Perfluoroalkyl sulfonates (PFSA) (>C8) and their direct precursors: Human health tier II assessment

29 June 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Nonanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-nonadecafluoro-, ammonium salt	17202-41-4
1-Decanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heneicosafluoro-, ammonium salt	67906-42-7
Sulfonic acids, C6-12-alkane, perfluoro-, potassium salts	68391-09-3

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 are salts of long-chain perfluoroalkyl sulfonate (PFSA) anions, which have the potential to dissociate into various environmentally persistent perfluoroalkyl sulfonate anions, including PFAS, containing >8 perfluorinated carbons.

No toxicological data are available for the chemicals in this group. NICNAS has developed an action plan to assess and manage chemicals which may degrade to perfluorinated carboxylic acids, PFSA and similar chemicals, which can be found in Appendix G of the Handbook for Notifiers on the NICNAS website (NICNASa). Under this action plan, perfluorooctane sulfonate (PFOS) hazard information is used to estimate the hazard of PFSA degradation products, apart from perfluorobutane sulfonate (PFBS). Greater bioaccumulation for PFSA of more than eight carbon atoms is assumed. Data for the critical effects of bioaccumulation and hepatotoxicity, developmental toxicity and carcinogenicity of individual chemicals in this group need to be provided to demonstrate that a lower toxicity profile applies.

Import, Manufacture and Use

Australian

Information collected by NICNAS indicates that chemicals in this group are not manufactured in Australia.

Whilst approximately 7.4 tonnes and 13.6 tonnes of PFSA (as technical grade and in products) were reported to be imported into Australia in 2006 and 2007, respectively, the majority of this volume was as chemicals based on PFBS, a four-carbon PFAS. Various PFSA surfactants (chain length unspecified) were reported to be imported in fire fighting foams. In 2007, approximately 60 tonnes of fire fighting foams containing 1–5 % of PFSA was held in stock at sites around Australia (NICNAS, 2013).

It is noted that some of the chemicals in this group could be present in the environment due to historic use, due to release from articles or as breakdown products resulting from the use of chemicals not covered by this assessment.

International

The following international uses for chemicals of this group have been reported by the Organisation for Economic Co-operation and Development (OECD, 2011) or identified through Galleria Chemica (Galleria Chemica):

- as fluorinated anionic surfactants;
- as intermediates; and
- in anti-reflective coatings in photolithography.

No evidence of the presence of these chemicals in consumer products was found in available North American databases (Household Products Database and Personal Care Council), indicating that the chemicals are not likely to be widely available for domestic or cosmetic uses.

All the chemicals in this group are pre-registered under the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) legislation but none have been registered under the REACH legislation at the time of assessment.

Restrictions

Australian

No known mandatory restrictions have been identified.

Measures taken to date to reduce the importation and use of PFSA compounds and their salts and precursors has largely been through NICNAS recommendations (published as alerts as part of NICNAS Factsheets) since 2002 and subsequent voluntary action by industry. NICNAS's first three alert Factsheets recommended that PFOS- and related PFAS-based chemicals be restricted to only essential uses for which no suitable or less hazardous alternatives were available (NICNAS, 2013).

International

In the United States of America (USA), all of the chemicals in this group are subject to a Significant New Use Rule (SNUR). These SNURs allow the continuation of a few limited, highly technical uses of these chemicals for which no alternatives are available, and which are characterised by very low volume, low exposure, and low releases. Any other uses of these chemicals required prior notice to and review by the US Environmental Protection Agency (EPA) (US EPA, 2002; US EPA, 2007).

Whilst PFOS is restricted in several countries (NICNAS), the chemicals in this group are not covered by these restrictions.

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 for the chemicals in this group.

International

No specific exposure standards are available for the chemicals in this group.

Health Hazard Information

In the absence of toxicological data on the individual chemicals, PFOS hazard information is used to estimate systemic hazards (see **Grouping rationale**). Based on the available information on PFCAs, bioaccumulation is likely to be greater for longer chain PFSA compared with PFOS, which might underestimate the toxicity of the chemicals in this group to some extent. Data for direct precursors of shorter chain PFSA have been used to estimate local toxicity hazards.

Toxicokinetics

Based on the available information, the chemicals of this group are expected to be rapidly absorbed after ingestion and, to a lesser extent, through inhalation. The chemicals are slowly eliminated, mainly in urine and are expected to accumulate in the liver (NICNASb, NICNASc). Elimination is substantially longer in humans than primates or rodents. The mean elimination half-life of PFOS in humans was estimated to be 5.4 years (3.9 - 6.9 years), based on the serum PFOS levels determined in retirees who had been exposed to PFOS during their working life (NICNASb). Longer chain PFCs are eliminated more slowly than shorter chains (OECD, 2013).

Limited biomonitoring data are available. Levels of PFOS in the blood of women nursing infants in Sweden have decreased between 1996 and 2010 (Glynn et al., 2012).

