Existing Chemical Secondary Notification Assessment Report
LTD/1058S

Australian Government
Department of Health
National Industrial Chemicals
Notification and Assessment Scheme

Fluorosurfactant FC-4430

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

GPO Box 58, Sydney NSW 2001 AUSTRALIA **www.nicnas.gov.au**

ISBN 978-0-9874434-8-9

Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), to aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals, providing information and making recommendations to promote their safe use. NICNAS assessments are carried out by staff employed by the Australian Government Department of Health in conjunction with the Australian Government Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This assessment report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director

NICNAS

Contents

Overview

Background

The notified polymer, Fluorosurfactant FC-4430, was assessed by NICNAS as a new chemical under the limited category in 2003 and is now listed in the Australian Inventory of Chemical Substances (AICS). Fluorosurfactant FC-4430 is a polymer with a molecular weight greater than 1000 Da and is a precursor of perfluorobutane sulfonate (PFBS) through breakdown in the environment. The original assessment covered industrial applications as a surfactant in protective thin layer protective coatings. It can be used in powder coating products and a variety of waterborne, solvent-borne and high-solids organic polymer coatings for electronic components in the computer and telecommunications industry, office furniture and pipes in chemical plants. Although the notified polymer was originally assessed for use in protective products for carpets, it is no longer used or intended to be used at any time in the future in these products. In 2013, additional information was provided that warranted a secondary notification of Fluorosurfactant FC-4430.

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: Chemical name, CAS number, Molecular and structural formula, Molecular weight, Spectral data, Polymer composition, Purity and Detailed use.

Import volumes and uses

The notified polymer will continue to be imported in a neat form into, and not be manufactured in Australia. It will be on-sold to formulators and reformulated into products containing up to 0.5% of the polymer. Additionally, it is imported in products containing up to 0.5% of the polymer.

The additional information submitted for the secondary notification assessment indicated that Fluorosurfactant FC-4430 is intended to be imported into Australia in much greater quantities than proposed in the assessment as a new chemical (up to 29.1 tonnes per annum compared to 10 tonnes per annum considered in the earlier assessment) and also in applications other than those originally notified.

Proposed new applications for the notified chemical include domestic decorative paints that would be available to consumers, as well as coatings and adhesives containing up to 0.3% of the notified polymer. Other new industrial applications for the notified polymer are in pre-formulated inks and in the manufacture of insulation foam. The insulation foam is to be used for production of articles and is for export purposes only.

New ecotoxicological data, relevant for environmental risk assessment, were also provided for the secondary notification assessment.

This secondary notification assessment focuses on the new data and reviews the potential risks to human health and the environment from the exposure to the notified polymer under the new circumstances. The report also considers relevant information on potential degradation products of the notified polymer, consistent with NICNAS's evolving approach to assessment of perfluorinated polymers.

Health effects

No new toxicity data were submitted for the secondary notification of the notified polymer. However, consideration of the toxicity of potential breakdown products is now included in this assessment.

The notified polymer has low acute oral and dermal toxicity in rats. It is a slight skin and eye irritant in rabbits and is not a skin sensitiser in guinea pigs. The 28-day repeat dose oral study in rats did not show any treatment-related changes in clinical observations, laboratory findings or effects in organs. The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg/day (the highest dose tested) in this study.

The notified polymer was not mutagenic in the bacterial strains tested, or clastogenic to human peripheral lymphocytes in vitro.

The notified polymer contains perfluoroalkyl side-chains that are potential precursors of perfluorobutane sulfonate (PFBS) in the environment. PFBS is a short, four-chain perfluorinated chemical known to be persistent in the environment. However, compared to longer chain perfluorinated compounds consisting of 7 perfluorinated carbons or more, PFBS has a less hazardous profile (NICNAS, 2005). Therefore, the human health hazards associated with the expected breakdown product (PFBS) of the notified polymer would be less severe than those associated with many of the expected breakdown products of the perfluoroalkyl polymers currently on the market that contain longer chain perfluorinated compounds, that are intended to be replaced by the notified polymer.

Occupational exposure and health risk

The risk to workers' health from the new industrial use of the notified polymer as a component in the manufacturing of insulation foam for export only is low. This is due to the highly automated manufacturing process that, combined with the use of PPE, results in minimal exposure. In the final insulation product, the notified polymer will be incorporated into the solid polymer matrix and hence will not be bioavailable during any processes following its manufacture and packaging.

For tradespeople using coatings, paints and inks containing the notified polymer, repeated dermal exposure and accidental ocular exposure may occur during application by brush, roller, mop or squeegee. Similarly, for end-users of adhesives containing the notified polymer, repeated dermal exposure and accidental oral and ocular exposure may occur during application of adhesives to surfaces using a cartridge applicator. The risk to these workers of systemic adverse effects is not considered to be unreasonable as the notified polymer has a high molecular weight (>1000 Da) with a low level of low molecular weight species, and is not expected to be bioavailable via the dermal route. In addition, sub-chronic oral studies do not indicate any significant toxic effects associated with systemic exposure to the notified polymer. The notified polymer has slight skin and eye irritant potential. However, risk of local dermal or eye effects is not considered to be unreasonable as the notified polymer is present at low concentrations in the paints and coatings (up to 0.5%) and adhesives (up to 0.3%). In addition, the PPE likely to be used by professional tradespeople is expected to further lower exposure to the notified polymer and its impurities. When the coating or adhesive has dried, the notified polymer will be bound within a matrix, and is therefore not likely to be bioavailable.

Repeated inhalation exposure of professional tradespeople to the notified polymer may occur during spray application. No repeat dose inhalation toxicity data are available to assess the risk associated with the potential exposure from this application. However, the risk is not considered to be unreasonable due to the low concentrations of the notified polymer in the end-use products, and due to the PPE used by professionals.

Systemic exposure of workers to break down products is not expected based on the stability of the notified polymer. However, workers may be exposed to perfluoroalkyl starting constituents and/or impurities of the notified polymer at relatively low concentrations. It is expected that the engineering controls and PPE utilised during these operations will act to mitigate any risk associated with such exposure.

Public exposure and health risks

For this secondary assessment, the polymer was notified for use as a surfactant in consumer applications, in decorative domestic paints and coatings and adhesives, at up to 0.3%. Paints and coatings containing the notified polymer will be available to the public for application by brush, roller, and possibly by spraying. For these uses, exposures to the notified polymer via the dermal and inhalation routes are possible. Adhesives containing the notified polymer will also be available to the public for application to surfaces using a cartridge applicator with potential exposures via the dermal, oral and ocular routes. However, consumers are not expected to use these products on a regular basis. Given the low toxicity profile of the notified polymer and its low concentrations in coatings, no unreasonable risk is expected for the public from this application. In addition, product literature is likely to contain recommendations for good work practices and use of PPE such as protective clothing and gloves and suitable protection for application by spray. This should also minimise the risk from potential inhalation-related adverse effects that may be associated with application of the coatings containing the notified polymer by spraying.

Public exposure via dermal contact with dried coatings or adhesives containing the notified polymer will be minimal as the notified chemical is present in low concentrations and bound within a matrix once the product has dried.

The public may be exposed indirectly to PFBS, which is expected to be formed by environmental degradation of the notified polymer; and exposure may increase over time due to the persistence of PFBS in the environment. A quantitative risk assessment for this exposure cannot be conducted. However, the available data indicate that PFBS has a less hazardous human health profile than the long-chain perfluoroalkyl substances (such as PFOA) that are the ultimate breakdown products of the majority of perfluoroalkyl polymers currently in Australian commerce. It is concluded that the risks to human health from indirect exposure to breakdown products of longer chain perfluoroalkyl substances will decrease following the increased introduction of the notified polymer, on the basis that the notified polymer is continuing to replace currently available long chain perfluoroalkyl polymers.

Environmental effects

New studies on marine species were provided for the secondary notification assessment, namely Marine Fish Toxicity, Marine Amphipod, Marine Copepod Toxicity and Marine Alga Toxicity studies. The notified polymer is classified as “Acute Category 2; Toxic to aquatic life” under the Globally Harmonized System (GHS) of classification based on the study with marine algae showing a PNEC of 32 µg/L. The notified polymer has low toxicity to the marine fish, amphipod and copepod species tested, and so was assessed as not harmful to those species.

As a comparison, the studies on freshwater species assessed during the original assessment of the notified polymer as a new chemical showed very slight toxicity to fish and algae and greater toxicity to invertebrates, indicating that the notified polymer may be harmful to these species. Based on the test with daphnia, a PNEC of 0.99 mg/L was determined.

On the basis of the risk quotient (PEC/PNEC) and the assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment.

Biodegradability of Fluorosurfactant FC-4430 could not be assessed at the time of its notification as a new chemical. For the secondary notification, test reports were provided on inherent biodegradation and on photolysis for the notified polymer. The biodegradation in the inherent biodegradation study was determined on the basis of target degradates and disappearance of the notified polymer itself, instead of mineralisation. Therefore, based on the lack of evidence for rapid ultimate degradation for the whole polymer, and considering its acute toxicity, the notified polymer is classified as Chronic Category 2: *Toxic to aquatic life with long lasting effects* under the GHS classification for the chronic hazard.

The likely degradation product, PFBS, is not considered to be toxic to aquatic organisms (NICNAS, 2005) and PFBS is not expected to be harmful to aquatic organisms on a short-term basis. However, PFBS is very persistent and there is a potential for it to accumulate in the environment. Nevertheless, long-term hazards to aquatic organisms could not be fully characterised as traditional long-term studies do not adequately address the potential hazard of very persistent compounds such as PFBS. However, it is known that whilst sulphonic acid moieties tend to be more toxic than the carboxylic acid of the same fluorinated carbon chain length, the ecotoxicity of perfluoroalkyl compounds also increases with increasing carbon chain length (Giesy et al., 2010).

Environmental exposure and risks

The risk quotient (RQ) for the notified polymer is determined to be < 0.1 (RQ = PEC/PNEC = 1.56μg/L/32μg/L), indicating that there is no unreasonable potential risk to the aquatic environment from the proposed use of the notified polymer. This RQ is based on a PEC for the notified polymer after it has been processed through a sewage treatment plant (STP). This is a maximum (conservative) value as it assumes no biodegradation, when the biodegradation study of the notified polymer shows that, although not precisely quantified, rapid primary degradation will occur.

Based on the risk quotient and the assessed use pattern, the notified polymer itself is not expected to pose an unreasonable risk to the aquatic environment in the short term. However, the notified polymer is assumed to eventually degrade to form PFBS, which may be delocalised from points of release. PFBS is an environmentally persistent chemical that has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFBS is considered to be less problematic when compared with long chain (C8 and above) perfluoroalkyl compounds that PFBS is expected to replace as a component of perfluoropolymers. In addition, current evidence suggests PFBS is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of polymers and chemicals that degrade to PFBS and other very persistent poly- and perfluoroalkyl compounds should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

Continuing release of PFBS is expected to result in increasing environmental concentrations over time. Hence, there is potential for ecotoxicologically significant concentrations to eventually be reached following its accumulation in the environment over a significant period of time. In this eventuality, precursors of PFBS such as the notified polymer are a potential source of PFBS in the environment even long after their use ceases. Thus, use and disposal of the notified polymer increases the environmental risk profile of PFBS over time.

Recommendations

The previous assessment of Fluorosurfactant FC-4430 contained the recommendations to minimise the occupational exposure to the notified polymer and its environmental release and effects (NICNAS, 2003) and is applicable to this assessment. No recommendations for applications of the notified polymer by the public were made at that time as such uses were not notified.

Public health recommendations

Hazard communication—Labels

It is recommended that products available for use by the public should carry the following safety directions on the label:

- Avoid contact with skin and eyes
- Avoid breathing of mists and sprays
- Use in well-ventilated areas, where possible
- In case of insufficient ventilation, wear suitable respiratory protection

Occupational health and safety recommendations

Engineering controls

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
    - Enclosed, automated processes, where possible
    - Provide adequate ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
    - Avoid contact with skin and eyes.
    - Avoid generation of and inhalation of dusts, mists and sprays.
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
    - Protective clothing/coveralls
    - Impervious gloves
    - Eye protection
    - Respiratory protection, if inhalation exposure may occur
- Guidance on the selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (Safe Work Australia, 2012b) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Environment

- The notified polymer should be introduced as part of a strategy to phase out the use of long chain perfluoroalkyl chemicals. The applicant is not aware of the chemicals in the products currently used to manufacture insulation foams in Australia.
- The applicant should seek ways to minimise the level of residual perfluoroalkyl monomers and impurities in the notified polymer. Such levels should be as low as practicable; where possible, the total weight of these constituents should not exceed the levels attainable utilising international best practice.
- To minimise exposure of the notified polymer to the environment, users of the notified polymer (or products containing the notified polymer) should employ best practice on-site treatment of waste streams to maximise removal of the notified polymer from waste streams that are released to sewer.
- Where possible, waste (including overspray) should be collected by end users for disposal by incineration or to landfill to minimise environmental exposure of the notified polymer.

Disposal

- The notified polymer should not be disposed to sewer. If the notified polymer or products containing the notified polymer cannot feasibly be disposed using a technique that will destroy the notified polymer, disposal should be to landfill where leaching to the water compartment will be managed.
- High-temperature incineration is the preferred method of disposal of perfluoroalkyl compounds due to their environmental persistence characteristics. In the case of incineration, combustion products will contain hydrogen fluoride. The incinerator should be equipped with suitable controls for combustion of halogenated materials.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change.

