Indirect precursors of short chain perfluorocarboxylic acids (PFCAs): Human health tier II assessment

12 December 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Butanamine, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(nonafluorobutyl)-	311-89-7
1-Pentanamine, 1,1,2,2,3,3,4,4,5,5,5-undecafluoro-N,N-bis(undecafluoropentyl)-	338-84-1
1-Pentanol, 2,2,3,3,4,4,5,5-octafluoro-	355-80-6
1-Hexanamine, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N,N-bis(tridecafluorohexyl)-	432-08-6
1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	647-42-7
2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	2144-53-8
2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,6-nonafluorohexyl ester	1799-84-4
Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[4-[(2,2,3,3,4,4,4-heptafluoro-1-oxobutyl)amino]-3-hydroxyphenyl]-	2923-93-5
Butanedioic acid, sulfo-, 1,4-bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) ester, sodium salt	54950-05-9
Silane, dichloromethyl(3,3,4,4,5,5,6,6,6-nonafluorohexyl)-	38436-16-7
Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(2,2,3,3,4,4,5,5-octafluoro-1-oxopentyl)amino]phenyl]-	72494-14-5
Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(octafluoro-1-oxopentyl)amino]phenyl]-	83003-52-5

Chemical Name in the Inventory	CAS Number
Hexanamide, 6-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(octafluoro-1-oxopentyl)amino]phenyl]-	97331-50-5
9-Octadecenoic (Z-)-, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol	220237-47-8
2,5-Furandione, dihydro-, monopolyisobutylene derivatives, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol	253682-99-4
1-methoxy 1,1,2,2,3,3,4,4,4-nonafluorobutane	163702-07-6

Preface

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

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

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

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

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

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

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

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

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

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group have the potential to degrade to short-chain perfluorocarboxylic acids (PFCAs) containing 3–6 perfluorinated carbons and are therefore considered to be 'indirect precursors of short-chain PFCAs'. The group also includes an additional polyfluorinated organic chemical, 2,2,3,3,4,4,5,5-octafluoro-1-pentanol (CAS No. 355-80-6), which has similar structural properties to some parent chemicals in this group.

NICNAS has developed an action plan to assess and manage chemicals that can degrade to PFCAs, perfluoroalkane sulfonic acids (PFSAs) and similar chemicals, which can be found on the NICNAS website under 'Data requirements for notification of new chemicals containing a perfluorinated carbon chain' (NICNASa). The primary assumption outlined in this action plan is that:

- perfluorinated chains that terminate with a hydrolysable group such as iodide or a silane will degrade to a PFCA containing one less perfluorinated carbon atom; and

- chemicals with a perfluorinated chain that terminates with an alkyl or aryl group will degrade to form a mix of PFCAs with both the original chain length and one less perfluorinated carbon atom (NICNASa).

Four of the chemicals in this group contain a chain of six perfluorinated carbons linked to another functional group through an ethylene unit. Under the action plan, these chemicals are assumed to have the potential to degrade either to perfluoroheptanoic acid or perfluorohexanoic acid (PFHxA). However, PFHxA is expected to be the major product when these precursors degrade environmentally (Butt et al., 2014; NICNASb). Therefore, the chemicals in this group are expected to degrade into one or more of the short-chain PFCAs including perfluorohexanoic acid (PFHxA), perfluoropentanoic acid (PFPeA), and perfluorobutanoic acid (PFBA) in the environment. The additional chemical in this group, 2,2,3,3,4,4,5,5-octafluoro-1-pentanol, is not a perfluorinated compound as the terminal carbon has a hydrogen atom. However, degradation of this compound in the environment may form stable short-chain polyfluorinated acids that have comparable properties to PFPeA and PFBA.

Short-chain PFCAs have been developed and used by industry as alternatives to the long-chain PFCAs (OECD, 2013). Simple, short-chain PFCAs and their salts (direct precursors) have been assessed earlier using the toxicity data available for PFHxA and PFBA, in order to compare their toxicity profile with that of PFOA (NICNASb).

Risks from direct exposure and secondary exposure have been considered.

Import, Manufacture and Use

Australian

NICNAS has previously assessed methyl perfluorobutyl ether (CAS No. 163702-07-6) for use as a cleaning and heat transfer agent, and as a cosmetic ingredient (NICNAS, 2006). The chemical is not manufactured or formulated in Australia. It is imported in formulated products in volumes ranging from 300–3000 kg.

No specific Australian use, import, or manufacturing information was identified for the remaining chemicals in this group. Information collected by NICNAS in 2006 indicated PFHxA, PFPeA and their derivatives are not currently imported or manufactured in Australia. However, this information could be incomplete because the call for information did not specifically include the PFCAs group (NICNAS, 2013).

International

The following international uses for some of the chemicals in this group have been identified through the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) dossiers, Galleria Chemica, the Substances and Preparations in Nordic Countries (SPIN) and the European Commission Cosmetic Ingredients and Substances (CosIng) database.

The simple fluorotelomer alcohol and methacrylate monomers in this group (CAS Nos. 647-42-7, 2144-53-8, 1799-84-4) are used as intermediates in the manufacture of polymers with fluorinated side-chains. In particular, the 6:2 fluorotelomer derivatives have been selected to replace 8:2 fluorotelomer chemistry (Buck, et al., 2011), and therefore are expected to have significant use. 2,2,3,3,4,4,5,5-octafluoro-1-pentanol (CAS No. 355-80-6) also has been identified for use as a chemical intermediate.

Methyl perfluorobutyl ether has reported cosmetic use as a solvent and viscosity controlling agent.

The perfluorotrialkylamines (CAS Nos. 311-89-7, 338-84-1 and 432-08-6) are marketed as speciality chemicals for use in the industrial electronics sector, with principal applications including use as heat transfer agents in semiconductor processing and electronics testing, and as solvents for computer disc drive lubrication (US EPA, 2007). Perfluorotributylamine (CAS No. 311-89-7) has also been used as a synthetic oxygen carrier (Kimelman-Bleich et al., 2009).

Limited current data were identified for the two salts in this group. Available information indicates that the succinate salt (CAS RN 54950-05-9) may have use as a wetting and levelling agent in emulsions and cleaning products (Ash and Ash, 2004).

Some chemicals in this group, (CAS Nos. 311-89-7, 338-84-1, 1799-84-4, 54950-05-9, 163702-07-6 and 2923-93-5) have been pre-registered under the REACH legislation. CAS Nos. 647-42-7, 2144-53-8, 355-80-6 and 38436-16-7 have undergone the registration process for use in the EU under the REACH legislation.

When North American databases were searched, no evidence was found that any of these chemicals were included in consumer products, indicating that the chemicals are not likely to be widely available for domestic uses.

Restrictions

Australian

Under Section 65 of the Act, the secondary notification of HFE-7100 (which contains methyl perfluorobutyl ether (CAS No. 163702-07-6)) may be required where an applicant or other importer or manufacturer of HFE-7100 becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Specific circumstances include:

- Manufacture of HFE-7100 has begun, or is likely to begin in Australia.
- Additional information has become available on the adverse health and/or environmental effects of HFE-7100.
- The use of HFE-7100 has changed, or is likely to change significantly.
- The amount of HFE-7100 introduced into Australia has increased, or is likely to increase significantly.

The Director must be notified within 28 days of the introducer becoming aware of any of the above circumstances.

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group 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

Data are available for five chemicals in this group (CAS Nos. 311-89-7, 2144-53-8, 647-42-7, 38436-16-7 and 163702-07-6). Data for CAS Nos. 311-89-7 are considered representative for the other perfluoro tertiary amines in the group (CAS Nos. 338-84-1, 432-08-6). Data for 2144-53-8 are considered representative for the other methacrylate (CAS No. 1799-84-4). Data for CAS No. 647-42-7 are considered representative of the toxicity of the other polyfluoro alcohol (CAS No. 355-80-6) and also of the systemic toxicity for CAS Nos 2144-53-8 and 54950-05-9, due to the likely metabolism to the 6:2 fluorotelomer alcohol (6:2-FTOH) by ester hydrolysis. Data for short-chain PFCAs have also been used to infer the toxicity of the chemicals in this group where they have been identified as key metabolites. Data for dialkyl sulfosuccinate salts have been used to infer the acute and local toxicity of CAS No. 54950-05-9 (CIR, 2013). The perfluorinated tertiary amines do not have the typical basicity of amines (USEPA, 2007), and so the typical local effects of amines are not expected.

