



Indirect Precursors of Perfluorooctanoic Acid (PFOA): Human health tier II assessment

01 July 2016

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-	678-39-7
2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluorodecyl ester	1996-88-9
2-Propenoic acid, 2-methyl-, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentafluorooctyl ester, polymer with 2-propenoic acid	53515-73-4
Propanamide, 3-[(.gamma.-.omega.-perfluoro-C4-10-alkyl)thio] derivatives	68187-42-8
9-Octadecenoic acid (Z)-, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-1-decanol	167289-73-8
2-Propenoic acid, 2-methyl-, methyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluorodecyl 2-propenoate, block	121065-52-9

Chemical Name in the Inventory	CAS Number
2,5-Furandione, dihydro-, monopolyisobutylene derivatives, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol	253683-00-0
Trimethylsiloxy silica, copolymer with 1,1,2,2-tetrahydroperfluoro-1-decanol	254889-67-3
2-propenoic acid, 2-methyl-3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heptadecafluorodecyl ester, polymer with methyl 2-methyl propenoate	93705-98-7

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are of concern because they have the potential to degrade to environmentally persistent perfluorinated carboxylic acids (PFCAs), including perfluorooctanoic acid (PFOA) (OECD, 2007).

Four of the chemicals in this group are structurally-related compounds; they all contain a chain of eight perfluorinated carbons linked to another group through an ethylene unit. The fifth chemical is a polymer with side chains that contain seven perfluorinated carbons linked through a methylene unit to a methacrylate co-polymer backbone.

NICNAS has developed an action plan to assess and manage chemicals which may degrade to PFCAs, perfluoroalkyl sulfonates and similar chemicals, which can be found in Appendix G of the Handbook for Notifiers on the NICNAS website (NICNASa). The primary assumption outlined in this action plan is that chemicals with a perfluorinated chain terminated with an alkyl or aryl group will degrade to form a mix of PFCAs including PFOA with both the original chain length and one less perfluorinated carbon atom (NICNASa).

Most chemicals in this group contain a chain of eight perfluorinated carbons linked to another functional group or polymer chain through an ethylene unit. Under the action plan, these chemicals are assumed to have the potential to degrade either to perfluorononanoic acid or PFOA. However, PFOA is expected to be the major product when these precursors degrade environmentally (Butt et al., 2014; NICNASb). The ester linkage in the fifth chemical is assumed to be susceptible to hydrolysis, which would release a fluoroalcohol that has the potential to be oxidised to PFOA (OECD, 2007). Therefore, potential environmental degradation of the chemicals in this group to PFOA is the principal focus of this assessment.

PFOA has been identified as a persistent, bioaccumulative and toxic (PBT) chemical (NICNASc). The degradation of PFOA is extremely slow compared with its rate of formation from precursor degradation. PFOA will be the final degradant from multiple precursors; therefore, the amount of PFOA in the environment (general or local) is expected to be higher than that of any of the individual precursors. Whilst polymers generally do not present significant risks, direct exposure to small molecule precursors, such as those in this assessment, can pose health risks. However, 8:2 fluorotelomer alcohol (8:2 FTOH; CAS No. 678-39-7) and 8:2 fluorotelomer methacrylate (8:2 FTMAC; CAS No. 1996-88-9), are not expected to have industrial use in Australia, and any use of the propanamide (CAS No. 68187-42-8) is expected to be limited (see **Import, manufacture and use** section). Consequently, the most important health risk is expected to arise from secondary exposure to PFOA through the environment. As such, the focus of this assessment is on the long-term effects of the chemicals due to their degradation to PFOA. Acute and local effects have not been considered.

Import, Manufacture and Use

Australian

In July 2006, NICNAS (NICNASd) collected information on the manufacture, importation and uses of perfluorinated chemicals, including PFOA-related substances and products/mixtures containing these substances, for the calendar years 2004 and 2005. Information provided to NICNAS indicated that no PFOA-related chemicals were manufactured in Australia. Introduction of 8:2 FTOH and 8:2 FTMAC in Australia is not expected as they are only used in manufacturing PFOA-related chemicals (see below).

An antifoam product containing <10 % of a PFOA-related chemical (CAS number not specified) was imported in 2005 for use in a dyeing process with sulfur dyes. The total quantity imported was approximately 10 kg.

However, it is noted that the chemicals assessed in this group could be present in the environment due to historic use or from release from articles not covered in this assessment.

International

Two chemicals in this group are reported to be used in manufacturing other fluorochemicals. The reactive methacrylate, 8:2 FTMAC, is used as a monomer in producing polymers with fluorinated side-chains. The 8:2 fluorotelomer alcohol is used mainly in manufacturing fluorinated surfactants and surface protection products (Buck et al., 2011). Traces of the latter chemical can be found in final products, in some cases even at measurable levels, as residual unreacted starting material (SFT, 2007; ECHA, 2013).

