

File No: EX/194 (LTD/1671, LTD/1672 and LTD/1673)

November 2016

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

**LTD/1671: Polyfluorinated Acrylic Alkylamino Copolymer ELN101570-19-A in
Capstone® ST-500**

**LTD/1672: Polyfluorinated Acrylic Alkylamino Copolymer ELN101570-19-B in
Capstone® Series**

**LTD/1673: Polyfluorinated Acrylic Alkylamino Copolymer ELN101570-19-C in
Capstone® Series**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the 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 Public 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**

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This assessment report is for an extension of the original assessment certificate for Polyfluorinated Acrylic Alkylamino Copolymer ELN101570-19-A in Capstone® ST-500. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
EX/194 (LTD/1671 LTD/1672 LTD/1673)	Laticrete Pty Ltd	Polyfluorinated Acrylic Alkylamino Copolymer ELN101570-19-A in Capstone® ST-500	ND*	< 10 tonnes per annum	Component of concrete/stone/tile sealants, paints/coatings and textile/fibre products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymers are not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymers are not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymers are not considered to pose an unreasonable risk to public health.

However, the notified polymers are potential precursors for perfluorohexanoic acid (PFHxA) in the environment, and PFHxA is persistent in the environment. Due to the environmental distribution of PFHxA resulting from the use pattern of the notified polymers, secondary human exposure to PFHxA via the environment may occur. The notified polymers are replacing long chain polyfluoroalkyl polymers, which could result in secondary human exposures to perfluorooctanoic acid (PFOA) and longer chain perfluorocarboxylic acids (PFCAs). PFOA and longer chain PFCAs are more hazardous to human health and have higher bioaccumulation potential, compared to PFHxA. The overall human health risk posed by the notified polymers is less than that of the substance they each replace.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymers themselves are not considered to directly pose an unreasonable short-term risk to the environment.

However, degradants of the notified polymers, along with associated impurities and residual monomers of the notified polymers, are potential precursors of the very persistent chemical, PFHxA. The assessed use pattern of the notified polymers does not control the release of breakdown products into the environment during use and after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified polymers and their degradation products is unknown. This situation may change if further data on the environmental behaviour of the notified polymers and their poly- and perfluoroalkylated degradation products (including PFHxA) were to become available.

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Spray products containing the notified polymers should carry the following safety directions on the label:
 - Avoid breathing of vapours, mists and sprays
 - Use in well-ventilated areas, where possible
 - In case of insufficient ventilation, wear suitable respiratory equipment

(Material) Safety Data Sheet

- The (M)SDS for products containing the notified polymers should include the following:
 - Avoid breathing of vapours, mists and sprays
 - Use in well-ventilated areas, where possible
 - In case of insufficient ventilation, wear suitable respiratory equipment

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymers:
 - Enclosed, automated processes, where possible
 - Airless spray or low pressure spray equipment should be utilised during spray operations, where possible
- 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 polymers as introduced or in formulated products:
 - Avoid breathing of vapours, mists and sprays
 - Avoid prolonged spraying
 - Maintain good hygiene practices
- 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 polymers as introduced or in formulated products:
 - Respiratory protection when conducting spray operations in areas with insufficient ventilation
 - Gloves
 - Coveralls

Guidance in 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* (SWA, 2012) 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 polymers 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 polymers should only be introduced as part of a strategy to phase out the use of long chain perfluoroalkyl chemicals.
- The notifier should seek ways to minimise the level of residual polyfluoroalkyl monomers and impurities in the notified polymers. 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.
- The following control measures should be implemented by users of the notified polymers, or products containing the notified polymers, to minimise exposure of the notified polymers to the environment:
 - Best practice on-site treatment of waste streams should be employed to maximise removal of the notified polymers from wastewaters.

Disposal

- If the notified polymers or products containing the notified polymers cannot feasibly be disposed using a technique that will destroy or irreversibly transform the perfluoroalkyl components of the notified polymers, disposal should be to landfill.

Emergency procedures

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

Regulatory Obligations

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. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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 ten tonnes per annum for each notified polymer;
 - any of the polymers have a number-average molecular weight of less than 1000;
 - the use changes from a component of concrete/stone/tile sealants, textile/fibre products, and coating/paint products;
 - the notified polymers are intended for use in spray products by consumers or professionals at > 5% individual concentration;
 - further information on the repeated inhalation toxicity of the notified polymers becomes available;
 - additional information has become available to the person as to an adverse effect of the poly- or perfluoroalkyl degradation products of the notified polymers (such as PFHxA);
 - additional information has become available to the person as to the environmental fate of the polymers or their poly- or perfluoroalkyl degradation products (such as PFHxA) 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 polymers has changed from concrete/stone/tile sealants, textile/fibre products, and coating /paint products, or is likely to change significantly;
 - the amount of polymers being introduced has increased, or is likely to increase, significantly;
 - the polymers have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymers on occupational health and safety, public health, or the environment.

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

AICS Entry

- When the notified polymers are listed on the Australian Inventory of Chemical Substances (AICS) their individual entry is proposed to include the following statement(s):
 - This polymer has been assessed by NICNAS and there are specific secondary notification obligations that must be met. Potential introducers should contact NICNAS before introduction.