Toxicokinetics

Very limited information is available on the toxicokinetics of the chemicals in this group.

In a pharmacokinetic study, varying doses (up to 10 mg/kg bw) of a mixture of 1-methoxy nonafluorobutane (CAS No. 163702-07-6) and its isomer, 1-methoxy nonafluoroisobutane (CAS No. 163702-08-7), were injected into the marginal veins of the ears of New Zealand White rabbits. Blood samples were collected pre-dose and at 4, 8, 12, 24 and 48 hours and on day eight post injection. All animals appeared normal and gained weight during the study. Results of the serum samples analysed by electrospray mass spectrometry showed the presence of significant amounts of PFBA (up to 0.64 mg/kg bw in the highest dose group), indicating that the chemical metabolises to the perfluoroalkyl carboxylic acid in the serum (NICNAS, 2006).

In a number of nose-only inhalation studies with 6:2 FTOH (CAS No. 647-42-7) in rats, the predominant metabolites in plasma were the intermediates, 6:2 fluorotelomer carboxylic acid (6:2 FTCA) and 6:2 fluorotelomer unsaturated carboxylic acid (6:2 FTUCA), and the terminal metabolites: 5:3 fluorotelomer carboxylic acid (5:3 FTCA), PFBA, PFPeA, PFHxA and perfluoroheptanoic acid (PFHpA). Overall, the non-compartmental and one-compartmental kinetic analyses indicate rapid elimination of the test substance from plasma with transient and terminal metabolite formation consistent with the known metabolism of the test substance. The calculated elimination half-lives were 1.3–15.4 hour (Russell et al., 2015; REACHa). In another study, 6:2 FTOH, administered orally to rats, had a half-life of 17 hours in the liver and 16 hours in fat. The metabolites detected in the blood and tissues (liver and adipose tissue) included PFBA, PFPeA, PFHxA, PFHpA and 5:3 FTCA. The substance was not detected in plasma (REACHa).

Information on oral absorption of any of the chemicals in the group is not available. Dermal absorption of 1-methoxy nonafluorobutane (CAS No. 163702-08-7) was found to be minimal in a dermal absorption study. The chemical, when administered daily at 15 mg/kg bw/day for five consecutive days to rabbit skin, did not result in any detectable levels of PFBA in the rabbit serum at any time after administration (NICNAS, 2006).

The perfluorotertiary amines in this group are chemically inert and not expected to undergo significant reductive and oxidative metabolism (US EPA, 2007). The methacrylates are expected to be hydrolysed to the corresponding FTOH. This is supported by in vitro data for CAS No. 2144-53-8 in mouse and rat hepatocytes (REACHb). The chemical, 2,2,3,3,4,4,5,5-Octafluoro-1-pentanol (CAS No. 355-80-6) has the potential to be oxidised to a close analogue of PFPeA.

Acute Toxicity

Oral

Based on the available data, the chemicals are considered to have low acute toxicity following oral exposure.

Acute oral toxicity studies are available for five chemicals in this group (CAS Nos. 311-89-7, 163702-07-6, 647-42-7, 2144-53-8 and 38436-16-7). For one of the chemicals (CAS No. 647-42-7) a median lethal dose (LD50) was 1750 mg/kg bw based on half the tested rats dying at this dose (Serex et al., 2014; REACHa). However in another study, the LD50 was >2000 mg/kg bw/day. The chemical CAS No. 38436-16-7 has a reported LD50 value >2000 mg/kg bw in a guideline study and an LD50 value of 890 mg/kg bw from a non-guideline study (only 2 animals/dose) (REACHc).

For the remaining three chemicals that were tested for acute oral toxicity, the LD50 was above 2000 mg/kg bw in rats (NICNAS, 2006; USEPA, 2007; REACHb). Based on data for a dialkyl sulfosuccinate salt (CIR, 2013; NICNASc), CAS No. 54950-05-9 are expected to have low acute oral toxicity.

Dermal

Based on the available data, the chemicals are considered to have low acute toxicity following dermal exposure.

Acute dermal studies with CAS Nos. 2144-53-8 and 647-42-7 in rats gave dermal LD50s of >5000 mg/kg bw (REACHa; REACHb). Based on data for a dialkyl sulfosuccinate salt (CIR 2013; NICNASc), CAS No. 54950-05-9 are expected to have low acute dermal toxicity.

In general, perfluoroaliphatic ethers and perfluorotertiary amines are chemically inert.

Inhalation

Acute inhalation toxicity of the four chemicals for which acute inhalation studies are available (CAS Nos. 311-89-7, 163702-07-6, 647-42-7 and 2144-53-8) was very low in rats. For all four chemicals, the median lethal concentration (LC50) was above 5 mg/L. There were no deaths, abnormal behavioural reactions or adverse body weight effects from exposure to the test material. Necropsy did not reveal any gross pathological alterations (NICNAS, 2006; USEPA, 2007; REACHa; REACHb).

Perfluorinated chemicals have been known to cause acute lung injury. Acute lung injury is characterised by respiratory problems ranging from mild to severe effects, and mortality, associated with acute or repeated exposures. Acute lung injury is generally considered to be of most concern when the compound has surface activity (Fischer, 2012). Among this group, the surface active chemicals is CAS No. 54950-05-9.

Corrosion / Irritation

Skin Irritation

Skin irritation studies conducted with four chemicals in this group (CAS Nos. 311-89-7, 163702-07-6, 647-42-7 and 2144-53-8) did not provide evidence of skin irritation effects (NICNAS, 2006; USEPA, 2007; REACHa; REACHb). All studies were conducted in rabbits according to the Organisation for Economic Cooperation and Development Test Guidelines (OECD TG) or the EU Method B.4 (Acute Toxicity: Dermal Irritation/Corrosion).

Based on the skin irritation data for a dialkyl sulfosuccinate salt (CIR, 2013; NICNASc), the chemical (CAS No. 54950-05-9) is expected to have skin irritant effects at high concentrations, warranting hazard classification (see **Recommendation** section).

The chemical (CAS No. 38436-16-7) was reported to be corrosive based on a non-guideline study (REACHc). The dichlorosilane moeity of chemical is expected to give similar properties to other chlorosilanes, which are widely recognised as corrosive chemicals (OECD SIDS, 2010; REACHf). Therefore hazard classification is warranted (see **Recommendation** section).

The remaining chemicals in this group (except CAS No. 54950-05-9 and CAS No. 38436-16-7) are considered to have low skin irritation potential.

Eye Irritation

Based on the data available, the majority of the chemicals in this group are considered to be, at the most, slight eye irritants.

Of the four chemicals tested for eye irritation effects in rabbits conducted according to the EU Method B.5 and the OECD test guidelines, two chemicals (CAS Nos. 647-42-7 and 2144-53-8) caused some irritation effects. For one of the chemicals (CAS No. 2144-53-8), iritis was noted in one rabbit, conjunctival redness in three rabbits and conjunctival chemosis and discharge in one rabbit. Fluorescein stain examinations were negative for corneal injury throughout the study. The treated eyes of the rabbits were normal by 24 or 48 hours after instillation of the test substance (REACHa; REACHb).

The other two chemicals (CAS Nos. 311-89-7 and 163702-07-6) produced negative results for eye irritation effects (NICNAS, 2006; USEPA, 2007).

Based on data for a dialkyl sulfosuccinate salt (CIR, 2013; NICNASc), CAS No. 54950-05-9 is expected to cause moderate eye irritation. Based on the skin corrosion reported for CAS No. 38436-16-7 the chemical has potential to cause severe eye damage.