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

- the importation volume exceeds 30 tonnes per annum for the notified polymer;
- the polymer has a number-average molecular weight of less than 1000;
- the notified polymer is intended for spray application by professionals using non-automated methods;
- information on the inhalation toxicity of the notified polymer becomes available;
- additional information has become available to the person as to an adverse effect of the polyfluoroalkyl degradation products of the notified polymer (such as perfluorobutanesulfonic acid);
- additional information has become available to the person as to the environmental fate of the polymer or its polyfluoroalkyl degradation products (such as perfluorobutanesulfonic acid) in relation to degradation or partitioning behaviour, including during water treatment processes;

or

(2) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on human health , or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Abbreviations and acronyms

AS	Australian Standard
CAS	Chemical Abstracts Service
ChV	algal chronic value
cm	centimetre
CO_2	carbon dioxide
d	day
EC50	median effective concentration
g	gram
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GLP	good laboratory practice
ha	hectare
IBCs	intermediate bulk containers
kg	kilogram
L	litre
LOAEL	Lowest Observed Adverse Effect Level
m	metre
mg	milligram
MSDS	Material Safety Data Sheet
N-MEFBSE alcohol	2-(*N*-methylperfluorobutane-sulfonamido) ethyl alcohol),
ND	New data
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No Observed Adverse Effect Level
PE pails	polyethylene pails
PEC	predicted environmental concentration
PFBA	perfluorobutyric acid
PFBS	perfluorobutane sulfonate
PNEC	Predicted No-effect Concentration
PLC	polymer of low concern
PPE	personal protective equipment
PPMv	parts per million volume
SDS	Safety Data Sheet
STP	sewage treatment plant
TWA	time weighted average
WHS	Work Health and Safety

1. Introduction

1.1 Background

The notified polymer, Fluorosurfactant FC-4430, was assessed by NICNAS as a new chemical under the limited category in 2003. The polymer is now proposed to be imported into Australia in much greater quantities and also in applications other than those originally notified. Therefore, a secondary notification assessment was warranted to review the potential risks to human health and the environment from exposure to the notified polymer under the new circumstances. This secondary notification assessment focuses on the new data provided. The additional data on import volumes and new uses have been incorporated into the report as appropriate and the implications of the data for the health and environmental risks of the notified chemical considered. This report also considers relevant information on potential degradation products of the notified polymer.

1.2 Declaration

A notice was published in the Chemical Gazette of November 2013, requiring a secondary notification of the notified polymer in accordance with Section 65(2) of the Act. The declaration of this secondary notification relates to the introduction of the notified polymer in Australia in greater quantities and for new applications not previously assessed.

The declaration required the provision of any information relevant to the assessment of the notified polymer that was not covered in the original new chemical assessment.

Information sought for this secondary notification assessment included the following:

1) Name(s) under which the polymer will be marketed.
2) Proposed uses of the polymer.
3) Concentration of the polymer in finished products.
4) Information on the composition of the notified polymer such as polymer constituents (including chemical name, CAS No., % starting weight) and impurities/residual monomers (including chemical name, CAS No., % residual weight).
5) The formulation type of the finished products (i.e. water-based or organic solvent based).
6) Import quantities and the proposed volumes in the various applications.
7) Information on occupational exposure during the proposed new uses for all workers handling the polymer.
8) Details of any adverse health effects on occupational health and safety observed since the certificate was issued.
9) Information about the environmental release from use of the polymer, including the expected release from each of the various application methods for all consumer products.
10) Information about the disposal of the polymer resulting from the proposed new use, including the volume of residual polymer in consumer packaging and the fate of this residual polymer.
11) Any additional information regarding the degradation of the polymer in the environment.
12) Australian SDS(s) and Labels for the notified polymer and any product containing the notified polymer being introduced.
13) Any additional data available on toxicological and/or ecotoxicological effects of the chemical.
14) The chemical that the notified polymer is replacing for use in foam manufacture.

1.3 Objectives

The objectives of this assessment are to review the new data made available since the publication of the new chemical assessment report, and where appropriate, revise the original assessment to:

- characterise the hazards of Fluorosurfactant FC-4430 to human health;
- characterise the potential occupational and public exposure to Fluorosurfactant FC-4430;
- characterise the risk of adverse effects resulting from exposure to workers and the general public;
- based on the above, make appropriate recommendations to control exposures and/or reduce potential health risks for workers and the general public as required; and
- characterise the environmental hazards and related risk and recommend controls as required.

1.4 Peer review

During all stages of preparation, this report has been subject to internal peer review by NICNAS.

1.5 Applicant(s)

Following the secondary notification declaration of Fluorosurfactant FC-4430, one company applied for assessment. The applicant's details are as follows:

3M Australia Pty Ltd (ABN 90 100 000 096)
Building A
1 Rivett Road
North Ryde NSW 2113

1.6 Exempt information

The applicant has claimed the following data items as exempt from publication under Section 75 of the Act: Chemical name, CAS number, Molecular and structural formula, Molecular weight, Spectral data, Polymer composition, Purity and Detailed use.

2. Chemical identity, physical and chemical properties

Physical and chemical data assessed by NICNAS in the new chemical assessment report (NICNAS 2003) are reproduced in this report. The new data are indicated as **ND**.

Fluorosurfactant FC-4430 has a Number Average Molecular Weight (Mn) greater than 1000 Da. No changes to the original composition of the notified polymer were reported. The notified polymer is a potential precursor of perfluorobutane sulfonate (PFBS) through breakdown in the environment (CAS name for PFBS when present as the acid: 1-Butanesulfonic acid, 1,1,2,2,3,3,4,4,4-nonafluoro-; CAS No.: 375-73-5).

The physical and chemical data of the polymer are shown in Table 2.1 below:

2.1 Physical and chemical properties

Property	**Value**	**Method/comment**
Appearance at 20^oC and 101.3 kPa	Viscous amber coloured liquid with mercaptan odour	
Boiling Point	210°C at 101.3 kPa	Data from the US PMN
Density	1 147 kg/m^3	Data from the US PMN
Vapour Pressure	$<9.3x10^{-3}$ kPa	Data from the US PMN
Water Solubility	6 211 mg/L at 22-23°C	OECD TG 105 Water Solubility (3M, 2001)
Specific gravity	1.15 **(ND)**	Data from SDS supplied by the applicant
Vapour density	5.7 at 20°C **(ND)**	Data from SDS supplied by the applicant
Viscosity	200-10000 centipoise **(ND)**	Data from SDS supplied by the applicant
Percent volatile	≤ 3% **(ND)**	Data from SDS supplied by the applicant
Hydrolysis as a function of pH	Method 1: average half-life of 20.2 years, 0.737 years and 0.19 years at pH 4, 7 and 9 respectively, based on appearance of the primary degradation product. Method 2: hydrolytic half-life 16.2 years independent of pH based on appearance of a subsequent degradation product.	A comprehensive hydrolysis study report was provided following OECD Guidelines (3M 2002a). The polymer was suspended into three sets of buffers containing <1% acetone co-solvent at nominal pH levels 4, 7 and 9 at a nominal concentration of 200 mg/L. Samples were analysed for the primary predicted degradation product 2-(*N*-methylperfluorobutane-sulfonamido) ethyl alcohol (N-MEFBSE alcohol). Four additional possible degradation products were monitored, namely, fluorochemical

Property	**Value**	**Method/comment**
	The hydrolytic half-life of fluorochemical alcohol was calculated to be a minimum of 1.7-2.3 years.	amide, primary fluorochemical amide, perfluorobutane sulfonate (PFBS), and perfluorobutyric acid (PFBA). The hydrolytic stability of fluorochemical alcohol was separately studied as well in buffered aqueous solutions. Two methods were used to estimate the hydrolytic half-life of the notified polymer. The first calculated the half-life based on the rate of appearance of the fluorochemical alcohol and two times the standard deviation of triplicate measurements. The second method calculated the minimum pseudo first order hydrolytic half-life of the notified polymer by calculating how fast it might degrade to generate PFBS. This assumes that PFBS is the only hydrolytic product formed.
Partition Coefficient (n-octanol/water)	Not Determined	Expected to partition to the interface between octanol and water due to its surfactant properties.
Adsorption/Desorption	Not determined	Log Koc was not determined. However, based on the result of a sewage sludge adsorption test (Appendix, A.2.2.3) it appears that the notified polymer is unlikely to adsorb and will be mobile in the soil or sediments.
Dissociation Constant	Not determined	No dissociable functionality
Particle Size	Not determined for a liquid	
Flash Point	100 °C	Closed cup method. It is likely that the results of this test were influenced by traces of solvent in the polymer
Explosive Properties	None known	
Flammability Limits	Not determined	
Autoignition Temperature	Not determined	

Property	Value	Method/comment
Reactivity	Not expected to be reactive	
Thermal Characterisation	A thermal characterisation test report was provided. The decomposition profile suggested that the notifier polymer contains approximately 5% highly volatile matter. This highly volatile component appears to influence the calculation of the kinetics parameters at lower conversion. At higher conversion, a 205 kJ/mole activation energy was calculated	3M (2001)
Indirect and Direct Photolytic Screening Test	No photolytic degradation by either direct or indirect mechanisms was observed nor detected. **(ND)**	(3M, 2001)

3. Manufacture, importation and use

The notified polymer will continue to be imported in the neat form into, and not be manufactured in, Australia. It will be imported in 4L and 20L polyethylene (PE) pails or 250L lined steel drums and reformulated into products containing up to 0.5% notified polymer. The container size for end use products will vary with their intended use. The notified polymer will be transported by ship, road and rail as appropriate. Additionally, FC-4430 will be imported in formulated ink products containing up to 0.5% of the notified polymer.

Maximum introduction volume of the notified chemical over the next five years will be up to 29.1 tonnes per annum, as compared to a maximum annual introduction of 10 tonnes per annum as originally assessed.

Existing uses
The notified polymer is a non-ionic polymeric fluorochemical surfactant. It is used in powder coating products and a variety of waterborne, solvent-borne and high-solids organic polymer coatings. The notified polymer was initially introduced as a direct replacement of partially fluorinated polymers containing fluorinated carbon chain lengths of ≥6 in various proportions.

The notified polymer is used in non-emissive, industrial coatings such as corrosion resistance coatings on electronic components for computers and telecommunications industry, signage, office furniture and pipes in chemical plants. The maximal concentration of the notified polymer in these products for industrial use is 0.5%. Although the notified polymer was originally assessed for use in protective products for carpets, it is no longer used or intended to be used at any time in the future in these products.

New uses
Proposed new uses for the notified chemical include trade and consumer applications in decorative domestic paints and coatings and adhesives containing up to 0.3%. The adhesives are used to bond various types of substrates such as plastics, metals, rubber or glass. Although the adhesives will be sold into the retail market, they are primarily intended for use by professional tradespeople.

Another new application for the notified polymer includes manufacture of insulation foam for export purposes only. The insulation foam is used for production of articles. The applicant was not aware of the chemical/chemicals that the polymer will be replacing in the manufacture of insulation foam.

The notified chemical will also be imported in formulated ink products at concentrations up to 0.5%. The inks are used as a component in a series of process colour inks designed specifically for application by screen processing onto signage material. The inks will not be sold to the public.

4. Exposure

Exposure to the notified polymer of both, workers and the public is likely for the new uses assessed in this secondary notification assessment. New information provided by the applicant in relation to the new uses and exposure are indicated as **(ND)**.

Exposure to the residual polyfluoroalkyl starting constituents and/or impurities of the notified polymer (polyfluoroalkyl chemicals containing perfluoroalkyl carbon chain lengths of four) is also possible. However, such exposure is limited by the relatively low concentration of polyfluoroalkyl impurities in the notified polymer and the end use products.

The notified polymer is a precursor of PFBS in the environment. This is likely to lead to secondary human exposure to PFBS. This exposure is unquantifiable and its implications are discussed in the health effects and risk assessment sections.

4.1 Occupational exposure

4.1.1 Operational description

For the existing industrial applications, the imported polymer is used to formulate powder or liquid products. Formulation process occurs at approximately 50 paint/coating manufacturing companies in Australia. At the reformulation site, the containers (4L and 20L polyethylene pails or 250L lined steel drums) are transported from a storage area to a blending area. The containers are opened by the operator and the contents either poured out manually (small containers) or pumped (large containers) using automated dosing equipment from the containers to a closed blending tank. Blending takes place in a bunded area supplied with local and general ventilation. Once blending has been completed, a QA sample is taken via a sampling port. The formulated product is then pumped via closed lines to the filling machine. The filling machine design varies depending on the types of end-use containers: 0.5L cans/plastic bottles to 250L steel or PE drums for paints and coatings or 10-250g plastic tubes or bottle cartridges for adhesives **(ND)**. The filling machine is automated, enclosed, bunded and supplied with local ventilation. The filled containers are packed into fibreboard boxes (for smaller containers) or transported with secondary packaging (larger containers) for distribution by road to end-users.

The concentration of the notified polymer in the final paint/coatings products for industrial uses will be up to 0.5%. At application sites, these paints/coatings products are applied to surfaces by dipping, roller coating, brush painting or spraying. The most likely route of exposure during these operations is the dermal route. Ocular and oral exposure routes are also possible but would be accidental. Inhalation exposure to the notified chemical in powder products is possible but is unlikely from liquid products due to its relatively low vapour pressure. Once applied to the desired article, the product is dried or heat cured on the surface rendering the notified polymer inert.

The adhesive is applied from a cartridge, which is designed to minimise exposure as there is no need for manual mixing. An applicator (manual or pressure-assisted) is used to depress the plunger and slowly extrude the adhesive onto a surface. End-users will open and load the adhesive cartridges and apply it to the surface as required. The adhesive is relatively viscous, ensuring that exposure from spills and splashes will be minimised. Any excess adhesive will be cleaned with a spatula or cloth. Once the adhesive is cured into a solid mass, exposure is minimal as the notified polymer will be trapped within the solid matrix **(ND)**.