(Material) Safety Data Sheet

The (M)SDS of a product containing the notified polymers provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

Extension Application:

The applicant for the extension application (Laticrete Pty Ltd) has provided an MSDS for a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified polymers by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified polymers were carried out by NICNAS and the Department of the Environment.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of Original Assessment Certificates:

For LTD/1671, LTD/1672 and LTD/1673

The Chemours Company (Australia) Pty Ltd (ABN 90 169 142 750)
7 Eden Park Drive
MACQUARIE PARK NSW 2113

IMCD Australia Limited (ABN 44 000 005 578)
1st Floor, 372 Wellington Road
MULGRAVE VIC 3170

For LTD/1671 only

Anderson Dry-Treat Trust & Salmon Dry-Treat Trust (ABN 28 702 168 959)
65 Nicholson Street
ST LEONARDS NSW 2065

Applicant for an Extension of the Original Assessment Certificate:

For LTD/1671 only

Laticrete Pty Ltd (ABN: 57 069 067 992)
29 Telford Street,
VIRGINIA QLD 4014

NOTIFICATION CATEGORY

Limited: Synthetic polymers, each with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical names, other names, CAS numbers, molecular and structural formulae, molecular weights, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

China (2011), United States of America (2011).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

LTD/1671: ELN101570-19-A (notified polymer)

Capstone® ST-500 (up to 30% notified polymer)

LTD/1672: ELN101570-19-B (notified polymer)

LTD/1673: ELN101570-19-C (notified polymer)

MOLECULAR WEIGHTS
> 10,000 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

The notified polymers contain a polyfluoroalkyl carbon side chain with six perfluorinated carbons.

DEGREE OF PURITY
> 98%

DEGRADATION PRODUCTS
The notified polymers are potential precursors for PFHxA in the environment (PFHxA – perfluorohexanoic acid – CAS name: Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-; CAS No. 307-24-4).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Slightly opaque, yellow aqueous dispersion.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in aqueous solution
Boiling Point	Not determined	Expected to decompose prior to boiling.
Density	Not determined	Imported in aqueous solution
Vapour Pressure	$< 1.3 \times 10^{-9}$ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Not determined	Expected to be low based on the high molecular weight and hydro/lipophobicity of the polymer. Based on structural considerations and aqueous product formulation, the notified polymers have the potential to disperse in water.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, hydrolysis is expected to occur very slowly under environmental conditions.
Partition Coefficient (n-octanol/water)	Not determined	On the basis of its hydro/lipophobic tendencies, the notified polymers are expected to partition between the octanol and water phases.
Adsorption/Desorption	Not determined	Generally, polymers similar to the notified polymers are expected to adsorb to soil, sediments and sludge. However, the notified polymers may have low absorption based on the presence of perfluoroalkyl functionalities which have both hydrophobic and lipophobic tendencies.
Dissociation Constant	Not determined	May have the potential to dissociate under environmental conditions (pH 4-9).
Flash Point	> 93 °C	(M)SDS
Autoignition Temperature	Not determined	Expected to decompose prior to any autoignition.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity

The notified polymers are expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymers are not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymers will not be manufactured in Australia. They will be imported into Australia at individual concentrations up to 30%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

LTD/1671

Year	1	2	3	4	5
Tonnes	< 5	< 5	< 5	< 5	< 10

LTD/1672

Year	1	2	3	4	5
Tonnes	< 5	< 5	< 5	< 5	< 10

LTD/1673

Year	1	2	3	4	5
Tonnes	< 5	< 5	< 5	< 5	< 10

PORT OF ENTRY

Sydney, Melbourne and Brisbane

TRANSPORTATION AND PACKAGING

The products containing the notified polymers (up to 30% concentration, individually) will be imported by sea in 20, 50, 200 or 1,000 kg polyethylene containers and transported within Australia by road.

USE

The notified polymers are intended to be introduced in order to phase out the use of partially fluorinated polymers containing fluorinated carbon chain lengths > 6 in various proportions (i.e., existing polymers). The use categories of the notified polymers are identical to those of the existing polymers they replace, as outlined below.

The notified polymers will be used in end-use products as oil and water repellents and stain release agents. Proposed uses for the products containing the notified polymers include: concrete, stone and tile sealers (up to 5% concentration); stain repellent for treatment of existing textile and fibre products (up to 10% concentration); factory applied stain repellent for textile and fibre products (up to 2% concentration); and coatings and paint (up to 5% concentration).

OPERATION DESCRIPTION

The notified polymers will not be manufactured in Australia. The notified polymers will be imported each at up to 30% concentration.

Reformulation

At the reformulation site the imported containers, in which one of the notified polymers is present at a concentration up to 30%, will be moved to the blending area, either by forklift or manually. The contents of the imported containers will either be manually poured into the blending equipment or for larger containers pumped through pipes into the blending tank. Reformulation of the imported products containing the notified polymers

will be enclosed and automated with local exhaust ventilation in place. Once reformulation is complete sampling for quality assurance purposes will take place and the products containing the notified polymers will be pumped to filling machines where it will be transferred to a variety of containers ranging from 0.5 L cans to 205 L drums and 1,000 L intermediate bulk containers.

Concrete, stone and tile sealers

In factory settings the concrete, stone and tile sealant products will be diluted and mixed, either manually or using pumping equipment, to a concentration of 0.5 – 5% and applied by spray using enclosed, robotic equipment, where it will also be dried prior to leaving the spray booth. When used in aftermarket settings, both by professionals and consumers, the concrete, stone and tile sealant products (concentration of 0.5 – 5%, individual notified polymer) will be applied using brushes, mops or rollers.