Sensitisation

Skin Sensitisation

Based on the available data, the chemicals in this group are not considered to be skin sensitisers.

The skin sensitisation potential of one of the chemicals in this group, 1-methoxy perfluorobutane (CAS No. 163702-07-6), was tested using the Buehler method in rabbits. Two weeks after the third weekly application of 0.4 mL of undiluted 1-methoxy perfluorobutane at the induction sites (induction phase), the test substance was administered on the dorsal anterior right quadrant of the animals (challenge phase). No signs of irritation were observed in the test group during the induction phase. At the 100 % challenge concentration, all scores in both test and control animals were zero. The results of the study indicated that 1-methoxy perfluorobutane is not a skin sensitiser.

Local lymph node assays (LLNAs) with the chemicals (CAS Nos. 2144-53-8, 647-42-7 and 2144-53-8) gave negative results (REACHb; REACHd; REACHe).

Information on the skin sensitisation effects of the remainder of the chemicals in this group is not available. In general, perfluoroaliphatic ethers and perfluorotertiary amines are chemically inert. Based on data for a dialkyl sulfosuccinate salt (CIR, 2013; NICNASc), CAS No. 54950-05-9 is not expected to be sensitising.

Repeated Dose Toxicity

Oral

Short- and long-term oral repeated dose toxicity studies are available for three of the chemicals in this group, 1-methoxy nonafluoroisobutane (CAS No. 163702-08-7), 6:2 FTOH (CAS No. 647-42-7) and tridecafluorohexylethyl methacrylate (CAS No. 2144-53-8) (NICNAS, 2006; REACHa; REACHb).

In a short-term repeated dose oral study with 1-methoxy nonafluoroisobutane, rats dosed at 0, 8, 40, 200 or 1000 mg/kg bw/day of the substance for 28 consecutive days did not show any serious adverse effects. No deaths occurred in any group throughout the observation period. Body weight, food consumption and urinalysis were comparable with the control group. In female rats, a decrease in spleen weights was noted in all dose groups, although no dose response was observed. In the 200 mg/kg bw/day group, increases in blood potassium level in males and decreases in total protein in females were observed. In the 1000 mg/kg bw/day group, increased albumin, alanine aminotransferase (ALT) and potassium levels were observed in males. At the end of the treatment period, an increase in absolute and relative liver weights was also observed in male rats. Histopathological examinations revealed centrilobular hypertrophy of the hepatocytes, but this was considered to be an adaptive response. The NOAEL for 1-methoxy nonafluoroisobutane, was determined to be 200 mg/kg bw/day based on the absence of systemic toxicity or histopathological effects at this level (NICNAS, 2006).

In a 28-day oral study in rats with 6:2 FTOH (doses of 25, 75 and 225 mg/kg bw/day), effects on body weight and body weight gain were observed at the 75 mg/kg bw/day dose, while at the higher dose (225 mg/kg bw/day) mortalities, changes in serum chemistry (higher albumin, total protein, globulin, urea nitrogen, creatinine, bilirubin, ALT and aspartate aminotransferase levels), increased liver and kidney weights and microscopic changes (kidneys, pancreas, sternal bone marrow and lymphoid tissues, liver and adrenal cortex) were observed. Difficulty during labour (dystocia) was also noted at the 225 mg/kg bw/day dosage level. A no observed adverse effect level (NOAEL) of 25 mg/kg bw/day was established in this study.

In another oral study, Crl:CD(SD) rats were given 1, 5 or 25 mg/kg bw/day γ-ω-perfluorooctyl methacrylate (CAS No. 2144-53-8) for 28 days. No deaths occurred during the dosing period. No clinical signs were observed. At the end of the dosing period, increased relative kidney weights in male and female rats and increased absolute and relative liver weights in females were observed in the 25 mg/kg bw/day group. The only major effect of the test substance was decreased iron pigment in the ameloblasts in the incisors in the 25 mg/kg bw/day group rats. Changes observed in liver and kidneys were reversible.

In a 90-day oral study with 6:2 FTOH (Serex et al., 2014) 0, 5, 25, 125 or 250 mg/kg/day of the chemical was administered to rats by gavage. At 25 mg/kg bw/day and higher dosages, changes were observed in haematology, clinical chemistry and urinalysis parameters (female rats only). Absolute and relative weights of the liver, kidneys and epididymis were significantly increased. Histopathological effects in the liver, such as oval cell hyperplasia, were noted in these rats at the 25 mg/kg bw/day dose.

Mortality occurred at the 125 and 250 mg/kg bw/day doses. Most of these deaths were attributed to degeneration and necrosis in the kidneys. Food consumption and body weights were significantly lower, and dental problems, excess salivation, urine-stained abdominal fur, piloerection, scant faeces and decreased motor activity were observed in these groups. The effects were more severe in female rats. Single cell hepatocellular vacuolation, hepatocellular hypertrophy, single cell necrosis, biliary hyperplasia, periportal inflammation and hepatocellular vacuolation were also observed. An NOAEL of 5 mg/kg bw/day was established based on the effects in the liver, and haematological and clinical chemistry parameters.

A group of CD-1 mice administered 1, 5, 25 or 100 mg/kg bw/day 6:2 FTOH by gavage, showed reduction in body weights and changes in red and white blood cell parameters and clinical chemistry parameters indicative of hepatocellular injury. Hepatocellular hypertrophy was observed at dose level 5 mg/kg bw/day and above in both sexes, but was considered non-adverse, as no histological effects were noted. The NOAEL for systemic toxicity was 25 mg/kg bw/day (males) and 5 mg/kg bw/day (females), based on effects at higher doses on mortality, clinical observations, body weight, haematology, clinical chemistry (liver-related) and liver weights (Mukerji et al., 2015).

In general, perfluoroaliphatic ethers and perfluorotertiary amines are chemically inert. Effects observed in the liver in studies with PFHxA and PFBA, which are potential metabolites for some of the chemicals in this group were generally mild and reversible (NICNASb). Effects seen with the three tested chemicals were mostly mild and reversible. Although liver and kidney weights were altered, no histological changes were observed with any of the chemicals. The available data are not considered sufficient to classify this group of chemicals as hazardous from prolonged exposure.

Dermal

No data are available.

Inhalation

Repeated inhalation exposure to chemicals from this group did not elicit any serious toxicological effects.

In a 90-day inhalation exposure study, groups of Sprague Dawley (SD) rats were exposed to the vapours of methyl perfluorobutyl ether (163702-07-6) for six hours a day, five days a week for 13 consecutive weeks (vapour concentrations 0, 15.4, 46.1, 76.8 and 153.7 mg/L). No treatment-related effects were evident in clinical signs, body weight gain or food consumption. Haematology, biochemistry and urinalysis investigations did not reveal any treatment-related changes. There were no deaths during the study. Statistically significant increases in the spleen, kidney, and liver weights, and an increase in palmitoyl CoA oxidase activities were observed in males exposed to 15000 ppm. Although there were statistically significant weight increases in the liver, spleen and kidneys, no histopathological findings were detected that could explain the organ weight changes in the spleen and kidneys.

An NOAEL of 76.8 mg/L was determined based on an increase in palmitoyl CoA activities (indicating peroxisome proliferation) observed at the highest dose (NICNAS, 2006).

In 4 separate sub-chronic (28-day) repeated dose inhalation studies with perfluorotributylamine, methyl perfluorobutyl ether and 6:2 fluorotelomer alcohol (CAS Nos. 311-89-7, 163702-07-6 and 647-42-7 respectively), Crl:CD SD rats were exposed to vapours of the three respective chemicals for six hours per day, five days a week, for up to 28 days. Exposure concentrations varied between experiments; the highest being 28881 ppm for methyl perfluorobutyl ether.

In all 4 studies, absolute and relative liver weights were increased. Centrilobular hepatocyte enlargement of the liver was observed in the high dose groups exposed to methyl perfluorobutyl ether. Also, in the high dose groups exposed to methyl perfluorobutyl ether, statistically significant increases in total protein in all male rats and, in a few male rats, palmitoyl CoA oxidase activity were observed (NICNAS 1999; NICNAS, 2006; REACHa; REACHb; Serex et al., 2012).