Polymers with fluorinated side-chains and surface protection products are used to treat surfaces to repel water, grease, dirt and oil. Commonly treated articles include sports and outdoor clothing, home textiles and upholstery, carpets and medical garments. These chemicals can also be used in products such as paints and lacquers, and waxes and polishes (ECHA, 2014).

The fluorotelomer-based chemicals also have commercial uses in non-stick coatings on cookware, in anti-foam formulations, in silicone rubber products as well as uses in analytical laboratories and in the automotive, mechanical, aerospace, chemical, electrical, medical, and building and construction industries (OECD, 2006; OECD, 2008).

In 2007, 8:2 FTOH was reported to be produced at a volume greater than 1,000 tonnes per annum in at least one Organisation for Economic Co-operation and Development (OECD) member country (OECD, 2013). Results from an OECD survey conducted in 2009 found 8:2 FTOH and 8:2 FTMAC to be produced in two countries. However, the response rate for this survey was very low and the data might not be representative (OECD, 2011).

No specific volume or production data were located for the polymers in this group. However, it was recently estimated that approximately 1000 tonnes of PFOA-related substances for textile and leather treatment are introduced per annum in the European Union (EU). It was further estimated that between 1000 and 10000 tonnes of PFOA-related substances contained in textile articles were additionally imported into the European Union (ECHA, 2014).

No use data were identified for the propanamide. Three chemicals in this group, 8:2 FTOH, 8:2 FTMAC and the propanamide, have been pre-registered for use in the EU under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation. However, no chemicals in this group have undergone the full registration process.

Restrictions

Australian

No known mandatory restrictions have been identified.

NICNAS has monitored the import and use of PFOA- and PFOA-related substances in Australia.

In 2007, a NICNAS Factsheet recommended that industry seek alternatives to PFOA and chemicals that may degrade to PFOA, and ultimately aim to phase out the use of these substances (NICNAS, 2013).

International

PFOA, its salts and substances with a perfluoroheptyl or perfluorooctyl moiety are listed under Schedule 1 (the Toxic Substances List) of the Canadian Environmental Protection Act 1999 (CEPA 1999) (Government of Canada, 2013). A proposal to prohibit the import, manufacture and use of these chemicals has been released, and is expected to be finalised by January 2016 (Environment Canada, 2012).

In January 2006, the United States Environmental Protection Agency (US EPA) launched a global PFOA stewardship program. The eight major companies that manufacture fluoropolymers and telomers committed to reduce facility emissions of all PFOA, PFOA precursors and related chemicals by 95% by no later than 2015 (compared with the 2000 baseline). The US EPA published an action plan on long-chain perfluorinated chemicals, covering the chemicals in this group, in 2009 (US EPA, 2009).

The chemicals in this group, except CAS No. 93705-98-7, are listed on the inventory of chemicals manufactured or processed in the USA, as published under the Toxic Substances Control Act 1976 (TSCA 1976) (US EPA, 2014). The US EPA proposed a

Significant New Use Rule (SNUR) for these chemicals in January 2015. Under the SNUR, approval must be sought for new uses of these chemicals after December 2015. The US EPA understands that existing uses of these chemicals will be phased out by December 2015 under a voluntary stewardship programme (US EPA, 2015).

In October 2014, a proposal to restrict the use of PFOA, its salts, and substances that can degrade to PFOA, under the REACH legislation, was published. The proposal covers manufacture, sale and use of the PFOA, its salts, and substances that can degrade to PFOA and if present in concentrations greater than two parts per billion (ECHA, 2014).

The OECD has been leading an international collaboration on the scientific assessment and surveys for perfluorinated chemicals.

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No exposure standards currently exist for the chemicals assessed in this review, or their degradation product PFOA.

International

No exposure standards exist for the chemicals assessed in this review. However, an occupational exposure limit of 0.005 mg/m³, time weighted average (TWA), was identified for PFOA in countries such as Japan and Switzerland (Galleria Chemica).

Risk Characterisation

Critical Health Effects

The primary health risk for the chemicals in this group is expected to arise from secondary exposure to PFOA (see **Grouping Rationale**). The polymeric PFOA precursors evaluated in this assessment generally do not present significant risks while in polymeric form. Data for the small molecule polymer precursors such as 8:2 FTOH, have not been evaluated as the chemicals are not considered to be introduced into Australia.

Long-term toxicity is reported for PFOA. Long-term health effects for PFOA and its ammonium salt (APFO) are summarised below. APFO rapidly dissociates into the perfluorooctanoate anion and is therefore considered relevant for PFOA risk assessment (see detailed information and relevant references in Human Health Tier II Assessment for *Perfluorooctanoic Acid (PFOA) and its Direct Precursors* (NICNASd)).