Stain repellent in aftermarket textile and fibre products

When used by consumers stain repellents for textile and fibre products will contain the notified polymers at individual concentrations up to 1% and are expected to be supplied in 500 mL spray pump packs. For commercial use, stain repellent in aftermarket textile and fibre products will be supplied at individual concentrations up to 10% with these typically being diluted to approximately 1% prior to being applied with low pressure spray.

Factory applied stain repellent for textile and fibre products

Products containing the notified polymers will be applied to textile and fibre products in the factories mainly by immersing the textile and fibre products in a bath containing the notified polymers at individual concentrations up to 2%. Any excess liquid will then be squeezed out and the textiles and fabrics dried in an oven which is supplied with local exhaust ventilation.

Coatings and paint

Coatings and paints containing the notified polymer at individual concentrations up to 5% will be used by both professional painters and the public. The coating and paint products will be applied by spray, roller or brush.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

The notified polymers may undergo slow degradation in the environment. As such, most potential exposure to workers and the public is expected to be to the notified polymers themselves, rather than to their degradation products. Exposure to the residual polyfluoroalkyl starting constituents and/or impurities of the notified polymers (discrete polyfluoroalkyl chemicals containing perfluoroalkyl carbon chain lengths ranging from four to ten) is also possible. Such exposure is limited by the relatively low concentration of polyfluoroalkyl impurities in the notified polymers in the imported products or in end-use products.

The notified polymers are potential precursors for PFHxA in the environment. This may lead to secondary human exposure to PFHxA. This exposure is unquantifiable.

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	4	10-20
Reformulation	2-8	210
Factory application	8-12	210
Tradesmen	2-8	365

EXPOSURE DETAILS

Transport and storage workers

Transport and storage workers will only come into contact with the notified polymers (up to 30% individual concentration) in the unlikely event of an accident.

Reformulation processes

Dermal and ocular exposure may occur when workers manually weigh and pour imported products containing the notified polymers (up to 30% individual concentration) into mixing equipment, or when connecting and disconnecting hoses, and during cleaning and maintenance operations. Inhalation exposures are not expected based on the expected low vapour pressure of the notified polymers and because aerosols are not expected during reformulation processes. The remainder of the formulation process, including packaging, is expected to be mostly automated and exposure is expected to be low.

Paints and coatings, aftermarket textile and fibre products, concrete, stone and tile sealants and inks

Dermal and ocular exposure of workers to the notified polymers (up to 10% individual concentration) may occur when workers are applying paints and coatings, floor care and cleaning products or concrete, stone and tile sealants by brush, mop or roller. There is also some potential for inhalation exposure when applying by low pressure spraying methods, though typically the notified polymers will be present at concentrations of up to 1% during such operations. PPE is expected to be worn, including gloves, protective clothing and respiratory protection when aerosols may be present. Professionals may be exposed on a repeated basis.

Factory applied stain repellent for stone, tile, textile and fibre products

Dermal and ocular exposure may occur if workers manually weigh and pour imported products containing the notified polymers (up to 30% concentration) into the application equipment, or when connecting and disconnecting hoses, and during cleaning and maintenance operations. Inhalation exposures are not expected based on the expected low vapour pressure of the notified polymers and because any spray application will be conducted in enclosed spray booths.

6.1.2. Public Exposure

Public exposure to the notified polymers (up to 5% concentration) may occur when concrete, stone and tile sealants, textile and fibre stain repellents, and paint and coating products are applied. Dermal, ocular and inhalation exposure may occur. Consumer exposure is expected to be acute in nature because repeated daily uses are considered unlikely and exposure is expected to be infrequent and short-term (i.e., duration of up to 15 minutes). Products may be applied using spray, with the highest concentration of a notified polymer expected to be sprayed being 5%. The highest exposures will occur when products are sprayed in enclosed settings. Aerosols of the notified polymers are expected to generate relatively large droplet sizes, given that the target is intended to be well-coated.

The public may make dermal contact with surfaces that have been painted with products containing the notified polymers. The notified polymers are expected to be cured within a stable matrix and will not be available for exposure.

The public may be exposed to the notified polymers through dermal contact with residues in treated articles, such as textiles. The notified polymers are expected to form a cohesive film via adsorption to the substrate fibres. Cleaning of the clothing and fabrics to which the notified polymers are applied is expected to be undertaken and may result in the notified polymer becoming dislodged and available for exposure.

There may also be potential for members of the public to inhale or ingest small quantities of fabric/furnishing fibres or household dust from indoor environments. This may involve the inhalation or ingestion of fibres to which the notified polymers are bound, or perhaps inhalation or ingestion of the notified polymers (present in household dust that has been removed from the articles), or polyfluoroalkyl impurities of the notified polymers.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer (LTD/1671) at concentrations of < 25% are summarised in the following table. For full details of the studies, refer to Appendix B. No toxicological studies were provided on the other polymers (LTD/1672 and LTD/1673); however, LTD/1671 is considered to be an acceptable analogue for these other polymers.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 2,000 mg/m ³ /4 hour; low toxicity*
Rat, acute inhalation toxicity	LC50 > 970 mg/ m ³ /4 hour; low toxicity*
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating

Mouse, skin sensitisation – Local lymph node assay
 Mutagenicity – bacterial reverse mutation

no evidence of sensitisation
 non mutagenic

* The values in the inhalation studies represent the actual concentration of the notified polymer.