The notified chemical will also be used in the manufacture of foam from a reaction of polyurethane monomers, which is then injected into moulds. The monomers and other components are piped to a mixing head where the polymerisation reaction commences. The foam is injected into the mould prior to forming the ridged shape. The mould is opened to release the moulded article. Overall, the foam manufacture is a highly automated process. The manufactured foam is for export purposes only **(ND)**.

Inks containing up to 0.5% of the notified polymer are not formulated in Australia. They are imported as the formulated product that is applied by screen processing onto sheeting prior to mounting on a sign substrate. Local exhaust ventilation is employed to control airborne exposure at manual transfer of the ink onto the screen dependent on the size of the application area. Exposure is minimised as workers are trained in the proper handling of screen process inks and will wear gloves and safety glasses. The amount of notified polymer used in this application is 10-30 kg/annum **(ND)**.

Number and category of workers

Category of worker	**Number**	**Exposure duration (h/day)**	**Exposure frequency days/year**
Warehouse/transport personnel	100	1-2	50
Formulation of end-use products	500	8	200
Manufacture of insulation foam **(ND)**	20	8	200
End use – painting/coating	1400	8	300
End use – inks **(ND)**	50-100	8	300
End use - adhesives	1000	8	300

Transport and storage workers

Occupational exposure to the notified chemical during transportation or storage is unlikely as the notified chemical is in sealed containers. Transport and storage workers will only come into contact (dermally and/or orally) with the notified polymer in the unlikely event of an accident. Workers involved in storage and transport will normally wear clothing that covers the body, safety glasses and gloves. In the event of a significant spill, clean-up workers will wear full personal protective equipment (PPE) such as protective clothing, safety boots, gloves and safety goggles.

Manufacturing of paints, coatings and adhesives

Factory operators transfer the notified polymer from the imported containers into closed stainless steel blending tanks (up to 10000L capacity), under local exhaust ventilation. The transfer operation involves opening the imported containers, connection of pumping equipment and transfer lines to the blending tank. High-speed dispersion and mixing are used to blend the coating components. The blend is then dosed with other components to form the finished coating. Exposure (dermal, ocular and inhalation) of workers to the polymer may occur during manual transfer of the notified polymer to small volume containers and during quality assurance testing and cleaning and maintenance of the equipment. The finished product is filled into various sizes and types of containers. Each filling line has a ventilation extraction system. Exposure is minimised by the use of PPE such as coveralls, safety glasses and gloves. While generation of dust/mists/aerosols is possible during blending/reformulation, engineering controls and PPE reported to be used will minimise potential exposure.

Manufacturing of insulation foam **(ND)**

Polyurethane foam manufacturing workers will open the drums containing the notified polymer and connect a flexible transfer hose and pumping equipment. The contents of the drums will be pumped to sealed, on-site holding tanks. Once the transfer is completed, the hose will be disconnected. Workers performing this operation will wear PVC aprons, overalls, impervious gloves, safety goggles, hard hats and respirators. As the isocyanate monomers, present as component of the polyurethane foam manufacturing mixture are hazardous and are sensitisers, proper precautions will be taken to avoid exposure. Foam production workers will also operate the foam plant. The plant is fully automated, sealed and supplied with local fume extraction. These workers will wear overalls and safety shoes. In the event of a malfunction of the plant or during routine maintenance, the foam plant will be shut down, and the lines will be flushed before maintenance workers commence work on the equipment.

Thus, minimal exposure of these workers to the notified chemical is expected. Dermal and ocular exposure may occur during transfer of the notified polymer from the transport containers to on-site holding tanks. The automated processes, enclosed mixing head, use of local exhaust ventilation and personal protective equipment worn by workers, will ensure that exposure will be significantly reduced. Workers may come into dermal contact with polyurethane foam containing the notified chemical. However, in this final form, the notified polymer will be incorporated into the solid polymer matrix and hence is not bioavailable.

It is reported that full precautions are taken to avoid exposure to any hazardous chemicals including exposure to isocyanates involved in the process of manufacturing of the foam.

Industrial applicators

Techniques involved during coating applications include roller-coating, brushing, dipping and spraying. The dipping process can involve manual application or be automated using a robot. Coil coatings are applied by a roller coater and may be done using (liquid) paints or coating powders.

Industrial paints and coatings are applied by a number of methods, while liquid automotive coatings are applied by spray. The formulated paint or coating is stirred, thinned and loaded into circulation tanks or spray guns. The workers involved may be exposed by skin contact and through inhalation to the finished paint or coating that contains a maximum of 0.5% notified polymer. Inhalation exposure is unlikely during factory application based on the expected low vapour pressure of the notified polymer given its relatively high molecular weight (>1000 Da). Exposure is reported to be minimised by the use of good manufacturing practices and PPE. Filtered exhaust systems are fitted at the operation sites. Applicators wear coveralls, safety goggles and impervious gloves. In addition, cartridge type respirators are used during spray application of the paints and coatings.

Powder coatings are applied to surfaces by spraying, roller coating or dipping. Exposure, (dermal, ocular and inhalation) to the notified polymer at ≤ 0.5% concentration, of workers may occur during application of the powder coatings. Exposure is expected to be minimised through the use of enclosed, automated systems (where possible), adequate ventilation and PPE described for the liquid-based applications above. Once the coating is cured, the notified polymer will be unavailable for exposure.

Inks are applied to sign sheeting using a screen process. The inks are poured into a rigid metal frame formed into a well by screen fabric stretched and fastened onto one side of the frame. The ink is then spread over the screen stencil using a rubber or plastic squeegee. The most likely route of exposure for workers is via the dermal route to the ink product (that contains a maximum of 0.5% notified polymer) during manual transfer of the ink onto the screen and during the squeegee application. Accidental ocular exposure is possible although unlikely. Inhalation exposure is considered to be low due to the low vapour pressure of products containing the notified chemical. Exposure is minimised as workers are trained in the proper handling of screen process inks and PPE such as gloves and safety glasses are used. Exposure is also limited by the use of local exhaust ventilation but would be dependent on the size of the application area and the accuracy of, and care taken by, the worker. Once the ink has dried, it is not available for exposure **(ND)**.

Tradespeople **(ND)**

Dermal or ocular exposures may occur when tradespeople apply the paints containing the notified polymer by brush, roller or mop. Inhalation exposure is also possible if application includes low-pressure spray and also during the clean-up process. Exposure may be minimised by the use of PPE such as protective clothing, gloves, safety goggles and suitable respiratory protection if spraying application is involved. Once applied, the notified polymer will adsorb to the substrate and be bound within the solid matrix, making further exposure to tradespeople negligible.

Dermal exposure may also occur when tradespeople apply the adhesive containing the notified polymer by extrusion of the product from a cartridge using either a manual or pressure-assisted applicator. Although possible, ocular and oral exposures are unlikely, as the adhesive is applied in a controlled manner and is relatively viscous, which ensures that exposure from splashes is minimised. Once the adhesive is cured, exposure is not possible as the notified polymer is trapped within the solid matrix.

4.2 Public exposure (ND)

The new proposed uses for the notified polymer include consumer products containing up to 0.3% of the notified polymer. Exposure of the public through the use of paints and coatings containing the notified polymer is possible as application will be by brush, roller, and possibly by spraying. The main route of exposure for these applications will be dermal, and inhalation with spray application. However, consumer exposure is expected to be low because it will be infrequent and short-term (2-5 days, once every 5-10 years for 2-4 hours/day). In addition, the notified polymer has a high molecular weight (>1000 Da) with a low level of low molecular weight species, and is not expected to be bioavailable via the dermal route. Public exposure via dermal contact with dried coatings containing the notified polymer will be minimal as the notified chemical is present at low concentrations and bound within a matrix once the coating has dried.

Although primarily marketed for intended use by tradespeople, adhesives containing up to 0.3% of the notified polymer may potentially also be used by the public. The application method and potential routes of exposure, described in Section 4.1 under ‘Tradespeople’, are the same for public usage. Consumer exposure is expected to be low because it will be infrequent and of short-term duration.

Exposure of the general public to the notified polymer during transport, storage industrial and consumer use is unlikely except in the event of an accidental spill.

Noting that the notified polymer is no longer used in carpet protection products, the public may still be exposed to the notified polymer through dermal contact with residues in carpets previously treated with the original protective product formulations. However, dermal exposure will be minimal as the notified polymer is expected to form a cohesive film via adsorption to the substrate fibres. Cleaning of the treated carpets may result in the notified polymer becoming dislodged and available for repeated exposure through inhalation or ingestion of fibres to which the notified polymer is bound, or the notified polymer or polyfluoroalkyl impurities present in household dust from treated carpets. Exposure will also be reduced further as treated carpets, with an estimated 12 year life, are replaced with new carpet untreated with the notified polymer.

4.3 Environmental exposure

4.3.1 Releases

Release from manufacture/reformulation

The notified polymer is imported in a neat form, which may be reformulated in Australia for existing uses and new proposed uses. The total volume of the imported notified polymer from all uses will be 29.1 tonnes per year **(ND)** predominantly for use in industrial and consumer coatings and adhesives that will be reformulated in Australia. Up to 0.1% (30kg/annum) of the notified polymer will be imported as a component in formulated industrial inks **(ND)**. In addition, about 11% of the notified polymer is used for manufacturing of insulation foam for export only. The estimates for the releases from these applications are shown in Table 4.1.

At the reformulation site for paint and coatings, no significant release of the notified polymer to the water compartment is expected. The applicant has provided estimations of the release to the environment from reformulation (Table 4.1). Any residues in empty containers are expected to be disposed of to landfill along with the containers.

Table 4.1 - Estimated release to on-site treatment plant during reformulation and equipment cleaning as well as cleaning of spills

Type of use	**Percentage of used volume released (A, %)**	**Percentage of import volume per use (B, %)**	**Annual release (C kg =A x B × 29100 kg*)**	**Annual days release (D)**	**Daily release kg/day (C/D)**
Coatings/paint-commercial/industrial	0.5	44	63.8	240	0.266
Coatings and paint-domestic	0.5	27	39.15	240	0.163
Adhesives	0.5	18	26.1	240	0.109
Foam Insulation	0.05	11	1.60	240	0.0066
Total daily release (kg/day)					0.545

* Based on a total volume of 29.1 tonnes/annum.

The above estimates in Table 4.1 for the release to on-site treatment plant are considered to cover the existing and new uses based on a total volume of 29.1 tonnes.

Release from uses

Industrial paints application: Sixty per cent is expected to be applied by brush application so no overspray is expected to occur. The remaining 40% is expected to be applied through spraying where up to 60% could be lost as overspray (24% of all the volume for this use).

Automotive coatings application: Application by spraying would result in approximately 60% loss from overspray which is expected to be disposed of to landfill or incineration. Due to the high water solubility of the notified polymer, discharge to sewer is possible depending on differences in waste collection at each industrial facility.

Coil coatings: Application could be efficiently performed by roller coating and losses are expected to be minimal and limited to equipment cleaning and spills, along with residues in empty containers.

Carpet application: No ongoing release estimation nor an exact date for the discontinuance of the use of the notified polymer in carpet protection products was provided by the applicant. As the notified polymer was originally assessed for this use in 2003 and, based on the 12 year average life of a carpet, it is regarded that the current release of the polymer to the environment from carpet wear and cleaning will be negligible.

For the industrial and consumer use **(ND)** of adhesives, the product is supplied in a cartridge, which is designed to minimise exposure, as there is no need for manual mixing of the two components. In addition, the adhesive is applied in a controlled manner and is relatively viscous, ensuring that exposure from spills and splashes will be minimal. Once the adhesive is cured into a solid mass, exposure will no longer be possible as the notified polymer will be trapped within the solid matrix.

The consumer paints and coatings are applied mainly by brush and roller, but it is possible that spray application may be used as well. Once the coating has dried, the notified polymer is expected to be bound within the coating matrix and will no longer be available for release. Studies summarised below (new data provided for the secondary notification assessment) (3M, 2002 b & c) demonstrated that the rate of release of the notified polymer from the dried coating was not significant under the test conditions.

Washing Study (ND)	The purpose of this study was to estimate if, and what levels of, the fluorinated species was released from the dry film containing the notified polymer under the test conditions
TEST SUBSTANCE	Notified polymer
METHOD DETAILS	Scrub washing. Two samples of paint, one blank control and one contains 0.1% of the notified polymer, were prepared and coated to Leneta plastic scrub panels that are used for a typical scrub test. The size and thickness of the coated films and the total amount of the notified polymer used in the films were not provided. The films formed were dried and cured for about 7 days under normal laboratory ambient conditions. Each of the coated panels was subjected to a scrub procedure using a clean sponge that was fitted into a scrub machine sponge holder. The scrubbing process was conducted twice, each for 25 cycles of scrubbing with the sponge under liquid scrub media. The scrub medium sample was collected at the end of each process for total fluorine and inorganic fluoride analyses.
Analytical Monitoring	The total fluorine analysis was conducted using Antek 9000F Analysis System. The system is based on oxy-pyrohydrolysis followed by final analysis with the fluoride ion specific electrode (ISE). The carbon-fluorine bond is oxy-pyrohydrolysed at 1050 °C. The product hydrogen fluoride (HF) was trapped in a buffer solution. The dissociated fluoride ions were measured with fluoride ISE at a controlled temperature. Inorganic fluoride was analysed using ORION EA940 meter/Fluoride electrode.
Remarks – Method	For fluorine analysis, a sample size of 25 µL was injected into the instrument. The calibration curve was based on standards prepared with FC-143 ($C_7F_{15}CO_2NH_4$) in the range of 1 ppm F to 5 ppm F at 10 µL injection.
RESULT	

Sample ID	Total fluorine (w/v ppm)	Inorganic fluoride (w/v ppm)
Wash water for blank control	~ 0.9	0.55
Wash water for blank control	~ 0.5	0.13
Wash water for 0.1 % sample	~ 0.7	0.15
Wash water for 0.1 % sample	~ 0.3	0.16

CONCLUSION

The above test outcome indicated no significant differences in the levels of total fluorine and inorganic fluoride between the test and control samples. This suggests that the rate of release of the fluorinated species from the dried coating was not significant under the conditions of the study.

