposes of this assessment, that the primary risk posed by the chemicals in this group results from the release of PFCAs. Due to the uncertainty of degradation pathway of perfluorosilanes, these chemicals should be treated as PFHpA precursors unless degradation data or reliable mechanistic information can demonstrate that they should be considered as PFHxA precursors. Therefore, this assessment will focus on long-term effects of PFHpA, using PFOA as an appropriate analogue for the reasons described above.

Import, Manufacture and Use

Australian

Based on information collected by NICNAS in 2006, indicated that the chemical was not expected manufactured, imported or used in Australia at that time (NICNAS, 2013).

It is noted that these chemicals could be present in the environment due to historic use, or due to release from articles or using precursor chemicals not covered by this assessment.

International

Tridecafluoro octyltriethoxysilane (CAS No 51851-37-7) is reported to be used as a binding additive in cosmetics (CosIng) as well as colourant-component in personal care products (Personal Care Products Council).

Some 6:2 fluorotelomer silanes or siloxanes (e.g. CAS No 51851-37-7 and 85857-17-6) are used in nanofilm spray products on surface coatings with non-stick properties, which are applied to surfaces such as bathroom tiles, floors, windows and textiles (UNEP, 2013; Wang et al, 2013; Danish EPA, 2015).

The 6:2 fluorotelomer trichlorosilane (CAS No 78560-45-9) has reported use as an intermediate (Galleria).

A fluoroalkyl silane product based on the tridecafluoro octyltriethoxysilane (CAS No 51851-37-7) acts as a surface modifier and can also be used as an adhesion promoter between inorganic materials and fluoropolymers (Evonik). It can be used on a wide variety of commercially important applications including:

- treatment of automotive glass ("wiperless windshield");
- easy-to-clean, water-repellent, UV-resistant coating of float glass (constructive glazing);
- additive for sol-gel systems;
- synthesis of fluorosilicones;
- coating of pigments;
- chemical vapour deposition (CVD) processes; and
- easy-to-clean coating on ceramics.

Restrictions

Australian

No known restrictions have been identified.

International

The following restrictions were reported for tridecafluorooctyltriethoxysilane (CAS No 51851-37-7):

In September 2013, Canada issued a Significant New Activity (SNA) notice for this substance. A significant new activity is defined as the use of the substance in Canada, in any quantity, other than its use as an industrial or commercial surface modification agent or as an industrial or commercial adhesion promoter between inorganic materials and fluoropolymers (Canada Gazette, 2013).

United States Environmental Protection Agency (US EPA) listed the chemical under Toxic Substances Control Act (TSCA), Section 5(a)(2) - Significant New Use Rules (SNURs) (Galleria).

Fluorotelomer silicones such as polyfluorooctyl triethoxysilane (tridecafluorooctyltriethoxysilane (CAS No 51851-37-7), a NanoCover™ product) used in a bathroom floor spray product and similar substances were banned in Denmark in April 2010 because of toxic effects on mouse lungs (UNEP, 2013).

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Very limited toxicity data were identified for the chemicals in this group. The chemicals can cause irritation to the eyes and skin (ECHA CLP) as well as irritation of the respiratory tract and acute lung injury if inhaled (Danish EPA, 2015; Hays & Spiller, 2014; Larsen et al, 2014; Norgaard et al, 2014). However, these chemicals are expected to be introduced into Australia in small quantities and, therefore, the primary health risk is expected to arise only from secondary, long-term exposure to the degradation products, the PFCAs. Therefore, this assessment will not concentrate on acute toxicity of these chemicals. Due to the uncertainty of the degradation pathway of these chemicals, they should be treated as PFHpA precursors, unless degradation data or reliable mechanistic information can demonstrate that they should be considered as precursors of PFHxA (see **Grouping rationale** section).

PFHpA and its precursors have been previously assessed by NICNAS (NICNASc). Hazard information from the assessment will be used to characterise the human health hazard of chemicals in this group.