Toxicokinetics, metabolism and distribution.

The notified polymers are not expected to cross biological membranes (skin or gastrointestinal tract) based on their high molecular weight (> 10,000 Da) and low proportion (< 1%) of low molecular weight species (< 500 Da). In addition, inhalation of the notified polymers themselves is not expected to result in significant absorption from the respiratory tract.

Acute toxicity.

The notified polymer was of low acute oral toxicity in rats.

Inhalation toxicity

Concerns exist that high molecular weight (> 10,000 Da) water insoluble polymers may cause overloading effects in the lungs (US EPA, 2013). Additionally, fluorinated polymers have been known to cause lung injury, which is characterised by respiratory problems ranging from mild to severe effects associated with acute or repeated exposures.

The notified polymer was of low acute inhalation toxicity in two separate studies conducted in rats (LC50 > 2000 mg/m³/4 hours and LC50 > 970 mg/m³/4 hours), as there were no deaths observed at the highest doses tested in these studies and there were no test substance-related clinical signs of toxicity. Respirable particles were generated during this study.

No repeated dose inhalation studies with the notified polymer have been submitted and thus uncertainties remain surrounding possible chronic respiratory tract effects following repeated exposures to the notified polymer.

Irritation and sensitisation.

The notified polymer was a slight skin and eye irritant in rabbits. The notified polymer (up to 30% concentration) was not a skin sensitizer in an LLNA assay in mice.

Mutagenicity/Genotoxicity.

The notified polymer was not mutagenic in a bacterial reverse mutation assay.

Health hazard classification

Based on the available information, the notified polymers are not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Toxicology of breakdown products

The notified polymers contain perfluoroalkyl side-chains that are potential precursors of PFHxA in the environment (PFHxA; CAS No. 307-24-4). PFHxA is a perfluorocarboxylic acid consisting of 5 perfluorinated carbons (a short chain perfluorinated chemical). The polymers that are proposed for replacement by the notified polymers are expected to breakdown to perfluorooctanoic acid (PFOA; CAS No. 335-67-1) (consisting of 7 perfluorinated carbons) and other per- and polyfluorocarboxylic substances with longer perfluoroalkyl carbon chain lengths. The toxicokinetic and toxicological properties of the long chain breakdown products are generally less favourable compared to the short chain breakdown products, with properties becoming less favourable with increasing perfluoroalkyl carbon chain length. In addition, it has been established that the bioaccumulation potential of perfluorocarboxylic acids increases with perfluoroalkyl carbon chain length (Conder, 2008; Giesy 2010).

A review of the literature indicates that PFHxA has a less hazardous human health profile, compared to PFOA (refer to Appendix C for details). It is therefore inferred that the human health hazards associated with the expected breakdown product of the notified polymer (PFHxA) are likely to be similar or less than the human health hazards associated with the expected breakdown products (PFOA and longer chain perfluorocarboxylic acids) of many per- and polyfluoroalkyl chemicals currently on the market and that are intended for replacement by the notified polymers.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Toxicological studies on the notified polymers were generally indicative of low hazard. Slight skin and eye irritation may occur during reformulation (up to 30% concentration) but automated processes are expected to be in place and PPE (coveralls, gloves and goggles) will be worn during reformulation, which will further minimise exposure. The risk to reformulation workers handling the notified polymers is therefore not considered to be unreasonable.

Repeated dermal exposure of workers to the notified polymers may occur during application of concrete, stone and tile sealants, textile and fibre stain repellents, and paint and coating products containing the notified polymers (at up to 10% concentration). The repeated dose toxicity of the notified polymers has not been investigated, however, systemic exposure to the notified polymers is expected to be low based on the high molecular weight ($> 10,000$ Da) of the notified polymers and the low proportion ($< 1\%$) of low molecular weight species < 500 Da. Systemic exposure of workers to breakdown products (e.g., PFHxA) is not expected based on the stability of the notified polymers. Worker exposure to impurities of the notified polymers is not expected to be significant ($< 0.1\%$). In addition, the use of engineering controls and PPE are expected to further lower exposure to the notified polymers, their breakdown products and impurities. Overall, the risk of repeat dose toxicity to workers resulting from repeated dermal exposure is not considered to be unreasonable.

Repeated inhalation exposure to the notified polymers (typically at up to 1% concentration) may occur during spray operations. The lack of repeat dose inhalation toxicity data is considered to be a data deficiency given the potential for lung injury and/or particle overloading that has been observed with certain other types of polyfluorinated polymers. This is of particular concern for workers who may use products containing the notified polymers every day. Based on the uncertainties surrounding repeated inhalation exposure to the notified polymers, measures should be taken to minimise exposure. The risk of inhalation toxicity resulting from repeated exposure to the notified polymers is not considered to be unreasonable, provided that users minimise inhalation of the notified polymers.

The risk to professionals of acute inhalation toxicity from the notified polymers is not considered to be unreasonable, as the controls used to minimise exposure to prevent repeated toxicity from inhalation are expected to also be protective of acute inhalation toxicity.

Workers may also be exposed to perfluoroalkyl impurities of the notified polymers at relatively low individual concentrations ($< 0.1\%$). It is expected that the engineering controls and personal protective equipment utilised during these operations (as outlined above) will act to mitigate any risk associated with such exposure.