TEST FACILITY

3M (2002b)

Outgassing Study (ND)

The purpose of this investigation was to estimate if and at what levels 2-(N-methylperfluorobutanesulfonamido) ethyl alcohol (N-MeFBSE alcohol) was liberated into the gas phase as the applied paint cures at room temperature.

TEST SUBSTANCE

Notified polymer

METHOD DETAILS

FTIR outgassing analysis. Samples for the outgassing analyses were prepared by placing a small pool of paint on the top edge of a Leneta (scrub) panel. N-MeFBSE alcohol was referred to as the C4 alcohol. The hypothesized source of the NMeFBSE alcohol during the paint curing process would be a degraded product from the notified polymer in the alcoholic paint formulation.

The pool of paint was spread into a band resulting a paint sample with an area of 100 cm^2 (10 cm × 10 cm). The test paint contained the notified polymer at 0.1% (w/v).

The coated films were dried and analysed in the FTIR cells for one week. The samples were weighed, giving approximate cured weights of 1.0 and 1.1 g.

The outgassing studies were conducted using two Midac Corporation FTIR I series instruments with 10 meter gas tape cells to analyse the released alcohol. Inorganic fluoride was analysed using ORION EA940 meter/Fluoride electrode. The cell temperature was held at ambient conditions throughout the course of this experiment.

Analytical monitoring

MIDAC AutoQuant^{TM} software (Classical Least Squares analysis) in connection with HANST and 3M library reference spectra was used to identify and quantify the outgassed compounds. The method analysed for the following compounds: ammonia (NH_3), hexane, and perfluorobutanesulfonyl fluoride (PBSF). Hexane was used as a surrogate compound for all hydrocarbon compounds. It is also assumed that all the hydrocarbon was from butyl carbitol, a known species in the paint formulation.

Remarks – method	With a 0.02 parts per million by volume (PPMv) detection limit, conversion of approximately 2% (1.6%) of the notified polymer to NMeFBSE alcohol due to alcoholysis should be detected if liberated into the gas phase.
RESULT	For both the blank control and test samples, NH_3 approached a maximum equilibrium concentration of approximately 22 PPMv after about 24 hours. The measured maximum value for butyl carbitol was 16-19 PPMv for both samples after about 44 hours of outgassing. N-MeFBSE alcohol and other fluorochemicals were not detected at or above the detection limit of 0.02 PPMv.
CONCLUSION	The above test outcome indicated no significant differences in the levels of NH_3, butyl carbitol, N-MeFBSE alcohol and other fluorochemicals between the test and control samples. This suggests that the rate of release of the fluorinated species from the dried coating was not significant under the conditions of this study.

Release in Australia from use of insulation foam is not expected since the foam will be exported.

Estimations of the releases to sewer from all the uses of the notified polymer based on the new increased import volume are shown below:

Table 4.2 - Estimated release to domestic sewer during use

Type of use	**Percentage of used volume released (A, %)**	**Percentage of import volume each use (B, %)**	**Annual release (C =A x B × 29100 kg)**	**Annual days release (D)**	**Daily release kg/day (C/D)**
Coatings/paint-industrial / commercial	2	44	255.2	365	0.70
Coatings and paint-domestic	2	27	156.6	365	0.429
Adhesives	0.5	18	26.1	365	0.072
Cryogenic Insulation	0	11	0	365	0
Total daily release (kg/day)					1.20

The estimates for release to domestic sewer from Table 4.3 above are considered representative of the existing and planned new uses based on a total volume of 29.1 tonnes. Total daily release of the notified polymer from both existing and new uses was calculated to be 1.20 kg/day.

Release from disposal

The majority of the imported notified polymer will be adsorbed onto the surface of the associated substrates or incorporated into the coating matrix of the manufactured articles, and share the fate of the associated articles. No significant release of the notified polymer to the aquatic environment is expected from these pathways.

Sources of potential release will be residues in empty containers, splashes and drips during decanting, mixing and loading into application equipment, cleaning of brushes and rollers and other equipment. Any spills are expected to be collected using adsorbent material or cloth. Other wastes may be absorbed onto used newspapers prior to disposal. Collected wastes are expected to be disposed of to landfill.

Therefore, no significant release of the notified polymer to the aquatic environment is expected from the disposal.

4.3.2 Fate

The majority of the notified polymer is expected to adhere to the coated/treated substrates following application of the products containing the notified polymer. Treated articles and other dried residues containing the polymer are expected to ultimately be disposed of to landfill. When associated with the article to which the product containing the notified polymer has been applied, the polymer is not likely to be mobile in landfill. Hence, it is not expected to be bioavailable to aquatic organisms.

A small amount of the polymer may be released to sewer from reformulation and use. Predictions of the environmental partitioning behaviour of poly- and perfluoroalkyl polymers remain uncertain based on current knowledge because of limited data and their unique properties. In particular, the usual predictive models for partitioning during sewage treatment are inapplicable for chemicals containing perfluoroalkyl functionality as they assume lipophilicity for hydrophobic functionality, whereas the perfluoroalkyl functionality is both hydrophobic and lipophobic. However, the notified polymer consists of predominantly hydrophilic components and a minor amount of perfluoroalkyl functionality. Tests on water solubility prove that the notified polymer is miscible in water and is unlikely to adsorb on soil/sediment. Therefore, the notified polymer may potentially be mainly present in STP effluent and released to public water. The non-hydrophilic degradates (e.g. perfluoroalkyl functionalities) may also potentially be present in biosolids that will be reused and applied to agricultural soils throughout Australia.

The notified polymer is not expected to rapidly hydrolyse under environmental conditions. The original assessment for the polymer as a new chemical reported an average half-life of 20.2 years, 0.737 years and 0.19 years at pH 4, 7 and 9, respectively, based on a test study for the rate of appearance of the predicted, primary degradation product 2-(*N*-methylperfluorobutane-sulfonamido) ethyl alcohol (N-MEFBSE alcohol). This primary degradation product is then expected to further degrade through a number of possible prefluoroalkyl-containing intermediates to ultimately produce PFBS. The same test study also reported a hydrolytic half-life of 16.2 years independent of pH, assuming that PFBS is the only hydrolytic product formed.

For the secondary notification, the applicant provided a 2003 biodegradation study (section 5.2.2.1) that was still underway at the time the notified polymer was originally assessed by NICNAS. The results indicate rapid transformation of the notified polymer, involving an initial cleavage of the pendant perfluoroalkyl chain, in media designed to imitate exposure to municipal wastewater treatment sludge. However, the fate of the perfluoroalkyl functionality was not investigated in this study. To address this uncertainty, an unpublished review **(ND)** on the biodegradation potential of PFBS-based urethane and acrylate polymers, such as the notified polymer was submitted by the applicant. The review indicates similar primary degradation pathways for these polymers as for standard hydrocarbon-based polymers.

Taken together, the information suggests that biodegradation of the backbone of the notified polymer is expected to occur slowly under environmental conditions due to its high molecular weight. However, the notified polymer contains pendant chains that are expected to be rapidly cleaved from the notified polymer.

Furthermore, the unpublished review indicated that the PFBS-based urethane and acrylate polymers also have the potential to undergo weathering via photolysis in the environment. Ultimately, photolysis pathways of these polymers have the potential to form PFBS, perfluorobutanoic acid (PFBA) and nonafluorobutane with half-lives of the polymer being less than two years. However, in the newly provided study (see 5.2.2.2) the notified polymer was found not to photolyse, although it may undergo non-photolytic degradation. The backbone of the notified polymer is expected to be resistant to photolysis but with the potential to degrade under environmental conditions.

In surface waters, agricultural soils and landfill, the notified polymer is expected to degrade over extended periods of time to form water, oxides of carbon and nitrogen, and degradation products containing poly- and perfluoroalkyl functionality. The expected initial polyfluoroalkyl degradation products are assumed to undergo further degradation to form, among other compounds, the very persistent perfluoroalkyl degradation product, perfluorobutanesulfonic acid (PFBS). It is noted that some volatile, sulfonate-containing degradation products have the potential to undergo long range atmospheric transport and thus may result in translocation of PFBS in the environment.

Potential degradation products

PFBS is expected to be recalcitrant in the environment, and potentially undergo long-range transport while mainly staying in the water column (NICNAS, 2005). The susceptibility of PFBS for long-range transport is increased compared to long chain perfluoroalkyl compounds, such as perfluorooctanoic acid (PFOA), because its degradation precursors are expected to be more volatile and more likely to enter the atmospheric compartment (NICNAS, 2005). PFBS is expected to be very persistent and has limited potential to hydrolyse, photolyse or biodegrade (NICNAS, 2005). The increased potential for long-range transport is of concern for PFBS-based compounds as they are increasingly used as replacements for long chain perfluoroalkyl compounds. Increasingly higher use of PFBS-based compounds may result in the accumulation of PFBS in regions where PFBS or PFBS-based compounds have not been intentionally released, including in pristine environments.

By 2005, there was limited detection of PFBS in the environment (NICNAS 2005). However, a recent study detected PFBS in 24% of water samples taken from the Greenland Sea with concentrations ranging from < 51 to 65 pg/L (Zhao 2012). As long chain perfluoroalkyl acids are phased out in preference for short-chain polyfluoroalkyl chemistry containing a four-carbon perfluorobutyl moiety (like the notified polymer), the introduction of chemicals degrading to PFBS may lead to a measurable increase over time of the environmental levels of PFBS. The scale and time-frame of such an increase, and its relevance to characterising the long term environmental risk profile of PFBS, currently remain unknown.

Due to its high molecular weight that limits the ability to cross biological membranes, the notified polymer is not expected to bioaccumulate. The available evidence indicates that the assumed major degradation product, PFBS, is expected to have a lower bioaccumulation potential than long chain perfluoroalkyl compounds (C8 and above) as the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy et al., 2010). The reported half-life of PFBS in rainbow trout was 3.3 days in a dietary accumulation study (NICNAS 2005).

4.3.3 Predicted environmental concentration

Based on the release estimates from reformulation and uses, the expected concentration of the notified polymer entering a sewage treatment plant (STP) can be calculated as shown below.

Release from reformulation (limited site)

Maximum total daily release to one STP catchment of 500 ML daily effluent volume	0.545 kg/day*
Concentration in STP	1.09 µg/L

*Drawn from Table 4.1

Release from uses (national wide)

Maximum total daily release to sewer	1.20 kg/day*
Average concentration in sewer Australia-wide (4,523 ML)	0.266 µg/L

*Drawn from Table 4.3

Based on the above release data of the notified polymer and the observed rapid cleavage of the perfluoroalkyl chain from the notified polymer in media imitating an STP plant, it is difficult to estimate the likely concentration of the notified polymer in STP effluent. Hence, 1.36 µg/L (1.09 µg/L + 0.266 µg/L) is used for risk assessment as the conservative maximum predicted concentration of the notified polymer in STP sewage water, including releases from reformulation and use assuming no biodegradation occurs.

Based on the above assumptions, the conservative maximum Predicted Environmental Concentration (PEC) of the notified polymer, for this assessment is calculated below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.36	µg/L
PEC - Ocean:	0.136	µg/L

The re-use of STP effluent for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.36 µg/L may potentially result in a soil concentration of approximately 9.04 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 45 µg/kg and 90 µg/kg, respectively. However, it is again noted that these calculations of notified polymer concentration are conservative, and are unlikely to eventuate due to the rapid primary degradation of the notified polymer in the STP prior to release to the environment.

Considerations of potential degradation products of the notified polymer

The notified polymer is known to rapidly undergo a primary cleavage of the perfluoroalkyl chain in an STP environment, which is assumed to ultimately form the persistent degradant, PFBS via a number of intermediate substances containing the PF alkyl residue. PFBS is likely to mostly partition to the aqueous compartment (NICNAS, 2005). Hence, a consequence of the expected rapid primary biodegradation of the notified polymer in the STP and subsequent release to the environment described in section 4.3.2 above is that PFBS will gradually be produced and be released to the environment. In contrast, release of perfluoroalkyl contaminants into the environment has historically been linked to direct releases of low molecular weight poly- and perfluoroalkyl chemicals, such as poly- and perfluoroalkyl monomers during perfluoropolymer manufacture and reformulation processes, rather than breakdown of the polymers themselves.

Efforts have been made globally to control releases of perfluoroalkyl contaminants, such as by reducing the presence of residual polyfluoroalkyl monomers and impurities in polymers. Thus, as these efforts succeed, it is expected that indirect releases from the degradation of polyfluoroalkyl polymers will become a significant source of persistent perfluoroalkyl compounds in the environment in the future. Compared to long chain perfluoroalkyl compounds, there has been limited detection of PFBS in the environment. However, as the long chain perfluoroalkyl compounds are phased out in preference for short-chain polyfluoroalkyl chemistry containing four-carbon perfluorobutyl moieties, the environmental levels of PFBS may increase. Based on the appearance of the primary degradant, N-MEFBSE alcohol, the hydrolysis half-life of the notified polymer itself is relatively short (less than one year) at neutral and basic pH and is relatively long (more than 20 years) at acidic pH. However, based on accumulation of PFBS, the half-life of the notified polymer, including the perfluoroalkyl residue in its various degradant forms, is likely to be at least 16.2 years independent of pH. However, large uncertainties remain with calculating the contribution of indirect sources to the environmental load of perfluoroalkyl compounds. These uncertainties include determination of the timeframe over which release may occur and global transport mechanisms. Therefore, a PEC for indirect releases of

PFBS arising from proposed use and disposal of the notified polymer in Australia cannot be determined.