In several other short-term repeat dose inhalation studies with 6:2 fluorotelomers, mild effects on the liver were reported (DeLorme et al., 2011; Serex et al., 2013). These findings were consistent with the oral studies, indicating that route to route (oral - inhalation) extrapolation for systemic effects is appropriate. The effects of repeated inhalation exposure to chemicals from this group were not considered to be serious.

Genotoxicity

Several in vitro and in vivo genotoxicity studies were conducted with four chemicals from this group. Only one in vitro mammalian gene mutation test for one chemical (CAS No. 647-42-7) gave positive results. The rest were all negative for all four chemicals (USEPA, 2007; REACHa; REACHb).

There is no evidence for genotoxic potential of a dialkyl sulfosuccinate salt (CIR, 1993; NICNASc).

Based on these results, it is concluded that chemicals in this group are not mutagenic.

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

Reproductive toxicity studies are available for methyl perfluorobutyl ether (CAS No. 163702-07-6) and 6:2 FTOH (CAS No. 647-42-7). Studies carried out in rats and mice with these chemicals did not show any effects on reproductive or developmental parameters (NICNAS, 2006; REACHa).

In an inhalation one-generation reproductive study, Wistar rats were exposed by nose-only inhalation to methyl perfluorobutyl ether (CAS No. 163702-07-6) at atmospheric concentrations of 31.0 g/m^3, 77.5 g/m^3 and 129.1 g/m^3 for six hours daily. Fertility and reproductive performance in all test groups were comparable with the control groups. The mating index, fecundity index, fertility index and gestation index were comparable among the groups. The numbers of stillborn pups and post implantation losses were also comparable. Macroscopic observation in stillborn pups and pups that died during lactation did not indicate any abnormality in their development. Gross examination of parental animals at necropsy did not reveal any treatment-related findings.

In a one-generation study, Crl:CD rats were given 25, 75 and 225 mg/kg bw/day of 6:2 FTOH (CAS No. 647-42-7) by gavage. Males received 14 daily doses before mating and were dosed throughout the mating period through to the day before being euthanised for a total of 32–34 doses. Females received 14 daily doses before pairing and through to lactation day 3 for a total of 39–44 doses. Reproductive performance, precoital interval and gestation length were unaffected by the test substance at all doses.

In a second one-generation rat reproductive toxicity study with 6:2 FTOH (O'Connor et al., 2014), Crl:CD (SD) rats were fed 5, 25, 125 or 250 mg/kg bw/day of the substance, beginning 70 days before cohabitation, through cohabitation (maximum 14 days) and continuing through to the day before euthanasia. There were no test-substance-related necropsy observations. The pre-cohabitation oestrous cycle and mating and fertility parameters were unaffected even at the highest doses of the test substance (250 mg/kg bw/day). No NOAEL was established for the reproductive toxicity.

There was a significant increase in the number of pups found dead, presumed cannibalised and some were euthanised due to adverse clinical observations on postnatal day one at the 125 and 250 mg/kg/day doses. Pup body weights per litter were significantly reduced in the two high dose groups. No other abnormalities were observed in the surviving pups at necropsy. There were no adverse maternal or developmental effects observed at up to 125 mg/kg bw/day. At 250 mg/kg bw/day, increases in skeletal variations (ossification delays in the skull and rib alterations) were observed. The reduction in body weights of the pups was seen at the same doses that affected dams (125 and 250 mg/kg bw/day) and thus were not considered to be developmental toxicity effects.

In a mice one-generation reproductive toxicity study, CD-1 mice were fed 1, 5, 25 or 100 mg/kg bw/day of 6:2 FTOH (Mukerji et al., 2015) by gavage during premating, mating, gestation, and lactation. Mortality occurred at the highest dose (100 mg/kg bw/day). Surviving animals in this group exhibited clonic and tonic convulsions, ataxia, tremors, lethargy, pallor, and/or respiratory impairments. There were no effects on reproductive performance, litter size, sex ratio, live born index, or viability index at any dose level. Under the conditions of the study, the test substance was not a selective reproductive toxicant. The NOAEL for reproductive toxicity was >100 mg/kg/day.

Litters (F1) of the high dose parents exhibited delayed maturation, which was likely to be due to the overt systemic toxicity observed in the dams. The litter size was also small. There were no effects on litter parameters and no adverse pathology findings in F1 males or females at the 25 mg/kg bw/day dose and lower. The

NOAEL for viability and growth of the offspring was 25 mg/kg bw/day, based on the clinical observations of delayed development in pups, and reductions in pup survival and pup body weight during lactation at 100 mg/kg bw/day.

Methyl perfluorobutyl ether (CAS No. 163702-07-6) did not have any effects on the developmental parameters in rats.

In general, perfluoroaliphatic ethers and perfluorotertiary amines are chemically inert. Developmental effects in mice (stillborn and postnatal deaths, late maturation) were observed with PFHxA and PFBA (potential metabolites for some of the chemicals in this group) at relatively high doses (NICNASb).

Risk Characterisation

Critical Health Effects

Critical health effects for direct exposure to the chemicals in this group are limited to possible skin and eye irritation effects for CAS No. 54950-05-9 and corrosive effects for CAS No. 38436-16-7.

This group of chemicals have the potential to degrade to short-chain perfluorocarboxylic acids (PFCAs) containing 3–5 perfluorinated carbons. The data available indicate that the toxicological profile for short-chain PFCAs (C4–C6) suggests potentially better human health outcomes and less bioaccumulation than long-chain perfluoroalkyl substances (NICNASb). Chronic low-level effects on human health have not been identified.

Public Risk Characterisation

Methyl perfluorobutyl ether (CAS No. 163702-07-6) has reported use in cosmetics. Given the low toxicity profile for this chemical, the risk to the public is not considered to be unreasonable. Based on the available use information, the rest of the chemicals in this group are not likely to be available for domestic or cosmetic uses. Hence, the public risk from direct use of these chemicals is not considered to be unreasonable.

Secondary exposure to short-chain PFCAs in the environment

Public exposure to short-chain PFCAs could occur through secondary exposure in the environment. It is noted that the perfluorinated carboxylic acid degradants formed from the parent chemicals in this group may have multiple sources. These perfluorinated components are highly persistent and environmental levels can continue to increase over time due to indirect release pathways (NICNASd).

Available data indicate that short-chain PFCAs have lower toxicity and are more rapidly eliminated than the long-chain perfluoroalkyl substances. Chronic low-level effects on human health have not been identified. The chemicals in the short-chain PFCA group are persistent in the environment, but have a short half-life in humans. Further assessment of the chemicals in this group may be necessary if information becomes available indicating adverse health effects from either the parent chemicals or their principal degradation products.

Occupational Risk Characterisation

During product formulation, dermal or 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 local health effects, two of the chemicals in this group (CAS No. 54950-05-9 and CAS No. 38436-16-7) could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure are implemented.

These 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.

Available data support an amendment to the hazard classification in the HCIS (Safe Work Australia) for CAS No. 54950-05-9 and CAS No. 38436-16-7.(refer to **Recommendation** section).

NICNAS Recommendation

The chemicals in this group have been assessed as having the potential to give rise to short-chain perfluorocarboxylic acids (PFCAs). Limited available toxicological data on these chemicals indicate a lower toxicity profile compared with long-chain PFCAs. However, should information become available indicating adverse health effects, further assessment of the chemicals in this group may be necessary to assess the risk of secondary exposure to short-chain PFCAs.

Sufficient information is available to recommend that risks for workplace health and safety be managed through changes to classification and labelling for two of the chemicals (CAS Nos. CAS No 54950-05-9 and CAS No. 38436-16-7).

Regulatory Control

Work Health and Safety

Two chemicals in the group (CAS Nos. 54950-05-9 and 38436-16-7) 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 skin irritation only applies to the chemical (CAS No. 54950-05-9) and the classification for corrosivity only applies to the chemical (CAS No. 38436-16-7).