6.3.2. Public Health

The public will apply concrete, stone and tile sealant products, textile and fibre products, and coating/paint products containing the notified polymers (up to 5% concentration) by brush, mop, roller or spray and may experience dermal, ocular or inhalation exposure. Exposure is expected to be short-term and infrequent (certainly less frequent than that experienced by professional users).

Slight skin and eye irritation resulting from ocular exposure to the notified polymers is not expected based on the low concentration in end-use products (up to 5% concentration). Dermal exposure to the notified polymers (up to 5% concentration) is not expected to result in adverse effects, based on the low toxicity of the notified polymers. Additionally, the risk to public health from exposures to perfluoroalkyl impurities during use of products containing the notified polymers (up to 5% concentration) is not considered to be unreasonable based on their low individual concentration ($< 0.1\%$) in end-use products.

Lung injury from inhalation exposure to the notified polymers cannot be ruled out. The lack of repeated dose inhalation data for the notified polymers is of less concern for public exposure based on the expected infrequent exposure. Additionally, the notified polymers are present at a relatively low concentration (up to 5%) in final spray products. Based on these considerations, the risk to public health from use of spray products containing the notified polymer is not considered to be unreasonable.

Therefore, the risk to public health from exposures to the notified polymers and perfluoroalkyl impurities during application of concrete, stone and tile sealants, textile and fibre stain repellents, and paint and coating products is not considered to be unreasonable.

The public may be exposed to the notified polymers and relatively low levels of perfluoroalkyl impurities through dermal contact with surfaces or articles that have been treated with products containing the notified polymers. This exposure may be on a long term repeated basis. The high molecular weight ($> 10,000$ Da) of the notified polymers and the low proportion ($< 1\%$) of low molecular weight species < 500 Da is expected to prevent any significant dermal absorption. The risk to public health from repeated dermal contact with the notified polymers is therefore not considered to be unreasonable. Additionally, the risk to public health from exposures to perfluoroalkyl impurities resulting from dermal contact with treated surfaces or articles is not considered to be unreasonable based on their low individual concentration ($< 0.1\%$) in end-use products.

The public may be exposed indirectly to PFHxA, formed by degradation of the notified polymers in the environment. Such exposure may increase over time due to the persistence of PFHxA in the environment. A quantitative risk assessment for this exposure was not conducted. However, the available data indicates that PFHxA has a more favourable toxicological profile and bioaccumulation potential than the long chain perfluoroalkyl substances that are the ultimate breakdown products of the majority of perfluoroalkyl polymers currently in Australian commerce (such as PFOA). In particular, it is noted that the polymers being replaced contain perfluoroalkyl carbon chain lengths > 6 . It is concluded that the risks to human health from indirect exposure to breakdown products of perfluoroalkyl substances will decrease following introduction of the notified polymers, on the basis that the notified polymers are intended to replace currently available long chain perfluoroalkyl polymers.

It should also be noted that the notified polymers have been approved for the same uses in the US for a manufacture/import volume greater than the volume under consideration in Australia.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymers will be imported as aqueous dispersions at concentrations of up to 30% into Australia. These will be further reformulated/repackaged into containers of various sizes depending on the end use. Typical liquid blending will be used to manufacture various products. During this process any spilled material will be recycled where possible or collected for disposal to landfill. Once mixing is complete the product is automatically pumped to filling machines for packaging into containers. Empty containers, mixing vessels and transfer lines are cleaned with water and recycled into subsequent batches where possible. The notifier estimated less than 2 kg/day release of the notified polymers to the sewerage system from reformulation and equipment cleaning.

RELEASE OF CHEMICAL FROM USE

The majority of the imported notified polymers will be adsorbed onto the surface or incorporated into the surface matrix of the treated substrates after application. The application methods include brushes, mops or rollers for concrete, stone and tile sealers, low pressure spray for aftermarket textile and fibre products, bath application for factory applied stain repellent for textile and fibre products, and spray, roller or brush for coating and paint uses. Sources of potential release will be residues in empty containers (factory and site use), 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 newspaper prior to disposal to landfill. The notifier estimated that up to 2 kg/day of the notified polymers may be released to sewer from uses.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymers are expected to adhere to the substrate's surface to which it has been applied. However, for the use in concrete, stone and tile sealers, and in textile and fibre products abrasion of the floor surface by foot traffic is expected to result in some relocation of the notified polymers. Estimates for losses due to abrasion from these uses are not available. The notified polymers that remain associated with stone, tiles, and textile are expected to share the fate of the associated articles. The majority of the articles are expected to ultimately be disposed of to landfill. The notified polymers applied to surfaces may also degrade as a result of weathering upon being exposed to environmental conditions. Degradation may result in the widespread release of

perfluorohexanoic acid (PFHxA) to surface waters, landfill and landfill leachates, soils, and other regions where release is not foreseen.

Empty drums are expected to be sent to a drum recycler for reclamation. Any wastes containing the notified polymers are expected to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the introduced notified polymers are expected to adhere to the applied substrates following application of the product containing the notified polymers. Treated articles and other dried residues containing the notified polymers are expected to ultimately be disposed of to landfill. When associated with the articles to which the products containing the notified polymers have been applied, the notified polymers are not likely to be mobile or bioavailable in landfill.