5. Hazard assessment

5.1 Human health hazard assessment

This section contains a short summary of the data relevant to the human health hazard assessment of the notified polymer. The robust summaries of the data available for the assessment of Fluorosurfactant FC-4430 as a new chemical are reproduced from the New Chemical report without any modification in the Appendix of this report.

No new toxicity data were submitted for the secondary notification of the notified polymer. However, consideration of the toxicity of potential breakdown products is now included in this section

Summary of toxicity data for the notified polymer

Endpoint	*Assessment Conclusion*
Rat, acute oral	LD50 >2000 mg/kg bw, low toxicity
Rat, acute dermal	LD50 >2000 mg/kg bw, low toxicity
Rat, acute inhalation	No data submitted
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation
Rat, oral-gavage repeat dose toxicity - 28 days.	NOAEL = 1000 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic
Genotoxicity – in vivo	No data submitted

Based on the high molecular weight of the polymer (>1000 Da) and low proportion of low molecular weight species, the potential of the notified polymer to be dermally or orally absorbed following exposure is limited. The extent to which the notified polymer will be absorbed/cleared from the lungs following inhalation exposure to powders is uncertain.

The notified polymer has low acute oral and dermal toxicity in rats. It is a slight skin and eye irritant in rabbits and is not a skin sensitiser in guinea pigs.

The 28-day repeat dose oral study in rats did not show any treatment related changes in clinical observations, laboratory findings or effects in organs. The no observed adverse effect level (NOAEL) was established as 1000 mg/kg/day (the highest dose tested) in this study.

The notified polymer was not mutagenic in the bacteria strains tested, or clastogenic to human peripheral lymphocytes in vitro.

*Toxicity of potential breakdown products (**ND**)*

The notified polymer contains perfluoroalkyl side-chains that are potential precursors of perfluorobutane sulfonate (PFBS) in the environment, a short-chain perfluorinated chemical. Comparison of perfluorinated chemicals, including PFBS (4 perfluorinated carbons) and other longer chain compounds, consisting of at least 7 perfluorinated carbons) shows that generally, toxicological properties of the long chain perfluoroalkyl compounds are less favourable compared to the short chain perfluoroalkyl products, with properties becoming less favourable with increasing perfluoroalkyl carbon chain length.

Therefore it is concluded that the human health hazards associated with the expected breakdown product (PFBS) of the notified polymer would be less severe than the human health hazards associated with many of the longer chain breakdown products of the long perfluoroalkylchain-based polymers currently on the market that are intended to be replaced by the notified polymer.

5.2 Environmental hazard assessment

5.2.1 Environmental effects

A summary of the environmental effects to fish, daphnia, and alga based on the studies submitted for the assessment of the notified polymer as a new chemical is presented below. The robust summaries of these data are reproduced from the assessment of the notified polymer as a new chemical without any modification in the Appendix of this report.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 765 mg/L	Not harmful
Daphnia Toxicity	48 h EC50 = 99 mg/L	Harmful
Algal Toxicity	96 h EC50 = 763 mg/L	Not harmful
Inhibition of Bacterial Respiration	3 h EC50 = 786.2 mg/L	Not harmful

New studies **(ND)** on marine species were provided for the secondary notification assessment and are briefly summarised below followed by the robust summaries of the studies.

Endpoint	*Result*	*Assessment Conclusion*
Marine Fish Toxicity **(ND)**	96 h LC50 >3.2 mg/L*	Not harmful
Marine Amphipod **(ND)**	10 d LC50 = 166 mg/L	Not harmful
Marine Copepod Toxicity **(ND)**	48 h LC50 = 132 mg/L*	Not harmful
Marine Alga Toxicity **(ND)**	72h E_rL50 = 3.24 mg/L*	Toxic

*Filtered Water Accommodated Fraction (WAF)

Based on the marine alga result and applying an assessment factor of 100 (justified because acute tests are available on three trophic levels) the resultant Predicted No-effect Concentration (PNEC) is 32 µg/L.

Based on the toxicity of the notified polymer to marine algae, the notified polymer is considered to be toxic to aquatic organisms under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (UNECE, 2009). Therefore, the notified polymer is classified as "Acute Category 2; Toxic to aquatic life" under the GHS.

Acute toxicity to marine fish (ND)

TEST SUBSTANCE	MTDID 3504 (notified polymer)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - semi-static
Species	Turbot *(Scophthalmus maximus)*
Exposure Period	96 hours
Salinity	33 to 35‰
Analytical Monitoring	None
Remarks – Method	The study is compliant with international codes of Good Laboratory Practice. According to the study, earlier studies using the algal species *Skeletonema costatum* and the invertebrate *Acartia tonsa* determined that the limit test should be conducted at the concentration of 3.2 mg/L. Therefore, definitive test concentrations were prepared as 0 (control) and 3.2 mg/L.

The study was conducted in one replicate with 7 fish for each test vessel at a nominal concentration of 3.2 mg/L. The test substance nominal concentrations were prepared as "water-accommodated fractions" according to the OSPAR (1995) guidelines. The test solutions were filtered before use. There was no chemical analytical confirmation of the actual dissolved concentrations.

RESULTS

Concentration mg/L	Number of Fish	Mortality				
Nominal		*2h*	*24h*	*48h*	*72h*	*96h*
0	7	0	0	0	0	0
3.2	7	0	0	0	0	0

LC50	>3.2 mg/L at 96 hours.
NOEC	3.2 mg/L at 96 hours.
Remarks – Results	All test validity criteria are met. No mortality or abnormal behaviour was noted during the test. According to the study author, the dissolved concentrations were likely to be lower than given in this report as the sample was poorly soluble in seawater. However, it is noted in the (fresh) water solubility test that the notified polymer is considered to be miscible in fresh water. It is possible that sea water containing high level of ions may reduce the solubility of the notified polymer in water. This LC50 indicates that the notified polymer is not considered to be harmful to marine fish up to its seawater solubility limit.
CONCLUSION	The notified polymer is not harmful to marine fish.
TEST FACILITY	Chemex (2006a)

Acute toxicity to marine amphipod (ND)

TEST SUBSTANCE	MTDID 3504 (notified polymer)
METHOD	Static test conditions according to SOP E211 based on Paris Commission Guidelines 1995 "A sediment bioassay using an amphipod *Corophium sp"*
Species	*Corophium sp.*
Exposure Period	10 days
Salinity	37 to 38 ‰
Analytical Monitoring	None
Remarks – Method	The study is compliant with international codes of Good Laboratory Practice. Following a preliminary test, a definitive study was conducted in 2 replicates with 10 animals for each test vessel at nominal concentrations of 0 (Control) 100, 180, 320, 560 and 1,000 mg/kg wet sediment. The 10 day LC50 value was estimated and 95% confidence limits calculated using ToxCalc version 5.0 "Comprehensive Toxicity Data Analysis and Database Software".

RESULTS

Concentration mg/kg		Number of test animals	Percent mortality %
Wet sediment	Dry sediment		
0	0	20	2
100	116	20	20
180	213	20	80
320	375	20	95
560	653	20	100
1000	1175	20	100

LC50 (10 day)	166 mg/kg dry sediment (95% CI = 128 – 201 mg/kg dry sediment)
Remarks – Results	The 10 day LC50 was estimated to be 166 mg/kg dry sediment as determined by the Maximum Likelihood-Probit Method. Based on the UC classification for soil dwelling organisms (for agricultural chemical standard), the notified polymer is considered to be slightly toxic to *Corophium sp.*
CONCLUSION	The notified polymer is slightly toxic to *Corophium sp.*
TEST FACILITY	Chemex (2006b)

Acute toxicity to marine Copepod (ND)

TEST SUBSTANCE	MTDID 3504 (notified polymer)
METHOD	Static test conditions according to SOP E207 based upon ISO T*C147/SC5/WG2* protocol by Thompson (1990): Water Quality: Determination of acute lethal toxicity to marine copepods (Copepoda, Crustacea)
Species	*Acartia tonsa*
Exposure Period	48 hours
Salinity	34 ‰
Analytical Monitoring	None
Remarks – Method	The study is compliant with international codes of Good Laboratory Practice. Following a preliminary test, the definitive study was conducted in 2 replicates with 10 animals for each test vessel at nominal concentrations of 0 (Control) 100, 180, 320, 560 and 1000 mg/L. The test substance nominal concentrations were prepared as "water-accommodated fractions" according to the OSPAR (1995) guidelines. The LC50 values were estimated and the 95% confidence limits were calculated using ToxCalc version 5 "Comprehensive Toxicity Data Analysis and Database Software".

RESULTS

Nominal concentration mg/L	Number of test animals	Percent mortality at 48 h
0	20	0
100	20	5
180	20	100
320	20	100
560	20	100
1000	20	100
3,5 Dichlorophenol	20	75

LC50	132 mg/L at 48 h (95% CI = 128 – 136 mg/L)
NOEC	100 mg/L at 48 h
Remarks – Results	The 48 hour LC50 value of MTDID 3504 to *Acartia tansa* was estimated by ToxCalc analysis to be 132 mg/L as determined by the Maximum Likelihood-Probit method. The highest no observed effect concentration (NOEC) after 48 hours was 100 mg/L. Therefore, the notified polymer is considered not harmful to *Acartia tonsa.*

CONCLUSION The notified polymer is not harmful to *Acartia tonsa.*

TEST FACILITY Chemex (2006c)

Acute toxicity to marine alga (ND)

TEST SUBSTANCE	MTDID 3504 (notified polymer)
METHOD	Static test conditions according to SOP E209 based on ISO/DIS BS EN ISO 10253: 1998 "Water quality - Marine Algal Growth Inhibition Test with *Skeletonema costatum and Phaeodactylum tricornutum.*
Species	*Skeletonema costatum*
Exposure Period	72 hours
Light intensity	6000-10000 lux continuous white light
Concentration range	0, 0.5, 1, 2.2, 4.5, 10 mg/L (nominal)
Remarks – Method	The study is compliant with international codes of Good Laboratory Practice. The test substance nominal concentrations were prepared as "water-accommodated fractions" according to the OSPAR (1995) guidelines. The EL50 values were estimated graphically and 95% confidence limits calculated according to the method of ToxCalc™ Version 5.0 "Comprehensive Toxicity Data Analysis and Database Software".

RESULTS

Biomass	Growth
E_bL50 mg/L at 72h	*E_rL50 mg/L at 72 h*
0.62 (95% CI = 0.49-0.76)	3.24 (95% CI = 1.4 – 13.69)

Remarks – Results	The test validity criteria were met. The notified polymer is considered toxic to marine alga.
CONCLUSION	The notified polymer is toxic to marine alga.
TEST FACILITY	Chemex (2006d)

5.2.2. Environmental Fate

No studies were available to address the ready biodegradability of Fluorosurfactant FC-4430 for its notification as a new chemical. For the secondary notification, the applicant provided new test reports on inherent biodegradation and on photolysis for the notified polymer. Below are the summaries for the tests' details followed by overall conclusions, taking into account the other relevant environmental fate studies that were provided for the new chemical notification that are reproduced in the Appendix of this report without modifications.

Inherent biodegradability (ND)

TEST SUBSTANCE	FC-4430
METHOD	US EPA Zahn-Wellens/EMPA Test (OPPTS 835.3200) and US EPA Modified SCAS (OPPTS 835.3210)
Inoculum	Municipal wastewater treatment sludge
Exposure Period	28 days
Auxiliary Solvent	Not applied
Analytical Monitoring	The samples were analysed using High Performance Liquid Chromatography/Mass Spectrometry (HPLC/MS)
Remarks - Method	The test substance was suspended in Medium A (mineral salts medium and sludge), Medium B (mineral salts medium, sludge, and antimicrobial agent) and Medium C (mineral salts medium and antimicrobial agent). After incubation for varying intervals, samples of the test substance were prepared using solid phase extraction (SPE). The target analytes were the predicted degradation products 2-(N-methylperfluorobutanesulfonamido) ethyl alcohol (N-MeFBSE alcohol or N-MeFBSE-OH), Perfluorobutane sulfonylamido (methyl)-acetate (M370), 2-N-methyl-perfluorobutanesulfonamide (NMeFBSA), perfluorobutanesulfonamide (FBSA), perfluorobutane sulfonate (PFBS), and perfluorobutyric acid (PFBA).

RESULTS

Medium A (test substance exposed to uninhibited sludge) degradation results[1]

Analyte[2, 3]	Day 0	Day 4	Day 14	Day 28
N-MeFBSE-OH	26%	1.0%	0.40%	<0.15%
M370[2]	0.84%	114%	58%	63%
N-MeFBSA	<3.5%	1.2%	0.47%	0.26%
FBSA	<0.92%	1.4%	1.9%	2.4%
PFBA	<1.0%	<0.20%	0.12%	0.37%
PFBS	<0.33%	0.28%	0.97%	2.3%

[1] The percentage degradation was based on the theoretical amount of fluorine available in the initial dose of the test substance. The percentages reported in the table above were determined by dividing the average amount of analyte found in each test vessel by the theoretical amount if the test substance totally biotransformed into the specific analyte.