Risk Characterisation

Critical Health Effects

The chemicals in this group could induce slight to moderate irritation in eyes and skin as well as acute lung injury if inhaled. However, these chemicals are expected to be introduced into Australia in small quantities and, therefore, the primary health risk is expected to arise only from secondary, long-term exposure to the degradation products, PFHpA (see **Grouping rationale** section). It is not currently clear whether the hazards for PFHpA (C7) are comparable to the long-chain PFOA (C8) or to the short-chain PFCAs (C6) (NICNASc). Therefore, due to uncertainty, PFOA hazard information is used, as a worst case, to estimate the hazard of PFHpA and its precursors.

The critical health effects for risk characterisation include systemic long-term effects (hepatotoxicity and developmental toxicity). The evidence for carcinogenicity is regarded as limited. For further information, see Tier II Human Health risk assessment for PFOA and direct precursors (NICNASc).

Public Risk Characterisation

Based on the available use information, the chemicals (especially CAS No 51851-37-7) may be present in cosmetics and personal care products as a binding additive. The concentrations of the chemical in cosmetics or personal care products is not

known but is expected to be low. Therefore, the public risk from direct use of these chemicals from these uses is not considered to be unreasonable.

Spray products containing chemicals in this group may present acute inhalation hazards and should information become available that these products are in use in Australia, further risk management may be required.

Secondary exposure to PFCAs via the environment

The primary health risk is expected to arise from secondary, long-term exposure to the degradation products of the chemicals in this group, with the main concern being PFHpA. It is noted that the degradation products are persistent and potentially bioaccumulative (NICNASc). Chemicals which are persistent and bioaccumulative remain in the environment and accumulate in biota over an extended period of time. However, currently reported blood levels of PFHpA are similar to levels found for PFHxA, which is more rapidly eliminated compared with PFHpA (NICNASb). This indicates that current exposure to PFHpA is generally low.

Occupational Risk Characterisation

Based on the available use information, the chemicals are not likely to be used by workers in significant quantities in Australia. Therefore the chemicals are not considered to pose an unreasonable risk to the health of workers.

Long term occupational exposure to low concentrations of PFHpA could occur while using these chemicals.

NICNAS Recommendation

The breakdown product of the chemicals in this group has the potential to cause adverse outcomes for the environment and public health. These chemicals are currently listed on the Australian Inventory of Chemical Substances (AICS), and are available to be introduced into Australia without any further assessment by NICNAS. Other chemicals with a reduced potential for adverse human health and environment outcomes are becoming available but, given the properties of these chemicals, their assessment as new chemicals under the Industrial Chemicals (Notification and Assessment) Act 1989 (the ICNA Act) is still required to fully characterise the human health and environmental risks associated with their use.

NICNAS will consider the chemicals in this group as being indirect precursors to PFHpA and subject to similar recommendations to these (NICNASe), unless information is made available to show that the dominant degradation product is PFHxA.

Regulatory Control

Advice for consumers

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

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 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.

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Nielsen, 2012. PFOA isomers, salts and precursors. Literature study and evaluation of physico-chemical properties. Klif project no. 3012013. Accessed March 2016 at <http://www.miljodirektoratet.no/old/klif/publikasjoner/2944/ta2944.pdf>

Norgaard AW, Hansen JS, Sorli JB, Levin M, Wolkoff P, Nielsen GD, Larsen ST, 2014. Pulmonary toxicity of perfluorinated silane-based nanofilm spray products: solvent dependency. Toxicol Sci 137(1), 179-188. doi: 10.1093/toxsci/kft225. Epub 2013 Oct 4.

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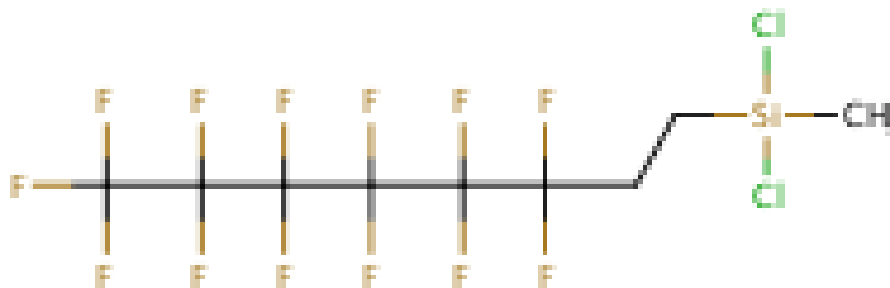
Last Update 21 April 2016