Some of the notified polymers may be released to sewer during reformulation, use and disposal. In general, cationic polymers have the potential to be removed from influent in sewage treatment plants (STP) via sorption to sludge. However, predictions of the environmental partitioning behaviour of polyfluoroalkyl 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. The assumption that cationicity and/or high molecular weight results in efficient removal by sorption to sludge during conventional wastewater treatment has not been verified by supporting data for this class of chemical. Thus, noting the potential for the notified polymers to disperse in water, the notified polymers, and any associated degradation products and/or impurities/residual monomers of poly- or perfluoroalkyl compounds, may remain in the aqueous phase following wastewater treatment. As such, the notified polymers, the degradation products and the poly- or perfluoroalkyl impurities/residual monomers in wastewater have the potential to be released in STP effluent directly to surface waters or reused in the irrigation of agricultural soils throughout Australia.

Over time, the notified polymers are expected to become dissociated from the articles. The notified polymers have the potential to disperse in water but it is not expected to hydrolyse under environmental conditions (pH 4 to 9, 25 °C) based on structural considerations. Investigations of the biodegradation potential of fluoroacrylate polymer and fluorotelomer-based urethane polymer in aerobic soils (Russell *et al.*, 2008; Russell *et al.*, 2010; Washington *et al.*, 2009) indicate very limited degradation of the fluorinated polymers. Biodegradation of the backbone of the notified polymers are expected to occur slowly under environmental conditions due to their high molecular weight. Thus, the notified polymers are considered to be persistent in the soil, sediment and water compartments.

In surface waters, agricultural soils and landfill, the notified polymers are expected to eventually degrade to form water, oxides of carbon and nitrogen and degradation products containing polyfluoroalkyl functionality. The expected initial polyfluoroalkyl degradation products are assumed to undergo further degradation to form, among other compounds, the very persistent perfluorocarboxylic acid, PFHxA. It is noted that some volatile degradation intermediates have the potential to undergo long range atmospheric transport and thus may result in translocation of PFHxA in the environment. The notified polymers also contain low levels of impurities that may degrade to form PFOA and other long-chain perfluorocarboxylic acids.

PFHxA is expected to be recalcitrant in the environment, and potentially undergo long range transport while mainly staying in the water column. In water, it is expected to be very persistent and will not hydrolyse, photolyse or biodegrade.

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

Due to their high molecular weight which limits the ability to cross biological membranes, the notified polymers are not expected to bioaccumulate. The available laboratory (Higgins *et al.*, 2007; Martin *et al.*, 2003ab; Woodcroft *et al.*, 2010) and field (Falandysz *et al.*, 2006; Falandysz *et al.*, 2007, Furdui *et al.*, 2007) evidence indicates that PFHxA is expected to be less bioaccumulative than PFOA and other long chain perfluoroalkyl

compounds, which PFHxA-chemistry is replacing (although PFHxA and PFOA are not considered bioaccumulative). However, both are bioavailable and can be detected in wildlife as demonstrated by monitoring studies (Kumar *et al.*, 2009; Ye *et al.*, 2008ab; Wang *et al.*, 2008). In general, the available evidence indicates that the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy *et al.*, 2010). Therefore, PFHxA has a lower bioaccumulation potential than PFOA and other long chain perfluoroalkyl substances.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) from this process is calculated assuming a worst-case scenario that there is no removal of the notified polymers during STP processes.

Reformulation/repackaging process

It is estimated that less than 2 kg of the notified polymers may be released to the aquatic compartment on a daily basis through the disposal of wastewater generated during its reformulation/repackaging. Using a daily effluent flow rate of 456 ML for a major city, the STP effluent concentration can be calculated to be 4.39 µg/L.

Use processes

It is estimated that about 2 kg of the notified polymers may be released to the aquatic compartment on a daily basis through the disposal of wastewater generated from uses. Using a daily effluent flow rate of 4523 ML national wide, the STP effluent concentration can be calculated to be 0.44 µg/L.

Therefore, the maximum STP effluent concentration can be calculated as 4.83 (4.39 + 0.44) µg/L. The predicted environmental concentration (PEC) for the aquatic compartments is calculated as follows:

Predicted Environmental Concentration (PEC) for release to the aquatic compartment during use

Combined effluent concentration	4.83	µg/L
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River	4.83	µg/L
PEC – Ocean	0.483	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymers in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 4.83 µg/L may potentially result in a soil concentration of approximately 32.2 µg/kg. Assuming accumulation of the notified polymers in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymers in the applied soil in 5 and 10 years may be approximately 161 µg/kg and 322 µg/kg, respectively.

PEC for PFHxA and long chain perfluoroalkyl substances

The notified polymers are assumed to degrade and ultimately form the persistent degradant, PFHxA. However, the yield and rate of conversion of the notified polymers to PFHxA has not been established. Environmental monitoring data shows that PFHxA, and PFOA (which PFHxA-chemistry is replacing) are widely found in the environment, particularly in fresh water close to industrial sources, but also in some biota. Water appears to be the main compartment where PFHxA is found. High measured concentrations of both PFHxA and PFOA in surface waters in Germany have been associated with the legal application of waste materials to agricultural soils (Skutlarek *et al.*, 2006) indicating that these chemicals have the potential to enter the aquatic compartment following initial release into the soil compartment.