[2] M370 was calculated using M370 standard.

[3] The analytical accuracy for all analytes was ±20% or better.

Remarks - Results

The analytical results demonstrate that under the conditions of the study, the tested notified polymer is ultimately biodegraded (OPPTS 835.3210 "Modified SCAS Test" defines that a greater than 70% loss of starting material as ultimate biodegradability). The major metabolites identified from the test cultures were N-MeFBSE-OH (representing 26% degradation of the initial concentration of the notified polymer on day 0) and M370, representing 114% degradation of the initial concentration of FC-4430 on day 4. Complete mass balance between parent material and measured degradation products appears to have been achieved on day 4. The percentage of M370 dropped from 114% on Day 4 to 63% on Day 28. This suggests that almost all the test substance FC-4430 degraded and formed M370, which was subject to further degradation. However, no explanation was provided as to the dissipation of M370 over this period. The study author indicates that the data for M370 analysis should be taken semi-quantitatively since the purity for perfluorooctanesulfonylamido (ethyl) acetate (PSOSAA), which was used to quantify M370, was not thoroughly established. In this case, the determined percentage level for M370 is not considered to be reliable.

The reported degradation degree may be relevant to the biodegradation of the pendant segments, not the back bone of the notified polymer.

No information regarding the biodegradation of the perfluoroalkyl functionality or perfluoroalkyl compounds (PFBS and PFBA) was generated in the study.

CONCLUSION

The notified polymer is ultimately biodegradable. The biodegradation property of perfluoroalkyl functionality was not investigated.

TEST FACILITY

3M (2003)

Indirect and Direct Photolysis Screening Test (ND)

TEST SUBSTANCE	FC-4430
METHOD	US EPA Toxic Substance Control Act OPPTS 835.5270 & 835.2210
Light source and Spectrum	Atlas Sun-Test photoreactor xenon arc light source with UV special Suprax Filter (for simulation of natural sunlight from 300-800 nm)
Relative Intensity	261 W/m^2 of irradiation (Simulated for average natural daylight in Miami, Florida for an equivalent of 16 days.)
Spectrum of Test Substance	Not provided
Exposure Period	128 hours
Remarks – Method	Three sets of test systems were established: a set cooled at 0 °C, a set exposed to light in the photoreactor and a set stored in the photoreactor in the dark. After the 128 hour exposure period was over, all the three sets were analysed by HPLC/MS and GC/MS for predicted, stable degradation products: perfluorobutane sulfonate (PFBS); 2-(N-methylperfluorobutane-sulfonamido) ethyl alcohol (N-MeFBSE alcohol); 2-N-methylperfluorobutane sulfonamide (NMeFBSA); perfluorobutanesulfonamide (FBSA), perfluorobutyric acid (PFBA); octafluoro-2-butene, 1,1, 1,2,2,3,3,3,4,4-nonafluorobutane; 1, 1,1,2,2,3,3-heptafluoropropane; pentafluoroethane and 1,1,2-tetrafluoroethane.
RESULTS	No photolytic degradation by either direct or indirect mechanisms was observed.
Remarks – Results	Degradation to form N-MeFBSE alcohol and FBSA was observed under all conditions and in all controls. The study authors attributed this to hydrolytic and/or biological degradation and no reliable half-life estimate could be determined. This is considered reasonable. Degradation by hydrolytic, photolytic or biological degradation to form any of the remaining targets was not observed. The degradation of the notified polymer apparently occurred in samples exposed to the light to yield an increase in N-MeFBSE alcohol concentration by 92 ng/mL and N-MeFBSA by 3.6 ng/mL during the 128 hour exposure. The same products increased more significantly in the unexposed (128 hour dark control) samples, with N-MeFBSE alcohol increasing by 566 ng/mL and N-MeFBSA increasing by 4.1 ng/mL in those controls. This may indicate that the observed breakdown of the notified polymer to N-MeFBSE alcohol was due to a mechanism other than photolysis. The estimated shortest photolytic half-life was 1.06 years assuming a single product N-MeFBSE alcohol, or 8.69 years assuming a single-product FBSA. The estimated non-photolytic half-life was 58 days for FC-4430 to form N-MeFBSE alcohol.

CONCLUSION	Under the conditions of this test, the notified polymer was found not to photolyse, although it may undergo non-photolytic degradation
TEST FACILITY	Pace Analytical Services Inc (2001)

5.2.3. Overall Environmental Hazard Assessment

Based on the new toxicity studies with marine life, the notified polymer is considered to be toxic to aquatic organisms. It is classified as "Acute Category 2; Toxic to aquatic life" under the GHS classification based on the acute toxicity endpoint to marine algae. The PNEC is determined as 32 µg/L.

The degree of biodegradation in the new biodegradability study provided was determined on the basis of target degradates, particularly the primary degradant N-MEFBSE alcohol, instead of mineralisation. Therefore, based on the lack of evidence for rapid ultimate degradation for the whole polymer, and considering its acute toxicity, the notified polymer is classified as Chronic Category 2: *Toxic to aquatic life with long lasting effects* under the GHS for the chronic hazard.

The persistent degradation product, PFBS, is not considered to be toxic to aquatic organisms (NICNAS, 2005). The most sensitive aquatic species was found to be the mysid shrimp, with a 96-hour median effective concentration (EC50) of 372 mg/L. All the other aquatic organisms tested (fish, daphnids, alga and sewage microorganisms) were reported to have EC50s >1000 mg/L (NICNAS, 2005). Therefore, PFBS is not expected to be harmful to aquatic organisms on a short-term basis. With respect to the long-term hazard to the environment, traditional long-term studies do not adequately represent the potential hazard for very persistent compounds. Test studies are not available for PFBS for periods exceeding 21 days (Daphnia: 21 d NOEC = 502 mg/L). As PFBS is very persistent and there is a potential for it to accumulate in the environment, aquatic organisms will be exposed to PFBS for periods longer than 21 days. The long-term hazard to aquatic organisms has not been fully characterised.

The notified polymer contains short-chain polyfluoroalkyl chemistry and consists of a four-carbon perfluorobutyl moiety. Short-chain polyfluoroalkyl chemistry is intended to replace long chain polyfluoroalkylchemistry (C8 and above). Whilst sulphonic acid moieties tend to be more toxic than the carboxylic acid of the same fluorinated carbon chain of the same length, the toxicity of perfluoroalkyl compounds increase with increasing carbon chain length (Giesy et al., 2010). As a comparison, the available data indicate that, for example, PFOA or its salts are, at most, harmful to fish with 96-hour median lethal concentrations (LC50) ranging from 70 to 1550 mg/L (US FDA, 2009; ECHC, 2012). Forty eight hour median effect concentrations (EC50) based on immobilisation for Daphnia magna ranged from 34 to 1200 mg/L (ECHC, 2012), indicating that PFOA and its salts may be considered toxic to aquatic invertebrates on an acute basis. Reproduction studies on Daphnia over 21 days resulted in NOECs ranging from 13 to 89 mg/L. Ninety six-hour NOECs, based on growth rate, from algal toxicity studies ranged from 1.0 to 500 mg/L (ECHC, 2012). Therefore, PFBS is expected to have a less problematic ecotoxicological profile than the long chain perfluoroalkyl acids it is intended to replace.

6. Risk characterisation

6.1 Work health and safety (WHS)

The risk to workers' health from the new industrial use of the notified polymer as a component in the manufacturing of insulation foam is low. This is due to the highly automated manufacturing process resulting in minimal exposure, combined with the use of PPE. In the final product, the notified polymer is incorporated into the solid polymer matrix and hence will not be bioavailable during any processes following its manufacture and packaging.

For tradespeople using coatings (liquid and powder), paints and inks containing the notified polymer, repeated dermal exposure and accidental ocular exposure may occur during application by, dipping, brush, roller or squeegee. The paints and powder may also be used in spray applications. In a new industrial use, tradespeople using adhesives containing the notified polymer may be subject to repeated dermal exposure and accidental ocular and oral exposure during application to surfaces via a cartridge-based applicator. The risk to these workers for systemic adverse effects is not considered to be unreasonable as the notified polymer has high molecular weight (>1000 Da) with a low level of low molecular weight species, and is not expected to be bioavailable via the dermal route. In addition, sub-chronic oral studies do not indicate any significant toxic effects associated with systemic exposure to the notified polymer. The notified polymer has slight skin and eye irritant potential. However, risk from local dermal or eye effects is not considered to be unreasonable as the notified polymer is present at low concentrations in the paints and coatings (up to 0.5%) and adhesives (up to 0.3%). In addition, the PPE used by professional tradespeople is expected to further lower exposure to the notified polymer, its breakdown products and impurities. When the coating has dried or is cured, the notified polymer will be bound within a matrix and therefore not likely to be bioavailable.

Repeated inhalation exposure of the professional tradespeople to the notified polymer may occur during spray application. No repeat dose inhalation toxicity data are available to assess the potential risk associated with the potential exposure from this application. However, the risk is not considered to be unreasonable due to the low concentrations of the notified polymer in the end use products (up to 0.5%), and the use of personal protective equipment that will be recommended on the product literature to minimise exposure.

The occupational exposure from the original uses is most likely for formulation workers handling the neat notified polymer. However, exposure is expected to be low due to the engineering controls in place and the use of personal protective equipment during formulation. Considering the low likelihood for occupational exposure and the overall low toxicity profile of the polymer, the OHS risk for formulation workers is not considered to be unreasonable. The polymer is a slight skin and eye irritant however the risk of irritant effects is low because of the use of controls and PPE. Systemic exposure of workers to break down products is not expected based on the stability of the notified polymer. Workers may also be exposed to perfluoroalkyl starting constituents and/or impurities of the notified polymer at relatively low concentrations. It is expected that the engineering controls and personal protective equipment utilised during these operations will mitigate any risk associated with such exposure.

6.2 Public health risk estimation

Paints and coatings containing the notified polymer will be available to the public for application by brush, roller, and possibly by spraying. For these uses, exposure to the notified polymer via the dermal and inhalation route is possible but the public is expected to use these products only once every 5-10 years and usually for 2-5 days per project, for 2-4 hours/day. Adhesives containing the notified polymer, although intended for commercial use, will also be available for use by the public. Similar to the paint products, it is anticipated that the use will be relatively infrequent. The most likely route of exposure during adhesive application is dermal; however, ocular and oral routes are also possible.

The notified polymer has low acute oral and dermal toxicity and is not a skin sensitiser, and therefore the risk of acute effects and contact dermatitis is low. The notified polymer has slight skin and eye irritant potential. However, it is present at relatively low concentrations in the paints, coatings and adhesives. Therefore, no unreasonable risk is expected from these applications. In addition, the notifier has advised that product literature will contain recommendations for good work practices and use of protective clothing and PPE, including a suitable respiratory protection for applications by spray. This would also lower the risk of potential adverse effects via inhalation that may be associated with spray applications of the coatings. Acute inhalation toxicity studies are not available, but systemic exposure to the notified polymer has not been associated with any adverse effects in the animal studies.

The public may come in dermal contact with dried coatings and cured adhesives containing the notified polymer. However, the exposure to the notified polymer will be negligible due to the low concentration of the notified polymer in the coatings and adhesives (<0.3%) that will also be bound within a matrix of the dried products.

The public may be exposed indirectly to PFBS, expected to be formed by degradation of the notified polymer in the environment. Such exposure may increase over time due to the persistence of PFBS in the environment. A quantitative risk assessment for this exposure was not conducted. However, the available data indicate that PFBS has a less hazardous human health profile than the long-chain perfluoroalkyl substances that are the ultimate break down products of the majority of perfluoroalkyl polymers currently in Australian commerce. It is concluded that the risks to human health from indirect exposure to breakdown products of perfluoroalkyl substances will decrease following the increased introduction of the notified polymer, on the basis that the notified polymer is continuing to replace a currently available long chain perfluoroalkyl polymer. It is also noted that the notified polymer has been approved for the same uses in the US and Canada for manufacture/import volumes greater than what is under consideration in Australia.

6.3 Environmental risk estimation

6.3.1 Environmental Risk Assessment

The risk quotient (RQ) is determined to be < 0.1 (RQ = PEC/PNEC = 1.56µg/L/32µg/L), indicating that there is no unreasonable potential risk to the aquatic environment from the proposed use of the notified polymer. Again, it is emphasised that the PEC of 1.56µg/L for the notified polymer is a conservative maximum assuming no biodegradation, whereas as the notified polymer is known to undergo rapid primary degradation in an STP environment to release N-MEFBSE alcohol, which is assumed to ultimately degrade to PFBS, which may then be delocalised from points of release.

Perfluoroalkyl compounds are expected to be very persistent in the environment (for example, PFOA: $t_{½}$ (hydrolysis) >200 years; US EPA 2002) but PFBS is considered to have low potential for bioaccumulation. PFBS is not considered to be harmful to aquatic organisms at concentrations less than 372 mg/L on an acute basis. There is no available data on the long-term aquatic effects of PFBS beyond the limits of traditional long-term ecotoxicity tests.

The main environmental risks associated with polyfluoroalkyl polymers relate to the release of poly- and perfluoroalkyl degradation products, such as PFBS. However, it is not possible to quantify the long-term risks of PFBS to the environment due to knowledge gaps both in predicting environmental concentrations from indirect sources of release and the uncertainty surrounding long-term environmental effects. To date, the available data on environmental concentrations of PFBS indicate a low risk of environmental toxicity. However, the long-term environmental hazard to aquatic and terrestrial organisms has not been fully characterised and therefore the risk profile of PFBS is currently unknown. Further long term research should ideally be undertaken to characterise this risk.