Acute Toxicity

Oral

PFOS is classified as hazardous with the risk phrase ‘Harmful if swallowed’ (Xn; R22) in the HSIS. Based on the data for PFOS (oral median lethal dose (LD50) of 252 mg/kg bw for rats) (NICNASb), the chemicals in this group are expected to have moderate acute toxicity following oral exposure. Classification is considered to be warranted (see **Recommendation** section). If data become available for the individual group members, they should be used to determine individual classifications.

Dermal

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

Inhalation

Based on the data for PFOS (median lethal concentration (LC50) of 5.2 mg/L for rats) (NICNASb), the chemicals in this group are expected to have low acute toxicity following inhalation exposure. If data become available for the individual group members, they should be used to determine individual classifications.

Corrosion / Irritation

Skin Irritation

Based on data for the potassium salts of PFOS and PFBS, which are non-irritating (NICNASb; NICNASd), the chemicals in this group could be, at most, slight skin irritants.

Eye Irritation

The potassium salt of PFOS was a slight irritant in rabbits, but the effects were not sufficient for classification (NICNASb).

Sensitisation

Skin Sensitisation

No data are available for the chemicals in this group or PFOS. Direct precusors of PFBS are considered nonsensitisers (NICNASd).

Repeated Dose Toxicity

Oral

PFOS is classified as hazardous with the risk phrase ‘Toxic: Danger of serious damage to health by prolonged exposure if swallowed’ (Xn; R22) in the HSIS. Repeated exposure to PFOS resulted in hepatotoxicity and mortality; the dose–response curve for mortality is very steep for rats and primates. Adverse signs of toxicity include hepatic vacuolisation and hepatocellular centrilobular hypertrophy, gastrointestinal effects, haematological abnormalities, convulsions and death.

Classification for the chemicals in this group is considered warranted (see **Recommendation** section). If data become available for the individual group members, they should be used to determine individual classifications.

Genotoxicity

Based on results from negative in vitro and in vivo genotoxicity and mutagenicity studies for direct precursors of PFOS and PFBS (NICNASb; NICNASd), the chemicals in this group are not expected to be genotoxic.

Carcinogenicity

PFOS is classified as hazardous—Category 3 carcinogenic substance—with the risk phrase ‘Limited evidence of carcinogenic effect’ (Xn; R40 in the HSIS, Safe Work Australia). The chemical induced benign tumours of the liver and the thyroid gland (Sibinski, 1987; Biegel et al., 2001). Tumours of mammary glands were also observed in these studies; however, it has been argued that since the morphologic appearance, overall incidence, and distribution of the tumours observed in treated groups were similar to historical control data for mammary-gland tumours in untreated animals (Giknis and Clifford, 2004), the incidence of mammary gland tumours is not a result of chronic dietary administration of APFO (Hardisty et al., 2010).

In the absence of toxicological data on the individual chemicals, classification for the chemicals in this group based on PFOS data is considered warranted (see **Recommendation** section). If data become available for the individual group members, they should be used to determine individual classifications.

Reproductive and Developmental Toxicity

PFOS is classified as hazardous—Category 2 substance toxic to reproduction—with the risk phrases ‘May cause harm to the unborn child’ (T; R61) and 'May cause harm to breastfed babies' in the HSIS.

Postnatal deaths and other developmental effects were reported at low doses in offspring of rats exposed to PFOS. The available data indicate that reduced pup survival is mainly a result of in utero exposure to PFOS, although post-natal exposure via milk, in conjunction with in utero exposure, could also contribute to reduced pup survival. A number of studies have found PFOS in human breast milk (NICNASb).

Classification for the chemicals in this group is considered warranted (see **Recommendation** section). If data become available for the individual group members, they should be used to determine individual classifications.

Risk Characterisation

Critical Health Effects

The chemicals in this group are slowly eliminated from the body following absorption. The chemicals are expected to accumulate in the liver. The critical health effects for risk characterisation include systemic acute and long-term effects (hepatotoxicity and developmental toxicity and benign tumours of the liver and thyroid) from oral exposure.

Public Risk Characterisation

Use in consumer products

Based on the available use information, the chemicals 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 via the environment

Public exposure to the chemicals in this group could occur through secondary exposure via the environment. The chemicals in this group are not likely to be used in significant quantities in Australia. It is noted that the chemicals in this group could be present in the environment due to historic use, or due to release from articles or the use of indirect precursor chemicals not covered by this assessment. The chemical, PFDS was not detected in a survey of 65 foods and beverages packaged in glass, paper, plastic or cans conducted by Food Standards Australia New Zealand (FSANZ, 2010). Currently, it is recommended that the chemicals in this group be restricted to only essential uses for which no suitable or less hazardous alternatives are available. Further risk management will be determined as part of the IMAP Tier II Environment assessment report for these chemicals.

Occupational Risk Characterisation

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

The data available support amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Currently, it is recommended that the chemicals in this group be restricted to only essential uses for which no suitable or less hazardous alternatives are available. Further risk management will be determined as part of the IMAP Tier II Environment assessment report for these chemicals.

In addition, amendment to the hazard classification in the HSIS is recommended.