Some larger available data sets from the literature (McLachlan *et al.*, 2007; Skutlarek *et al.*, 2006; Nakayama *et al.*, 2007; So *et al.*, 2007; Ahrens *et al.*, 2009) include monitoring from a range of rivers in Europe, the USA and China, along with data from the Atlantic Ocean. Using these data (n ≥ 60), the 10th, 50th and 90th percentile concentrations for PFHxA are 1.0, 6.15 and 22.5 ng/L respectively, while those for PFOA are 2.94, 11.85 and 231.9 ng/L respectively. As use of chemicals that degrade to form PFHxA increases, levels of PFHxA may build up further in the environment.

PFHxA and other poly- and perfluoroalkyl substances have also been found in landfill leachate, with concentrations of PFHxA ranging from 270 – 790 ng/L (Huset *et al.*, 2011). As landfills are reservoirs of solid waste, and receive waste water treatment plant sludge, which may contain poly- and perfluoroalkyl substances, landfills have the potential to continue to release PFHxA and homologues well into the future.

Historically, release of poly- and perfluoroalkyl substances into the environment has been linked to direct releases of low molecular weight poly- and perfluoroalkyl substances, such as poly- and perfluoroalkyl monomers during polymer manufacture and reformulation processes, rather than breakdown of the polymers themselves. In order to limit the extent of direct release of potential PFHxA precursors to the environment, it is recommended that control measures be implemented to minimise the residual weight percentage of unreacted poly- and perfluoroalkyl monomer constituents and impurities in the notified polymers to the extent practicable. Zhao *et al.* (2013) report that fluorotelomer alcohol (FTOH) residual raw material content in FTOH-based polymeric products is generally less than 0.1%. Efforts have also been made globally to control releases of perfluoroalkyl acids, such as PFOA and potential precursors, by reducing the presence of residual poly- and perfluoroalkyl monomers and impurities in polymers. It is recommended that the total weight of residual monomers and impurities in the notified polymers containing polyfluoroalkyl functionality should not exceed the levels attainable utilising international best practice and the levels are further reduced using available technological advances, to the extent practicable.

By reducing the presence of residual poly- and perfluoroalkyl monomers and impurities in polymers, it is expected that indirect releases from the degradation of polyfluoroalkyl substances will become a significant source of persistent poly- and perfluoroalkyl substances in the environment in the future. PFHxA is already being detected in the environment and as the long chain poly- and perfluoroalkyl substances are phased out in preference for short-chain polyfluoroalkyl chemistry containing a six-carbon perfluorohexyl moiety, the environmental levels of PFHxA are expected to increase.

Half-lives of polyfluoroalkyl polymers in aerobic soil have been found to be indeterminate, with calculated half-lives ranging from decades to millennia (Russell *et al.*, 2008; Russell *et al.*, 2010; Washington *et al.*, 2009). The half-lives of PFHxA in various environmental media are also unknown and its partitioning behaviour is uncertain. Therefore, a PEC for indirect releases of PFHxA arising from proposed use and disposal of the notified polymers in Australia cannot be determined.

7.2. Environmental Effects Assessment

Ecotoxicological data for the notified polymer (LTD/1671) is summarised in the table below. A study report for acute toxicity to daphnia was submitted by the notifier. Details of this study can be found in Appendix B. The toxicity to fish and algae on an acute basis, and the toxicity to aquatic organisms on a chronic basis were calculated using the US EPA Interpretive Assistance Structure-Activity Relationship (SAR) for polymers containing cationic components (US EPA 2013). A worst-case approach was taken in calculation of the ecotoxicity.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Measured data for the notified polymers		
Acute Toxicity		
Daphnia Toxicity (48 hour)	EC50 > 120 mg/L	Not harmful
US EPA Interpretive Assistant SAR for the notified polymers		
Acute Toxicity		
Fish Toxicity (96 hour)	LC50 = 202.16 mg/L	Not harmful
Daphnia Toxicity (48 hour)	EC50 = 1087.71 mg/L	Not harmful
Algal Toxicity (96 hour)	EC50 = 170.27 mg/L	Not harmful
Chronic Toxicity		
Fish Toxicity	ChV = 11.23 mg/L	Not harmful
Daphnia Toxicity	ChV = 77.64 mg/L	Not harmful
Algae Toxicity	ChV = 35.56 mg/L	Not harmful

Based on worst-case SAR, the notified polymers are not harmful to aquatic organisms in environmental waters with typical levels of total organic carbon. Notwithstanding that the models have not been fully validated against fluorinated substances, the QSAR estimation procedure used here is a standard approach and is considered reliable to provide general predictions of the likely environmental effects of the polymers.

Effects of PFHxA and long chain perfluorocarboxylic acids

There are only limited available toxicity data for PFHxA to organisms, and these are limited to aquatic organisms. Based on the available literature, the most sensitive trophic level is algae. Latala *et al.*, (2009) reported the 72-hour median effect concentrations (72 h EC50) for three marine species as follows: 1.0 mg/L for blue green algae (*Geitlerinema amphibium*); 1.4 mg/L for diatom (*Skeletonema marinoi*); and, 4.0 mg/L for

green algae (*Chlorella vulgaris*). The data indicates that PFHxA is toxic to algae on an acute basis. The study also investigated the toxicity of PFOA to the three marine species: 0.25 mg/L for blue green algae; 0.37 mg/L for diatom; and, 0.98 mg/L for green algae. The data indicates that PFOA is very toxic to algae on an acute basis and demonstrate decreased toxicity of PFHxA compared with PFOA to three species tested.