There has been limited detection of PFBS in the environment. However, as the long chain perfluoroalkyl compounds are phased out in preference for short-chain polyfluoroalkyl chemistry containing four-carbon perfluorobutyl moieties, the environmental levels of PFBS are expected to increase. Continuing release of PFBS is expected to result in increasing environmental concentrations over time. Hence, there is potential for ecotoxicologically significant concentrations to eventually be reached following its accumulation in the environment over significant periods of time. In this eventuality, precursors of PFBS such as the notified polymer cannot be recalled after release and are a potential source of PFBS in the environment even long after their use ceases. Thus, use and disposal of the notified polymer increases the environmental risk profile of PFBS over time. Considering the potential for widespread release of PFBS from unreacted monomers in polymeric material, it is recommended to reduce the levels of impurities in the notified polymer, to the extent practicable.

High-temperature incineration is the preferred method of disposal of perfluoroalkyl compounds due to their environmental persistence characteristics. High-temperature incineration results in mineralisation of the perfluoroalkyl functionality to oxides of carbon and hydrofluoric acid. Incomplete combustion of perfluoroalkyl functionality may produce an array of partially oxidised fluorocompounds. Therefore, disposal of the notified polymer and its degradation products by incineration should only take place at facilities that demonstrate complete combustion of the perfluoroalkyl functionality and have adequate measures in place to control release of hydrofluoric acid.

6.3.2 Conclusion

On the basis of the risk quotient (PEC/PNEC) and the assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment.

However, degradants of the notified polymer, along with associated impurities and residual monomers of the notified polymer, are precursors of the persistent chemical, PFBS. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of PFBS is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown.

PFBS is an environmentally persistent chemical that has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFBS is considered to be less problematic when compared with long chain (C8 and above) perfluorocarboxylic acids that PFBS is expected to replace, noting that current evidence suggests PFBS is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of chemicals that degrade to release PFBS and other very persistent poly- and perfluoroalkyl compounds, should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

Appendix

The robust summaries of the (eco)toxicological studies analysed for the assessment of Fluorosurfactant FC-4430 as a new chemical are reproduced here without modification.

A.1. HEALTH TOXICITY STUDIES

A.1.1 Acute toxicity – oral

TEST SUBSTANCE	T-7329
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	1% aqueous carboxymethyl cellulose.
Remarks - Method	GLP & QA

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	3/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	On day 1, 5 animals had lethargy, and one female had uncoordinated movements and piloerection.
Effects in Organs	None.
Remarks - Results	None.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	NOTOX (2001a).

A.1.2 Acute toxicity – dermal

TEST SUBSTANCE	T-7329
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar.
Vehicle	None.
Type of dressing	Occlusive.
Remarks - Method	GLP & QA.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	All male animals had yellow staining on their treated skin areas. One male had slight erythema during day 2-4. Four female animals had slight erythema during day 2-6. Two females had scales during day 5-7.
Signs of Toxicity - Systemic	One male had lethargy and ptosis on day 1. Chromodacryorrhoea was observed in 4 animals during day 2-4.
Effects in Organs	None.
Remarks - Results	All animals had recovered from the symptoms between day 5 and 8.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	NOTOX (2001b).

A.1.3 Acute toxicity - inhalation

No study report was provided for assessment.

A.1.4 Irritation – skin

TEST SUBSTANCE	T-7329
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS

Lesion	Mean Score* Animal No.			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	0.3	0.3	0.3	2	24 hours	0
Oedema	0	0	0	0		0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Primary irritation index (PII) = 0.58
CONCLUSION	The notified polymer is slightly irritating to skin.
TEST FACILITY	NOTOX (2001c).

A.1.5 Irritation - eye

TEST SUBSTANCE	T-7329
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	GLP & QA.

RESULTS

Lesion	Mean Score* Animal No.			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Conjunctiva: redness	0.3	0.3	0.3	2	24 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	2	1 hour	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Fluorescein test showed no corneal epithetical damage in animals.
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	NOTOX (2001d).

A.1.6 Skin sensitisation

TEST SUBSTANCE	T-7329	
METHOD	OECD TG 406 Skin Sensitisation – maximisation test. EC Directive 96/54/EC B.6 Skin Sensitization - maximisation test.	
Species/Strain	Guinea pig/Dunkin Hartley	
preliminary study	Maximum Non-irritating Concentration:	
	intradermal:	<0.05%
	topical:	
main study		
Number of Animals	Test Group: 10	Control Group: 5
induction phase	Induction Concentration:	
	intradermal injection	
	topical application	
Signs of Irritation	Well-defined to moderate erythema was observed after intradermal and topical inductions in test animals.	

challenge phase		
1st challenge	topical application:	100%
	topical application:	vehicle

Remarks - Method

GLP & QA.

1% aqueous carboxymethyl cellulose was used as the vehicle.

RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after:			
		1st challenge		2nd challenge	
		24 h	48 h	24 h	48 h
Test Group	100%	0/10	0/10		
	vehicle	0/10	0/10		
Control Group	100%	0/5	0/5		
	vehicle	0/5	0/5		

Remarks - Results

Light yellow staining was observed on the treated skin areas 24 and 48 hours after challenge. This staining did not hamper the scoring of the skin reactions.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY

NOTOX (2001e).

A.1.7 Repeat dose toxicity-28 day oral

TEST SUBSTANCE

T-7329

METHOD

OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain

Rat/Wistar

Route of Administration

Oral – gavage.

Exposure Information

Total exposure days: 28 days;

Dose regimen: 7 days per week;

Post-exposure observation period: 14 days.

Vehicle

1% aqueous carboxymethyl cellulose.

Remarks - Method

GLP & QA.

The dose levels were selected from a 5-day range finding study, where no significant effects were noted at 150 and 1 000 mg/kg/day.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw/day	Mortality
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	1 000	0
V (control recovery)	5/sex	0	1
VI (high dose recovery)	5/sex	1 000	0

Mortality and Time to Death

One female in the control recovery group died after blood sampling, which was considered to be an accident related to the blood sampling procedure.

Clinical Observations

When compared to the control animals, the test animals had no clinical signs of toxicity or behavioural changes, or treatment-related changes in hearing ability, pupillary reflex, static righting reflex and grip strength, ophthalmoscopic examination, bodyweights or food consumption.

Increases in high and/or low sensor reading were observed in 2 animals of group I, 2 females of group III, 1 female of group IV, 1 female of group V and 1 female of group VI. These changes were considered to have occurred by chance without any toxicological relevance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

At the end of recovery, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin and mean corpuscular haemoglobin concentration values were decreased among males of group VI. The mean corpuscular volume values were below the historical data in the laboratory.

Bilirubin, sodium and calcium values in blood were decreased in group IV males at the end of treatment. Calcium levels remained low after recovery. Apart from bilirubin, all other values remained within the range of historical control data in the laboratory.

Effects in Organs

Kidney/bodyweight ratios in groups III and IV males were increased at the end of treatment.

Pathology

There were no macroscopic or microscopic findings recorded which could be attributed to the treatment of the test material.

Remarks – Results

The low bilirubin values at the end of treatment in group IV males were not considered toxicologically significant as an opposite effect would be expected in case of target organ toxicity.

Other changes in this study are not considered to be of toxicological importance because either the individual values remained within the range of historical control data in the laboratory, or no supportive evidence was observed microscopically.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study (the highest dose tested).

TEST FACILITY NOTOX (2001f).

A.1.8 Genotoxicity - bacteria

TEST SUBSTANCE	T-7329
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	S. typhimurium: TA1535, TA1537, TA98, TA100 E. coli: WP2 uvrA.
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0 b) Without metabolic activation: 0-5000 µg/plate.
Vehicle	DMSO
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in PreliminaryTest	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent				
Test 1	None.	None.	None.	None.
Test 2		None.	None.	None.
Present				
Test 1	None.	None.	None.	None.
Test 2		None.	None.	None.

Remarks - Results	Precipitation in the top agar was observed at 1 mg/plate and upwards. However, precipitation on the plates was not observed. The values of positive and negative controls were within historical control data ranges.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NOTOX (2001g).

.1.9 Genotoxicity – in vitro

TEST SUBSTANCE	T-7329
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human peripheral lymphocytes.
Metabolic Activation System	S9-mix.
Vehicle	DMSO

Remarks - Method GLP & QA.

Metabolic Activation	Test Substance Concentration (μg/mL)	Exposure Period	Harvest Time
Absent			
Test 1	0, 33, 100, 333	3	24
Test 2A	0, 3, 10*, 18, 24*, 33*, 42, 56	24/48	24/48
Test 2B	10*, 24, 33*, 56, 75*, 90, 100	24	24
Present			
Test 1	0, 3, 10, 33, 100, 333	3	24
Test 2A	0, 3, 10, 33*, 100*, 333*	3	48

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	Test Substance Concentration (μg/mL) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent			≥333 μg/mL	
Test 1		-	333 μg/mL	None.
Test 2A		-		None.
Test 2B		-		None.
Present				
Test 1		-	333 μg/mL	None.
Test 2A		-	333 μg/mL	None.

Remarks - Results

The average generation time (AGT) of the human peripheral lymphocytes ranged 15.4-16.4 hours.

Cytotoxicity was observed at 100 μg/mL and higher with 24/48 hour treatment and 24/48 hour fixation in the preliminary test. No inhibition of the mitotic index of 50% was reached in cultures treated for 24 hours with T-7329 in the absence of S9-mix.

Both in the absence and presence of S9-mix, T-7329 did not induce a statistically or biologically significant increase in the number of cells with chromosome aberrations.

The values of positive and negative controls were within historical control data ranges.

CONCLUSION The notified polymer was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY NOTOX (2001h).

A.1.10 Genotoxicity – in vivo

No study report was provided for assessment.

A.2. ENVIRONMENTAL TOXICITY STUDIES

A.2.1 Environmental Effects

A.2.1.1. Acute toxicity to fish

TEST SUBSTANCE	FC-4430
METHOD	OECD TG 203 Fish, Acute Toxicity Test. US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075 (1). ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	131 mg $CaCO_3$/L (range 128 – 132)
Analytical Monitoring	None
Remarks – Method	The study was conducted in duplicate with 10 fish for each test vessel (i.e. 20 fish per concentration). The test solutions were mixed for one minute after which it was observed that the solutions had a white cloudy colour with foam on the surface. The degree of colour and foam increased with concentration. By the end of the study the appearance of the test solution had not changed.

RESULTS

Concentration mg/L	Number of Fish	Mortality				
Nominal		2h	24h	48h	72h	96h
0	20	0	0	0	0	0
125	20	0	0	0	0	0
250	20	0	0	0	0	0
500	20	0	1	1	1	1
1000	20	0	14	17	17	17
2000	20	0	20	20	20	20

LC50	765 mg/L at 96 hours (95% C.I. = 650 – 888).
NOEC (or LOEC)	250 mg/L at 96 hours.
Remarks – Results	On day 3 the dissolved oxygen had dropped to 40% saturation (3.6 mg/L), therefore the vessels all received mild aeration. Sub lethal effects were noticed in the 500 ppm solution with one fish lying at the bottom of the tank. In the 1000 ppm solution, of those fish that were not dead, 2 were lethargic with one appearing normal.
CONCLUSION	This LC50 indicates that the notified polymer is practically non-toxic to fish.

TEST FACILITY	Wildlife International Ltd (2001b)

A.2.1.2.Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	FC-4430
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test. US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075. ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	131 mg $CaCO_3$/L (range 128 –132)
Analytical Monitoring	None
Remarks - Method	The study was conducted in duplicate with 10 daphnids for each test vessel (i.e. 20 daphnids per concentration). The test solutions were mixed for one minute after which it was observed that the solutions were clear and colourless. By the end of the study the appearance of the test solution had not changed. This is in contrast to the fish experiment described above.

RESULTS

Concentration mg/L	Number of D. magna	Number Immobilised	
Nominal		24 h	48 h
0	20	0	0
47	20	0	0
94	20	0	8
188	20	0	13
375	20	0	20
750	20	9	20
1500	20	14	20

LC50	99 mg/L at 48 hours (C.I. = 82 –120 mg/L)
NOEC (or LOEC)	47 mg/L at 48 hours
Remarks - Results	
CONCLUSION	The results suggest the notified polymer is classed as harmful to aquatic invertebrates.
TEST FACILITY	Wildlife International Ltd (2001c)

A.2.1.3. Algal growth inhibition test

TEST SUBSTANCE	FC-4430
METHOD	OECD TG 201 Alga, Growth Inhibition Test. US EPA Series 850 – Ecological Effects Test Guidelines. OPPTS Number 850.1075. ASTM Standard E-729-88a. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates and Amphibians.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	0, 31, 63, 125, 250, 500 and 1000 mg/L
Concentration Range Actual	Not determined
Auxiliary Solvent	None
Water Hardness	131 mg $CaCO_3$/L (range 128 –132)
Analytical Monitoring	None
Remarks - Method	Three replicate vessels were used for each concentration with the nominal algal concentration being 1.0 x 10^4 cells/mL.