Chemical Identities

Chemical Name in the Inventory and Synonyms	Silane, triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-perfluorooctyl triethoxysilane triethoxytridecafluorooctylsilane
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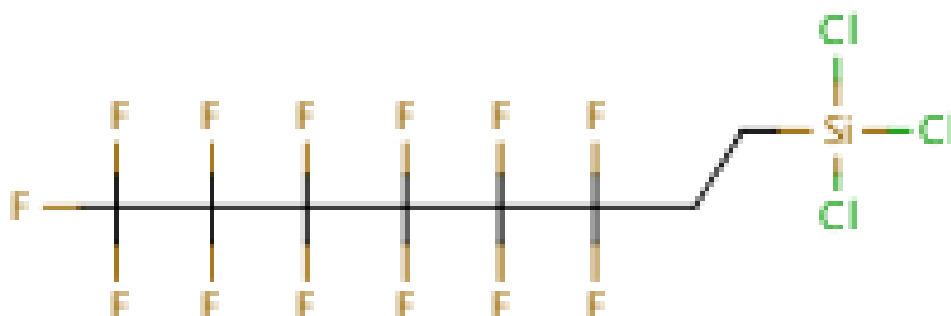
	tridecafluoro octyltriethoxysilane
CAS Number	51851-37-7
Structural Formula	
Molecular Formula	C ₁₄ H ₁₉ F ₁₃ O ₃ Si
Molecular Weight	510.36

Chemical Name in the Inventory and Synonyms	Silane, dichloromethyl(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-tridecafluoro octyldichloromethylsilane
CAS Number	73609-36-6
Structural Formula	



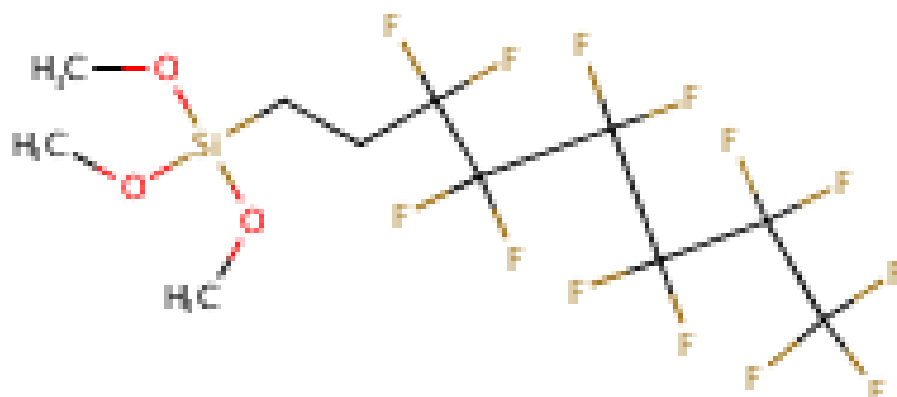
Molecular Formula	C ₉ H ₇ Cl ₂ F ₁₃ Si
Molecular Weight	461.12

Chemical Name in the Inventory and Synonyms	Silane, trichloro(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)- (tridecafluoro-1,1,2,2-tetrahydrooctyl) trichlorosilane trichlorotridecafluorooctylsilane tridecafluorooctyltrichlorosilane
CAS Number	78560-45-9
Structural Formula	