Increased mortality and liver toxicity were reported in mice, rats and monkeys following repeated oral exposure to APFO, and in rats following inhalation exposure. Hepatocellular hypertrophy, degeneration and focal to multifocal necrosis were reported with increasing severity between oral doses of 1.5–15 mg/kg bw/day in rats and mice.

The evidence of PFOA carcinogenicity is regarded as limited. Two experimental carcinogenicity studies reported APFO-induced liver adenomas, Leydig cell adenomas and pancreatic acinar cell tumours in rats. However, several epidemiological and medical surveillance studies of the workers at 3M plants (APFO manufacturing) in various cities of the US could not establish a link between PFOA exposure and cancer incidence.

The chemicals PFOA and APFO did not have any effect on fertility parameters in rats. In several mouse studies, as well as in a rat two-generation study, increased postnatal pup mortality, decreased pup body weight and delayed sexual maturation were observed in the absence of marked maternal toxicity. Studies in mice suggested that the postnatal developmental toxicity of APFO was mainly due to gestational exposure, and that exposure earlier in gestation produces greater responses.

However, there are questions relating to the human relevance of some of these findings. It is possible that the developmental effects of PFOA observed in mice may be, at least partly, mediated via mechanisms not relevant for humans, for instance through the peroxisome proliferator-activated receptor (PPAR). Mechanistic studies have shown that some of the effects of PFOA were either absent or attenuated in PPAR-knockout mice when compared to the wild-type (Abbott et al., 2007; Albrecht et al., 2013), raising the possibility that these effects are mediated through the PPAR pathway, not present in humans. However, currently there is no experimental evidence that the developmental effects observed in experimental animals are mediated via the PPAR pathway. In the absence of such evidence, the harmonised classification for developmental toxicity of PFOA is considered appropriate.

Public Risk Characterisation

Use in consumer products

Whilst the public can be exposed to articles treated with the polymers in this group, these are not expected to present significant risks while in polymeric form. Significant direct exposure to the small molecule polymer precursors is not expected. Therefore, public risk from these chemicals is not considered to be unreasonable.

Secondary exposure to PFOA via the environment

The primary health risk is expected to arise from secondary, long-term exposure to the degradation product (PFOA) from the polymers in this group. While long-term studies in animals show adverse effects from exposure to PFOA, epidemiological studies in workers exposed to these chemicals do not provide clear evidence of effects in humans, and exposure of the general public to similar levels is not expected. Blood monitoring data (international and national) suggested widespread exposure of the general population to low levels of PFOA (US EPA, 2005; Toms et al., 2014).

Nevertheless, PFOA is persistent and bioaccumulative in the environment and, therefore, has the potential to become a widely dispersed environmental contaminant. Once in the environment, persistent chemicals that are also highly bioaccumulative pose an increased risk of accumulating in exposed organisms and of causing adverse effects. They can also biomagnify through the food chain, resulting in very high internal concentrations, especially in top predators. Importantly, it is difficult or impossible to reverse the adverse effects of PBT chemicals once they have been released to the environment (NICNASc).

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 PFOA could occur while using these polymers or formulated products containing PFOA as a contaminant.

NICNAS Recommendation

Currently it is recommended that industry seek alternatives to PFOA and chemicals that can degrade to PFOA, and ultimately aim to phase out their use.

The chemicals in this group have been assessed as having 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 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.

It is recommended that NICNAS consult with industry and other stakeholders to consider strategies, including regulatory mechanisms available under the ICNA Act, to encourage the use of safer chemistry.

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 which could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical[s], 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.