RESULTS

Growth	
EC50	NOEC
mg/L at 96 h	mg/L
763 (95% C.I. = 179 - 1168)	250

Remarks - Results	At the end of the study a visual inspection indicated that algal growth had occurred in all concentrations. This effect was algistatic and not algicidal.
CONCLUSION	This EC50 indicates that the notified polymer is practically non-toxic to algae.
TEST FACILITY	Wildlife International Ltd (2001d)

A.2.1.4. Inhibition of microbial activity

TEST SUBSTANCE	FC-4430
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge (from a treatment plant that takes predominantly domestic effluent).
Exposure Period	3 hours
Concentration Range Nominal	0, 1, 3, 10, 30, 100, 300 and 1000 mg of active/L

Remarks – Method	3,5-dichlorophenol was used as the reference material. Nonlinear interpolation statistical analysis was used to calculate the EC50 values for the reference and test materials.
RESULTS	
EC50	786.2 mg/L
NOEC	100 mg/L
Remarks – Results	The reference material had an EC50 of 28.6 mg/L which lies between 5 and 30 mg/L, thus indicating that the test was valid.
CONCLUSION	The EC50 indicates that the notified polymer is unlikely to affect the respiration rate of activated sludge.
TEST FACILITY	Wildlife International Ltd (2001e)

A.2.2. Environmental fate

A.2.2.1. Ready biodegradability

Remarks – Results

A ready biodegradation test is being performed on the polymer, but the results are not yet available. In general, few studies have been conducted to investigate the biodegradability of perfluorinated or partially fluorinated surfactants. Biodegradation of partially fluorinated surfactants appears to be limited to the nonfluorinated portion of the molecule (Moody and Field, 2000).

A.2.2.2. Bioaccumulation

RESULTS

Not determined. The size of the molecule indicates it is unlikely to cross biological membranes. However, if the molecule is susceptible to biodegradation, the fluorinated moiety could be isolated and the behaviour of these compounds is not well understood.

In this regard, the company has provided a bioconcentration study of the fluorinated moiety, perfluorobutane sulfonate, potassium salt (PFBS). The study was conducted following US EPA guidelines using bluegill sunfish (*Lepomis macrochirus*) as the test organism. The test consisted of a 28 day uptake phase followed by a 16 day depuration phase. Two concentrations (0.5 mg/L and 5 mg/L) and a control group were tested. Concentrations in the negative control were <LOQ (0.125 mg/L), while in the 0.53 mg/L and 0.5 mg/L, concentrations averaged between 106% and 104% of nominal concentrations respectively.

Observations of mortality and clinical signs were undertaken throughout the study. Fish in the negative control appeared normal and healthy throughout while one fish died in the 5 mg/L treatment group on day 23 of the uptake phase of the test. All other fish in the test appeared normal with no treatment-related signs of toxicity.

Concentrations of PFBS in tissues of fish in the 0.53 mg/L test group in edible and nonedible tissues appeared to reach steady state at day 7. The mean measured tissue concentrations during this period of time were 0.113, 0.272 and 0.203 mg/Kg for edible, nonedible and whole fish respectively. During the depuration phase of the test, PFBS was eliminated rapidly with estimates of time to reach 50% clearance of 2.1, 2.9 and 1.3

	days for edible, nonedible and whole fish respectively. Concentrations of PFBS in tissues of fish in the 5 mg/L test group in edible and nonedible tissues appeared to reach steady state at day 3. The mean measured tissue concentrations during this period of time were 0.829, 2.24 and 1.57 mg/Kg for edible, nonedible and whole fish respectively. Steady state bioconcentration factor (BCF) values ranged from 0.16 in edible tissue to 0.43 in nonedible tissue. During the depuration phase of the test, PFBS was eliminated rapidly with estimates of time to reach 50% clearance of 1.9, 2.1 and 2.1 days for edible, nonedible and whole fish respectively. Based on this low BCF, PFBS is not expected to bioaccumulate in the food chain.
TEST FACILITY	Wildlife International Ltd (2001a).

A.2.2.3. Activated Sludge Adsorption

TEST SUBSTANCE	FC-4430
METHOD	US EPA. Fate, transport and transformation test guidelines. OPPTS 835.1110
Remarks - Method	The inoculum used was activated sludge. An oxygen bomb with ion selective electrode method was used to determine the total fluorine in the water and sludge along with a mass balance. The Freundlich sorption isotherm was then calculated. A preliminary adsorption study (Tier 1) over 48 hours with 6 different sludge/CaCl2 solution ratios ranging from 1/5 to 1/1000 indicated that the 1/20 ratio (5 g of sludge in 100 mL of 0.01 M CaCl2 solution) with a concentration of 1000 mg/L should be further investigated (Tier 2) for 24 hours. This was done in triplicate with triplicate controls with no sludge and a single control blank. The study was run for 48 hours with 5 mL aliquots being taken for sampling at 4, 8, 24 and 48 hours. Throughout the study the test sludge solutions were continuously mixed. Each aliquot was centrifuged to separate the aqueous and sludge phases, then analysed for fluorine content and mass balance calculated. In a tier 3 study, the sorption isotherm was determined using 5 test concentrations (50, 100, 250, 500 and 1000 mg/L) and a sludge/solution ratio of 1/20. The test was done as previously with the fluorine content being determined in the sludge. The sorbed mass per unit mass of sludge was then plotted and the Freundlich sorption isotherm calculated.
RESULTS	Tier 2 – Sorption constants (K) values were 16.3 and 17.2. Mass balance 88.4% average Tier 3 – Kf values was 51.4 with 1/n of 1.208. Mass balance 99.8% average
Remarks - Results	
CONCLUSION	The results indicate that the polymer is very highly mobile and will not adsorb to sewage sludge.
TEST FACILITY	Centre Analytical Laboratories Ltd (2001).

References

3M Corporate Analytical Technology Center (2001) Internal correspondence (unpublished report, provided by the notifier).

3M Environmental Laboratory (2001) Characteristation Study of FC4430 (Lot 1) Test Control Reference # TCR-00017-054 Phase: Solubility Determination. St Paul, MN(unpublished report, provided by the notifier).

3M (2002a) OECD 111 Preliminary Test: Hydrolytic Degradation of an Acrylate Polymeric Ester FC-4430 in Aqueous Buffered Solutions. St Paul, MN, USA, 3M Environmental Technology and Safety Services (unpublished report, provided by the notifier).

3M (2002b) EHS & R Proposed Test Procedure Study: Washing Study (Project No. 0010529221, March, 2002). St. Paul, MN, USA, 3M Specialty Materials Manufacturing Division, Analytical Laboratory (Unpublished report provided by the notifier).

3M (2002c) FTIR Static Headspace Outgassing 3M Best Paint witl1 and without FC4432 (Lot 2) floropolymer additive: Screening Study (Project No. 0010529221, March, 2002). St. Paul, MN, USA, 3M Specialty Materials Manufacturing Division, Analytical Laboratory (unpublished report provided by the notifier).

3M (2003) Inherent Aerobic Aquatic Biodegradability of Fluoroaliphatic Polymeric Ester of FC-4430 (Study No. E02-0913, October 2003). St. Paul, MN, USA, 3M Environmental Technology and Safety Services (unpublished report provided by the notifier).

Centre Analytical Laboratories, Inc. (2001) Activated Sludge Sorption Isotherm for FC4430. Centre Study Number 023-051, State College, PA. (unpublished report, provided by the notifier).

Chemex (2006a) The acute toxicity of MTDID 3504 to Turbot *(Scophthalmus maximus)* (Study number ENV7675/060608, November 2006) Cambridge, UK, Chemex Environmental International Limited (Unpublished report, provided by the applicant).

Chemex (2006b) The toxicity to *Corophium sp.* of MTDID 3504 (E06-034S) (Study number ENV7674/060608, August 2006) Cambridge, UK, Chemex Environmental International Limited (Unpublished report, provided by the applicant).

Chemex (2006c) The toxicity to *Acartia tonsa* of MTDID 3504 (Study number ENV7672/060608, August 2006) Cambridge, UK, Chemex Environmental International Limited (Unpublished report, provided by the applicant).

Chemex (2006d) The growth inhibition of the marine alga *Skeletonema costatum* by MTDID 3504 (Study number ENV7673/060608, August 2006) Cambridge, UK, Chemex Environmental International Limited (Unpublished report, provided by the applicant).

ECHC (2012) Screening Assessment Report; Perfluorooctanoic Acid, its Salts, and it Precursors, Environment Canada Health Canada, August 2012.

Geisy JP, Nail JE, Khim JS, Jones PD & Newsted JL. (2010) Aquatic Toxicology of Perfluorinated Chemicals. Rev Environ Contam Toxicol, 202: 1-52.

Moody C and Field J. (2000) Perfluorinated Surfactants and the Environmental Implications oftheir Use in Fire-Fighting Foams.*Published in* Environmental Science andTechnology, Vol. 34, No. 18, pp 3864-3870.

National Occupational Health and Safety Commission (1999b) National Guidance Material for Spray Painting. Australian Government Publishing Service, Canberra.

NICNAS (2003) New Chemical Assessment Report: Fluorosurfactant FC-4430 National Industrial Chemicals Notification and Assessment Scheme, Australian Government, Department of Health and Ageing, Sydney, Australia.

NICNAS (2005) Existing Chemical Hazard Assessment Report: Potassium Perfluorobutane Sulfonate, National Industrial Chemicals Notification and Assessment Scheme, Australian Government, Department of Health and Ageing, Sydney, Australia. http://www.nicnas.gov.au/__data/assets/pdf_file/0004/4927/Potassium_Perfluorobutane_Sulfonate_PDF.pdf

NOTOX (2001a) Assessment of acute oral toxicity with T-7329 in the rat (acute toxic class method), NOTOX Project 298147, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX (2001b) Assessment of acute dermal toxicity with T-7329 in the rat, NOTOX Project 298158, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX (2001c) Primary skin irritation/corrosion study with T-7329 in the rabbit (4 hour semi-occlusive application), NOTOX Project 298169, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX (2001d) Acute eye irritation/corrosion study with T-7329 in the rabbit, NOTOX Project 298171, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX. (2001e). Assessment of contact hypersensitivity to T-7329 in the albino guinea pig (maximisation test), NOTOX Project 298182, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX. (2001f). Subacute 28-day oral toxicity with T-7329 by daily gavage in the rat, followed by a 14-day recovery period, NOTOX Project 298204, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX (2001g) Evaluation of the mutagenic activity of T-7329 in the *Salmonella typhimurium* reverse mutation assay and the *Escherichia coli* reverse mutation assay (with independent repeat), NOTOX Project 298215, NOTOX, The Netherlands (unpublished report, provided by the notifier).

NOTOX (2001h) Evaluation of the ability of T-7329 to induce chromosome aberration in cultured peripheral human lymphocytes, NOTOX Project 298226, NOTOX, The Netherlands (unpublished report, provided by the notifier).

OSPAR (1995) OSPAR / PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry 1995.

Pace Analytical Services Inc. (2001) Photolysis Study for the Notified Polymer (Study number CA128, May 2001) Minnesota, USA, Pace Analytical Services Inc (Unpublished report, provided by the notifier).

Safe Work Australia (2011a) Code of Practice: Preparation of Safety Data Sheets for Hazardous Chemicals. Safe Work Australia, Australian Government Publishing Service, Canberra.

Safe Work Australia (2011b) Code of Practice: Labelling of Workplace Hazardous Chemicals. Safe Work Australia, Australian Government Publishing Service, Canberra.

Safe Work Australia (2012a) Code of Practice: Managing Risks of Workplace Hazardous Chemicals in the Workplace. Safe Work Australia, Australian Government Publishing Service, Canberra

Safe Work Australia (2012b) Code of Practice: Spray Painting and Powder Coating. Safe Work Australia. Australian Government Publishing Service, Canberra

Standards Australia/Standards New Zealand (1994a) Australian/New Zealand Standard 2210–1994, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994b) Australian/New Zealand Standard 1716–1994, Respiratory Protective Devices. Standards Association of Australia /Standards Association of New Zealand.

Thompson, RS (1990) Water quality determination of acute lethal toxicity of marine copepods (*Copepoda Crustacea*) United Kingdom proposal to ISO TC147/WG2, second draft November 1990.

UNECE (2009) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition. United Nations Economic Commission for Europe, New York and Geneva. Accessed October 2014 at http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

US EPA (2002) Revised Draft Hazard Assessment of Perfluorooctanoic Acid and its Salts. US Environment Protection Agency, Office of Pollution Prevention and Toxics Risk Assessment Division, 4 November 2002.

US EPA (2003) PBT Profiler, V 1.201. Office of Pollution Prevention and Toxics, US Environment Protection Agency. URL: http://www.pbtprofiler.net/

US FDA (2009) Environmental Assessment. US Food and Drug Administration, 22 April, 2009. Accessed October 2014 at: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM176786.pdf.

US PMN (unpublished, provided by the notifier).

Wildlife International Ltd. (2001a) Perfluorobutane sulfonate, potassium Salt (PFBS): A Flow-Through Bioconcentration Test with the Bluegill (*Lepomis macrochirus*). Report Number 454A-117, St Paul, Minnesota (unpublished report, provided by the notifier).

Wildlife International Ltd. (2001b) A 96-Hour Static Acute Toxicity Test with the Fathead Minnow (*Pimephales promelas*). Report Number: 454A-125, St Paul, Minnesota (unpublished report, provided by the notifier).

Wildlife International Ltd. (2001c) A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*). Report Number: 454A-126A, St. Paul, Minnesota (unpublished report, provided by the notifier).

Wildlife International Ltd. (2001d) A 96-Hour Static Acute Toxicity Test with the Fresh Water Algae (*Selenastrum capricornutum*). Report Number: 454A-127, St. Paul, Minnesota (unpublished report, provided by the notifier).

Wildlife International Ltd. (2001e) FC-4430 Activated Sludge, Respiration Inhibition Test. Report Number: 454A-105A, St. Paul, Minnesota (unpublished report, provided by the notifier).

Zhao Z, Xie Z, Möller A, Sturm R, Tang J, Zhang G & Ebinghaus R (2012) Distribution and long-range transport of polyfluoroalkyl substances in the Arctic, Atlantic Ocean and Antarctic coast. Environmental Pollution, 170(0): pp. 71-77.