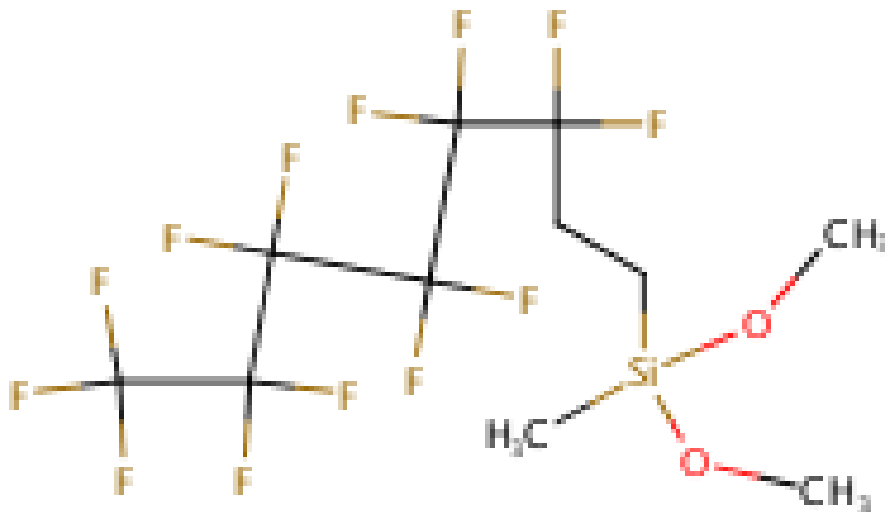
Molecular Formula	C ₈ H ₄ Cl ₃ F ₁₃ Si
Molecular Weight	481.54

Chemical Name in the Inventory and Synonyms	Silane, trimethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)- trimethoxytridecafluorooctylsilane tridecafluorooctyltrimethoxysilane
CAS Number	85857-16-5
Structural Formula	



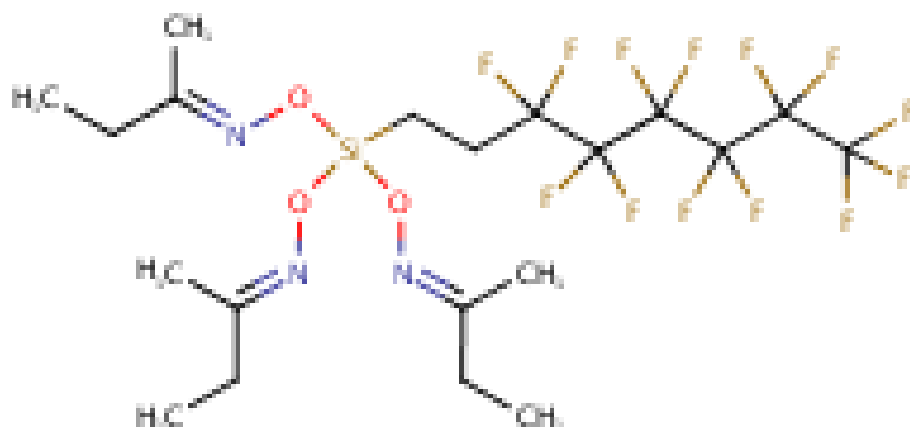
Molecular Formula	C ₁₁ H ₁₃ F ₁₃ O ₃ Si
Molecular Weight	468.28

Chemical Name in the Inventory and Synonyms	Silane, dimethoxymethyl(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-
CAS Number	85857-17-6
Structural Formula	



Molecular Formula	C ₁₁ H ₁₃ F ₁₃ O ₂ Si
Molecular Weight	452.28

Chemical Name in the Inventory and Synonyms	2-Butanone, O,O'-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silylidene]oxime
CAS Number	94158-20-0
Structural Formula	



Molecular Formula	C ₂₀ H ₂₈ F ₁₃ N ₃ O ₃ Si
Molecular Weight	633.52

Chemical Name in the Inventory and Synonyms	Siloxanes and silicones, dimethyl, methyl 3-(1,1,2,2-tetrafluoroethoxy)propyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl-
CAS Number	104780-70-3
Structural Formula	

	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Siloxanes and silicones, dimethyl, methyl 3-(1,1,2,2-tetrafluoroethoxy)propyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated
CAS Number	115340-94-8
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Siloxanes and silicones, dimethyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl
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CAS Number	115340-95-9
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Siloxanes and silicones, dimethyl, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated
CAS Number	115340-96-0
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	Siloxanes and silicones, methyl 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl, hydroxy terminated
CAS Number	115341-00-9
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	

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