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Not Applicable	Causes skin irritation - Cat. 2 (H315) Causes severe skin burns and eye damage - Cat. 1 (H314)

[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 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:

- 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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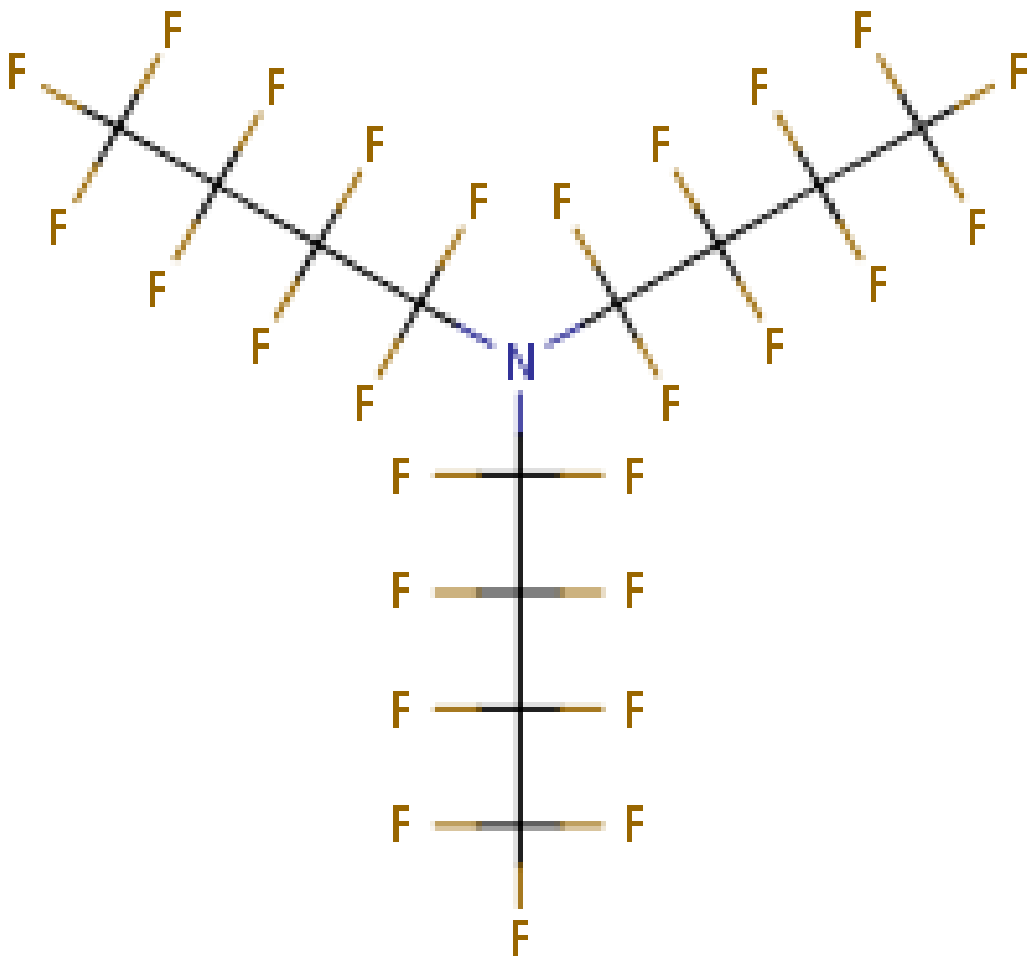
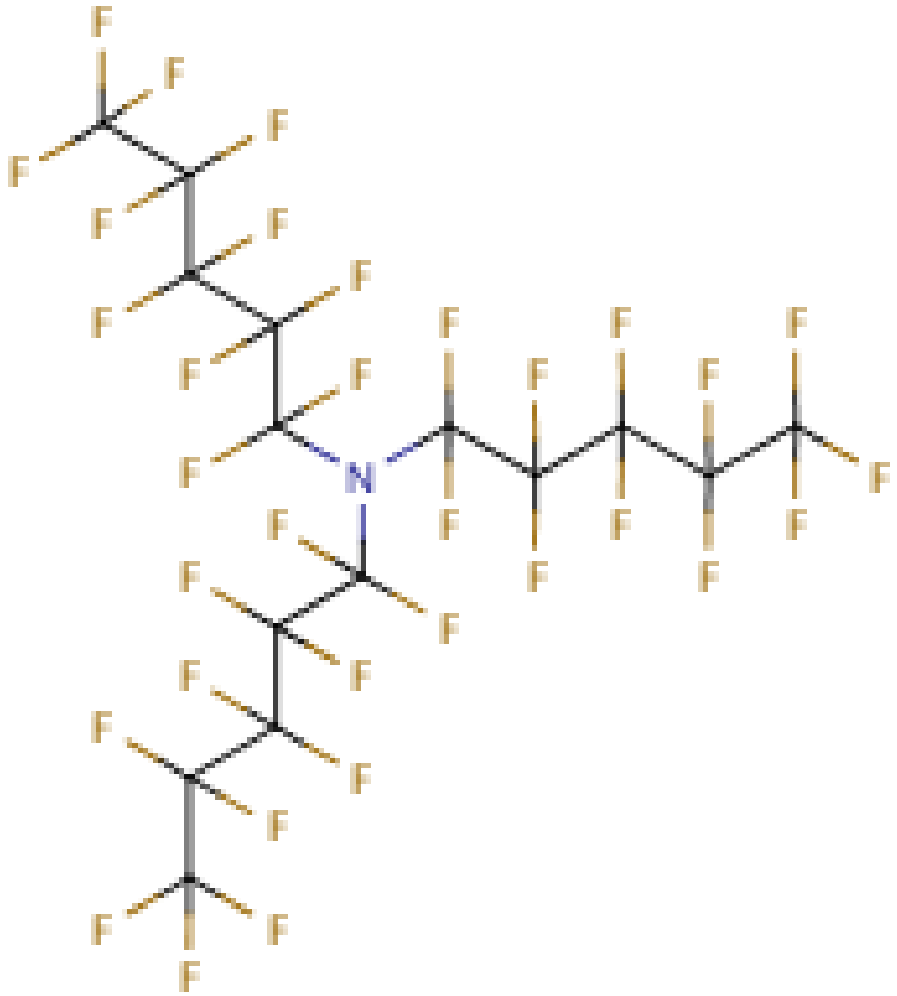
Last Update 12 December 2019

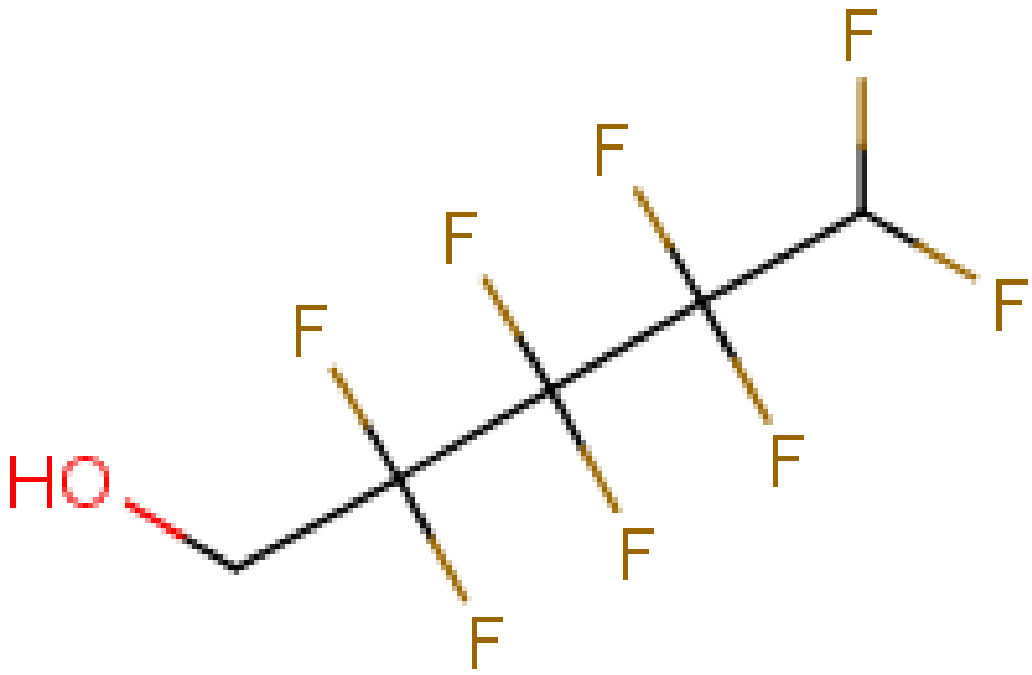
Chemical Identities

Chemical Name in the Inventory and Synonyms	**1-Butanamine, 1,1,2,2,3,3,4,4,4-nonafluoro-N,N-bis(nonafluorobutyl)-** perfluorotributylamine
CAS Number	311-89-7
Structural Formula	
Molecular Formula	C12F27N
Molecular Weight	671