Regulatory Control

Work Health and Safety

The chemicals are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards. If data on the individual group members become available, they should be used to determine individual classifications.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Toxic if swallowed - Cat. 3 (H301)
Repeat Dose Toxicity	Toxic: Danger of serious damage to health by prolonged exposure if swallowed (T; R48/25)	Causes damage to organs through prolonged or repeated exposure if swallowed - Cat. 1 (H372)
Carcinogenicity	Carc. Cat 3 - Limited evidence of a carcinogenic effect (Xn; R40)	Suspected of causing cancer - Cat. 2 (H351)
Reproductive and Developmental Toxicity	Repro. Cat 2 - May cause harm to the unborn child (T; R61) May cause harm to breastfed babies (Xn; R64)	May damage the unborn child - Cat. 1B (H360D) May cause harm to breast-fed children (H362)

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

- using closed systems or isolating operations;
- 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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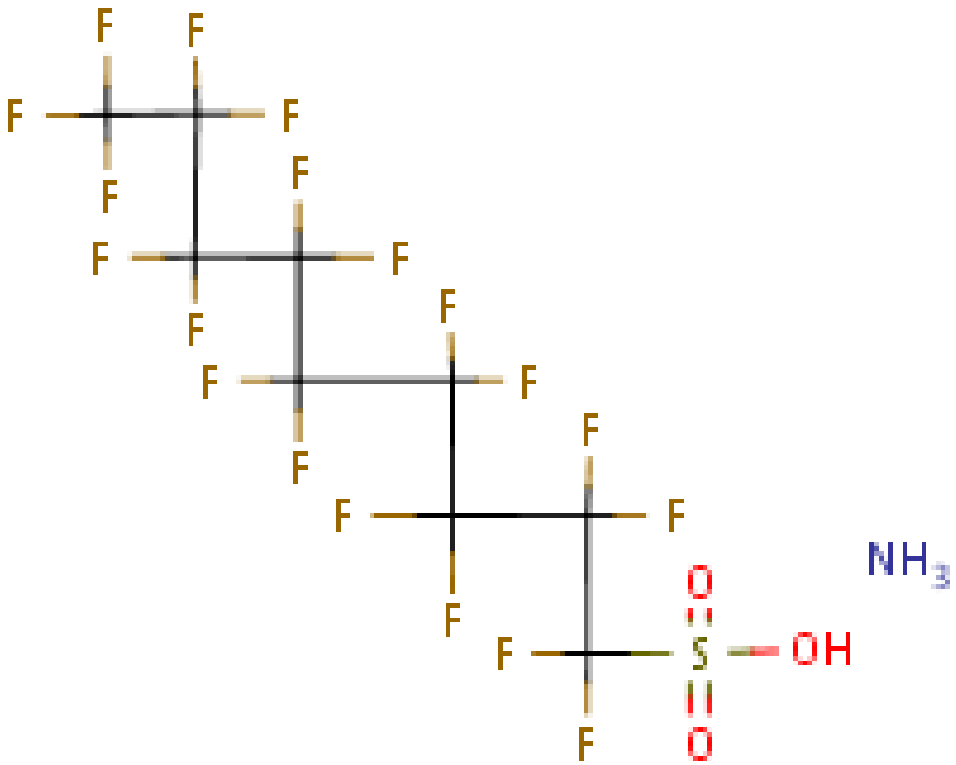
Last Update 29 June 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**1-Nonanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-nonadecafluoro-, ammonium salt** perfluorononanesulfonic acid, ammonium salt ammonium nonadecafluorononanesulfonate
CAS Number	17202-41-4
Structural Formula	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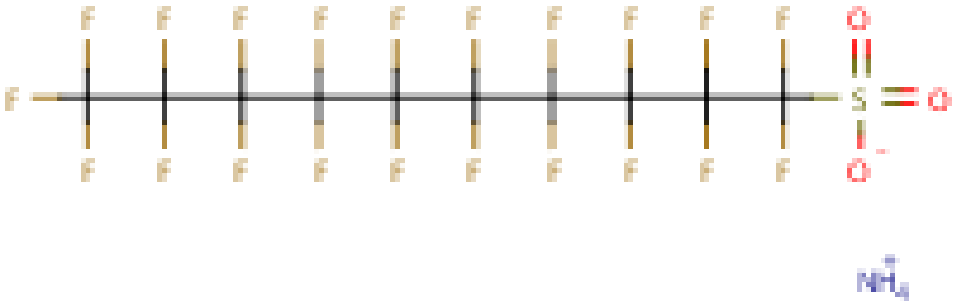
Molecular Weight	567.2

Chemical Name in the Inventory and Synonyms	**1-Decanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heneicosafluoro-, ammonium salt** perfluorodecanesulfonic acid, ammonium salt ammonium henicosafluorodecanesulfonate PFDS
CAS Number	67906-42-7
Structural Formula	

	
Molecular Formula	C10HF21O3S.H3N
Molecular Weight	617.2

Chemical Name in the Inventory and Synonyms	**Sulfonic acids, C6-12-alkane, perfluoro-, potassium salts** perfluoro-C6-12-alkylsulfonic acid, potassium salt
CAS Number	68391-09-3
Structural Formula	**No Structural Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	

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