References

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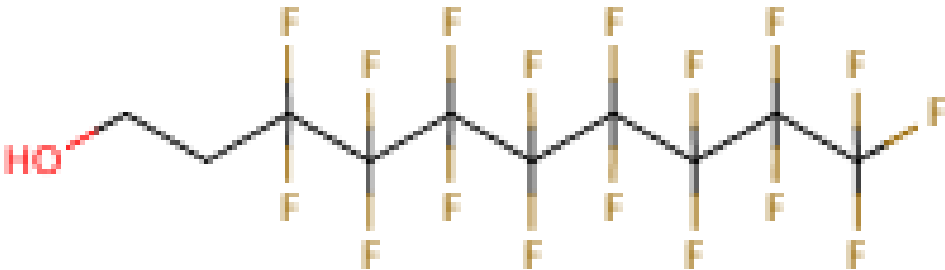
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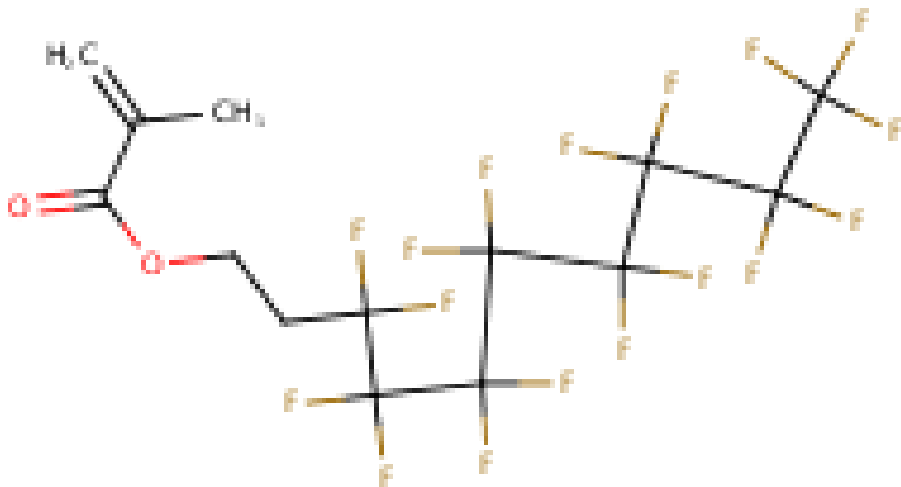
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Last Update 01 July 2016

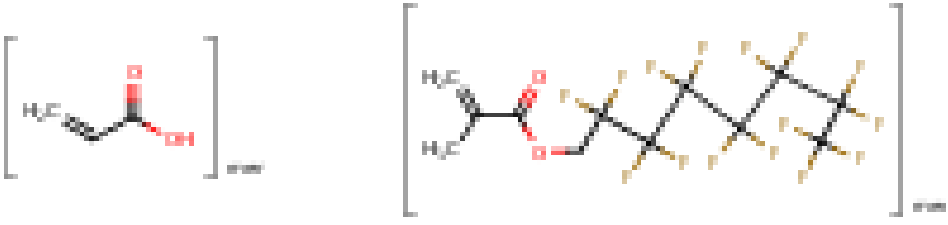
Chemical Identities

Chemical Name in the Inventory and Synonyms	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-1,1,2,2-tetrahydroperfluoro-1-decanol 1H,1H,2H,2H-perfluorodecanol 8:2 fluorotelomer alcohol 8-2 FTOH
CAS Number	678-39-7
Structural Formula	

Molecular Formula	C ₁₀ H ₅ F ₁₇ O
Molecular Weight	464.11

Chemical Name in the Inventory and Synonyms	<p>2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester 2-(perfluorooctyl)ethyl methacrylate 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl methacrylate 8:2 fluorotelomer methacrylate 8:2 FTMAC heptadecafluorodecyl methacrylate</p>
CAS Number	1996-88-9
Structural Formula	
Molecular Formula	C ₁₄ H ₉ F ₁₇ O ₂
Molecular Weight	532.20

Chemical Name in the Inventory and Synonyms	<p>2-Propenoic acid, 2-methyl-, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl ester, polymer with 2-propenoic acid</p>
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CAS Number	53515-73-4
Structural Formula	
Molecular Formula	(C12H7F15O2.C3H4O2)x
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Propanamide, 3-[(.gamma.-.omega.-perfluoro-C4-10-alkyl)thio] derivatives 3-(1,1,2,2-tetrahydroperfluoro-C4-10-alkylthio) propanamide
CAS Number	68187-42-8
Structural Formula	

**No Structural
Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	9-Octadecenoic acid (Z)-, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecfluoro-1-decanol 306-65-0A
CAS Number	167289-73-8
Structural Formula	No Structural Diagram Available
Molecular Formula	
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	2-Propenoic acid, 2-methyl-, methyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptaecafluorodecyl 2-propenoate, block
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CAS Number	121065-52-9
Structural Formula	No Structural Diagram Available
Molecular Formula	(C13H7F17O2. C5H8O2) x
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	2,5-Furandione, dihydro-, monopolyisobutylene derivatives, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluoro-1-decanol 306-71-8A
CAS Number	253683-00-0
Structural Formula	No Structural Diagram Available
Molecular Formula	
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Trimethylsiloxy silica, copolymer with 1,1,2,2-tetrahydroperfluoro-1-decanol 510-00-9A
CAS Number	254889-67-3
Structural Formula	No Structural Diagram Available
Molecular Formula	
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	2-propenoic acid, 2-methyl-3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heptafluorodecyl ester, polymer with methyl 2-methyl propenoate 2-(perfluorooctyl) ethyl methacrylate, polymer with methyl methacrylate
CAS Number	93705-98-7
Structural Formula	No Structural Diagram Available
Molecular Formula	(C ₁₄ H ₉ F ₁₇ O ₂ .C ₅ H ₈ O ₂) _x

Molecular Weight	Unspecified
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