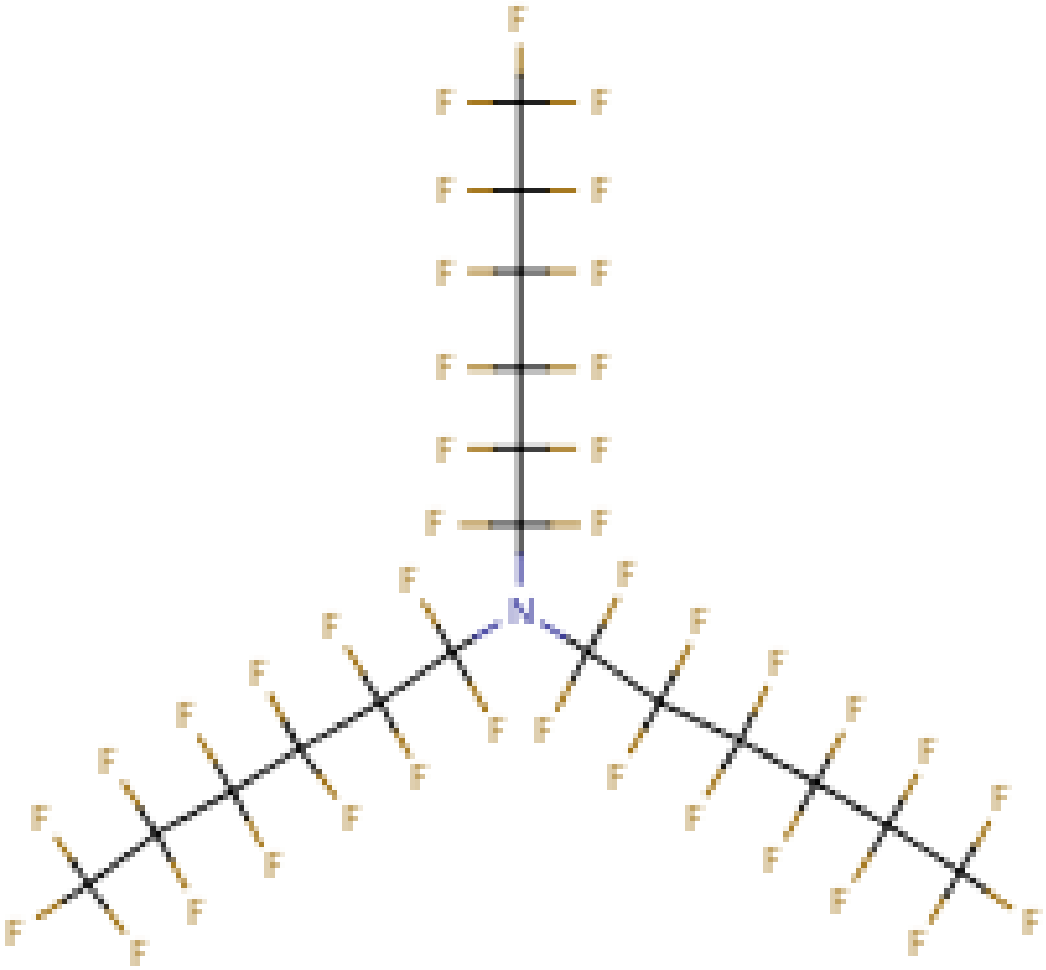
Chemical Name in the	**1-Pentanamine, 1,1,2,2,3,3,4,4,5,5,5-undecafluoro-N,N-bis(undecafluoropentyl)-**

Inventory and Synonyms	tris(undecafluoropentyl)amine perfluortripentylamine
CAS Number	338-84-1
Structural Formula	
Molecular Formula	C15F33N
Molecular Weight	821

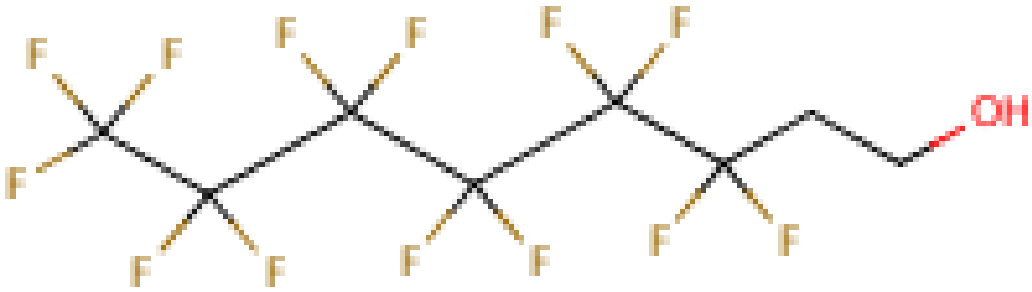
Chemical Name in the Inventory and Synonyms	**1-Pentanol, 2,2,3,3,4,4,5,5-octafluoro-** 1,1,5-trihydrooctafluoropentan-1-ol
CAS Number	355-80-6
Structural Formula	

	
Molecular Formula	C5H4F8O
Molecular Weight	232

Chemical Name in the Inventory and Synonyms	**1-Hexanamine, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-N,N-bis(tridecafluorohexyl)-** tris(tridecafluorohexyl)amine perfluorotrihexylamine
CAS Number	432-08-6
Structural Formula	

	
Molecular Formula	C18F39N
Molecular Weight	971

Chemical Name in the Inventory and Synonyms	**1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-** 1H,1H,2H,2H-perfluorooctanol 1,1,2,2,-tetrahydroperfluoro-1-octanol 6:2 FTOH 6:2 fluorotelomer alcohol
CAS Number	647-42-7
Structural Formula	

	
Molecular Formula	C8H5F13O
Molecular Weight	364

Chemical Name in the Inventory and Synonyms	**2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester** 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate tridecafluorohexylethyl methacrylate gamma-omega-perfluorooctyl methacrylate 6:2 fluorotelomer methacrylate 6:2 FTMAC
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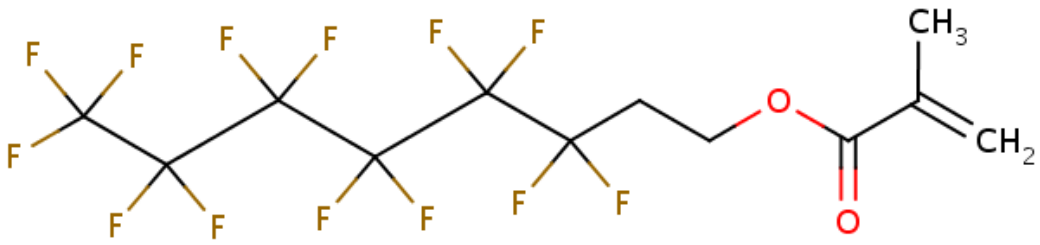
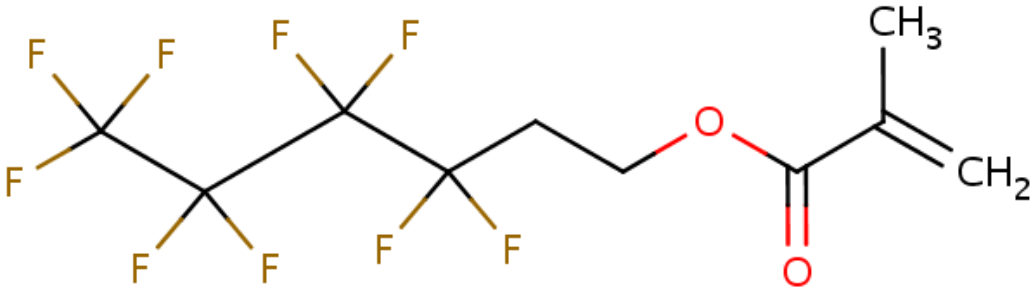
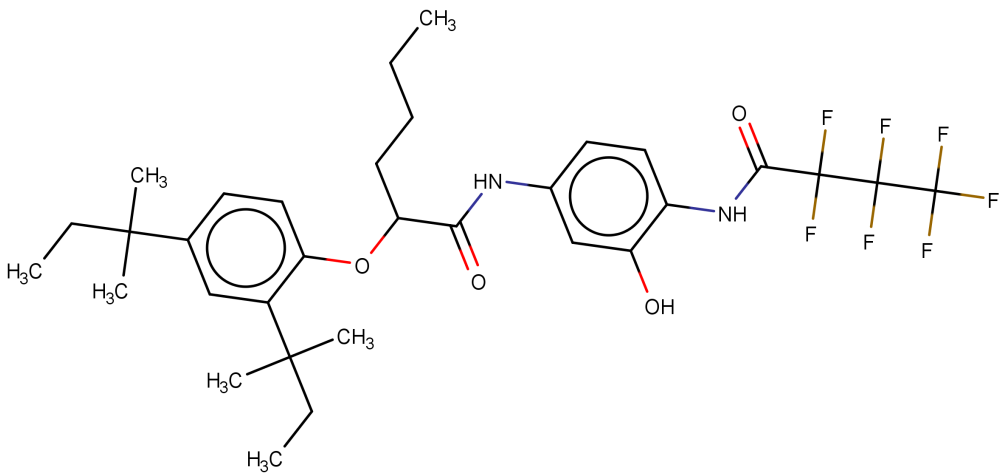
Structural Formula	

	
Molecular Formula	C12H9F13O2
Molecular Weight	432.18

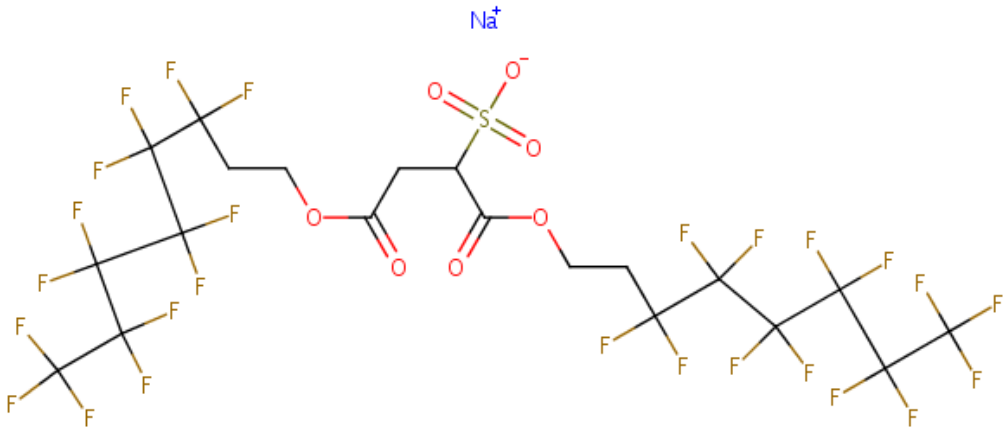
Chemical Name in the Inventory and Synonyms	**2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,6-nonafluorohexyl ester** methacrylic acid, 3,3,4,4,5,5,6,6,6-nonafluorohexyl ester 3,3,4,4,5,5,6,6,6-nonafluorohexyl methacrylate gamma-omega-perfluorohexyl methacrylate 4:2 fluorotelomer methacrylate 4:2 FTMAC
CAS Number	1799-84-4
Structural Formula	



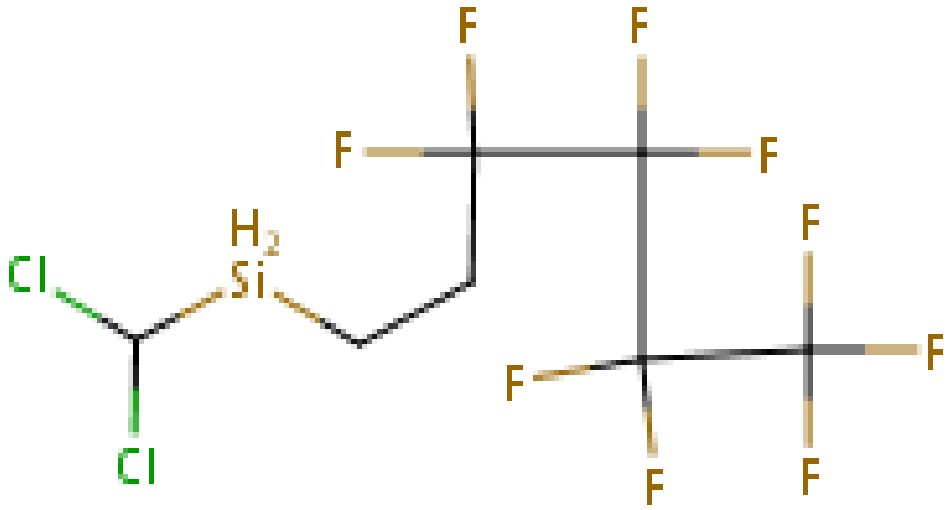
Molecular Formula	C10H9F9O2
Molecular Weight	332.16

Chemical Name in the Inventory and Synonyms	**Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[4-[(2,2,3,3,4,4,4-heptafluoro-1-oxobutyl)amino]-3-hydroxyphenyl]-**
CAS Number	2923-93-5
Structural Formula	

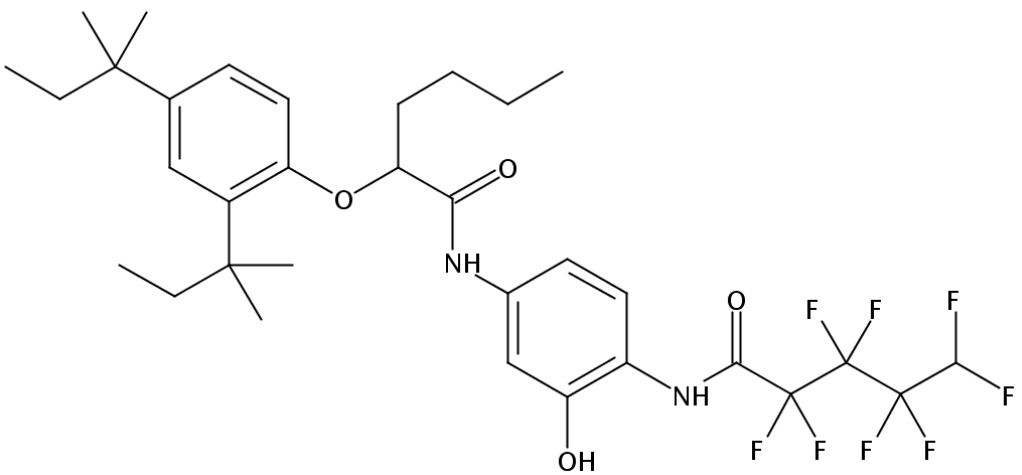
Molecular Formula	C32H41F7N2O4
Molecular Weight	650.67

Chemical Name in the Inventory and Synonyms	**Butanedioic acid, sulfo-, 1,4-bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) ester, sodium salt** sodium 1,4-bis(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) sulphonatosuccinate
CAS Number	54950-05-9
Structural Formula	
Molecular Formula	C20H12F26O7S.Na
Molecular Weight	912

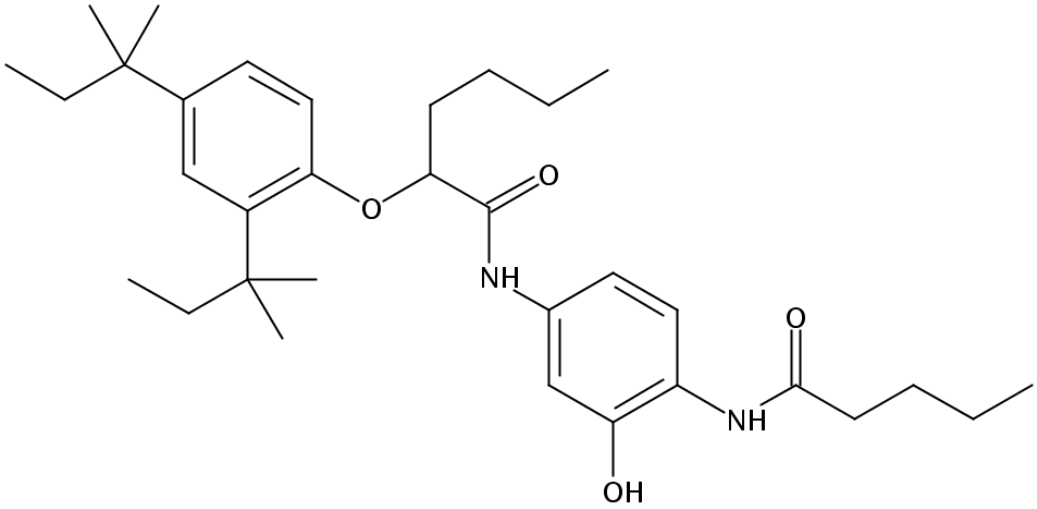
Chemical Name in the Inventory and Synonyms	**Silane, dichloromethyl(3,3,4,4,5,5,6,6,6-nonafluorohexyl)-**
CAS Number	38436-16-7
Structural Formula	



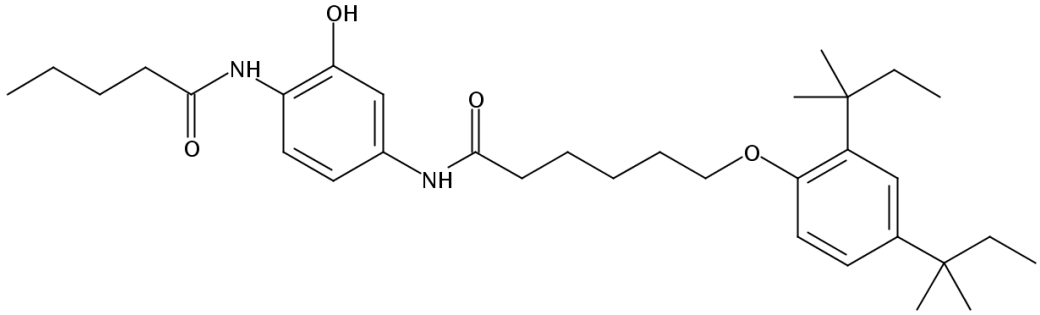
Molecular Formula	C7H7Cl2F9Si
Molecular Weight	361

Chemical Name in the Inventory and Synonyms	**Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(2,2,3,3,4,4,5,5-octafluoro-1-oxopentyl)amino]phenyl]-**
CAS Number	72494-14-5
Structural Formula	

Molecular Formula	C33H42F8N2O4
Molecular Weight	682.68

Chemical Name in the Inventory and Synonyms	**Hexanamide, 2-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(octafluoro-1-oxopentyl)amino]phenyl]-**
CAS Number	83003-52-5
Structural Formula	 8 (D1—F)
Molecular Formula	C33H42F8N2O4
Molecular Weight	

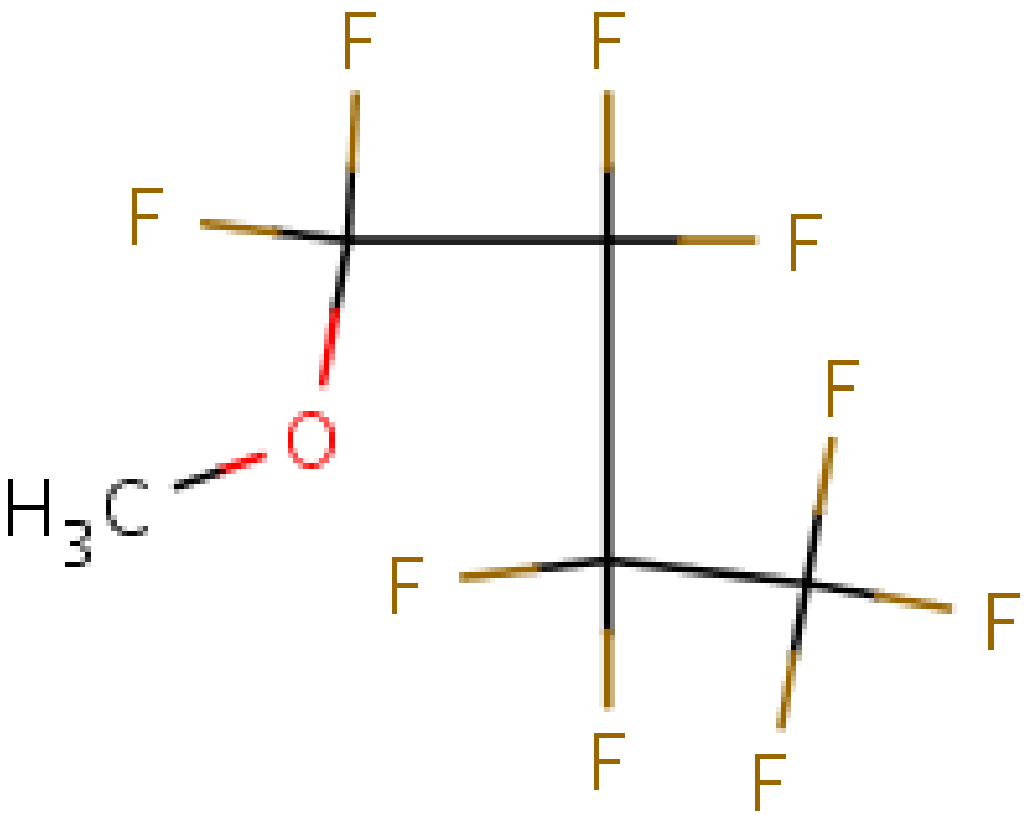
Chemical Name in the Inventory and Synonyms	**Hexanamide, 6-[2,4-bis(1,1-dimethylpropyl)phenoxy]-N-[3-hydroxy-4-[(octafluoro-1-oxopentyl)amino]phenyl]-**
CAS Number	97331-50-5
Structural Formula	

	 8 (D1—F)
Molecular Formula	C33H42F8N2O4
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**9-Octadecenoic (Z-)-, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol** 306-66-1A
CAS Number	220237-47-8
Structural Formula	**No Structural Diagram Available**
Molecular Formula	
Molecular Weight	unspecified

Chemical Name in the Inventory and Synonyms	**2,5-Furandione, dihydro-, monopolyisobutylene derivatives, reaction products with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol** 306-70-7A
CAS Number	253682-99-4
Structural Formula	

	No Structural Diagram Available
Molecular Formula	
Molecular Weight	unspecified

Chemical Name in the Inventory and Synonyms	**1-methoxy 1,1,2,2,3,3,4,4,4-nonafluorobutane** butane, 1,1,1,2,2,3,3,4,4-nanofluoro-4-methoxy methyl perfluorobutyl ether methoxyperfluorobutane
CAS Number	163702-07-6
Structural Formula	

Molecular Formula	C5H3F9O
Molecular Weight	250

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