Other data indicate that PFOA is not harmful to fish and aquatic invertebrates on an acute basis with median lethal or effect concentrations (L(E)C50) of greater than 100 mg/L (US FDA, 2009). The majority of the available data for the ammonium salt of PFOA (US EPA, 2002) show this substance is largely expected to be not harmful to fish and aquatic invertebrates, although one reported endpoint (fathead minnow 96 h LC50 = 70 mg/L) is below 100 mg/L.

Giesy *et al.* (2010) reported the relationship between increasing carbon chain length and increasing toxicity. Therefore, PFHxA is expected to have a less problematic ecotoxicological profile than PFOA and other long chain perfluorocarboxylic acids it is expected to replace. Long-term effects data that reflect or model the periods over which perfluorocarboxylic acids are present in the environment are not available for PFHxA or long chain perfluorocarboxylic acids. Therefore, the long-term hazard to aquatic organisms has not been adequately established and is unknown.

7.2.1. Predicted No-Effect Concentration

The most sensitive ecotoxicological endpoint for the notified polymers was the calculated chronic value (ChV) for fish. This endpoint was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 50 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

ChV (fish)	11.23 mg/L
Assessment Factor	50
PNEC:	225 µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	4.83	225	0.02
Q - Ocean	0.483	225	0.002

Based on the release from reformulation and use estimated by the notifier, the risk quotients (Q) for river and marine waters are less than 1, indicating the notified polymers will not be present at ecotoxicologically significant concentrations in surface waters. The available data indicate that the notified polymers may not be harmful to aquatic life. As polymers with high molecular weight, they are assumed to persist in the environment but are not expected to bioaccumulate. However, the notified polymers are assumed to eventually degrade to form PFHxA which may be delocalised from points of release.

Perfluoroalkyl substances are expected to be very persistent in the environment (for example, PFOA: $t_{1/2}$ (hydrolysis) > 200 years; US EPA, 2002) but PFHxA is considered to have a low potential for bioaccumulation. There is limited evidence in the published literature of PFHxA toxicity to aquatic organisms on an acute basis, although it is reported to be toxic to marine algae. There is no available data on the long-term aquatic effects of PFHxA 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 PFHxA. However, it is not possible to quantify the long-term risks of PFHxA to the environment due to knowledge gaps both in predicting environmental concentrations from indirect sources of release and the its long-term environmental effects. The latter point is considered a critical data gap as aquatic organisms are expected to have long-term exposure to PFHxA due to its persistence in the water compartment.

PFHxA is already wide-spread in surface waters and biota. Continuing release of PFHxA which has no known breakdown mechanism (at least in soil and water) could 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. In this eventuality, precursors of PFHxA such as the notified

polymers cannot be recalled after release and are a potential source of PFHxA in the environment even long after their use ceases. Thus, use and disposal of the notified polymers increase the environmental risk profile of PFHxA. The notified polymers also contain impurities which are assumed to degrade to form PFHxA and longer chain perfluorocarboxylic acids. Therefore, considering the dispersive use pattern of the notified polymers, it is recommended to reduce the impurities in the notified polymers that breakdown to form PFHxA and longer chain perfluorocarboxylic acids, to the extent possible.

Conclusions

On the basis of the PEC/PNEC ratio and assessed use pattern, the notified polymers themselves are not considered to directly pose an unreasonable short-term risk to the aquatic environment.

However, degradants of the notified polymers, along with associated impurities and residual monomers of the notified polymers, are potential precursors of the very persistent chemical, PFHxA. The assessed use pattern of the notified polymers does not control the release of breakdown products into the environment during use and after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile of the notified polymers and their degradation products is unknown. This situation may change if further data on the environmental behaviour of the notified polymers and their poly- and perfluoroalkylated degradation products (including PFHxA) were to become available.

The assumed major degradation product, PFHxA, is environmentally persistent and has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFHxA is considered to be less problematic when compared with long chain (C8 and above) perfluoroalkyl acids that PFHxA is expected to replace. Nonetheless, the introduction and use of chemicals that degrade to release PFHxA and other very persistent poly- and perfluoroalkyl compounds should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

In order to limit the extent of direct release of potential PFHxA and long chain perfluorocarboxylic acid precursors to the environment, it is recommended that control measures be implemented to minimise the residual weight percentage of unreacted polyfluoroalkyl monomer constituents and impurities in the notified polymers to the extent practicable. Where possible, the total weight of residual monomers and impurities in the notified polymers containing polyfluoroalkyl functionality should not exceed the levels attainable utilising international best practice. It is recommended that the levels remain within this range and are further reduced using available technological advances, to the extent practicable.

RISK ASSESSMENT FOR EXTENSION APPLICATION

There are no changes under the proposed extension to the introduction volume, the use, or the occupational, public and environmental exposure. The extension application is not expected to impact on the original human health and environmental risk assessment and recommendations.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer (LTD/1671, < 25% concentration in water)

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
 Species/Strain Rat/Crl:CD(SD)
 Vehicle Test substance administered as supplied
 Remarks - Method No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	1 female	5,000	0/1
II	2 female	5,000	0/2

LD50 > 5,000 mg/kg bw (test substance, uncorrected for the purity of the notified polymer)

Signs of Toxicity There were no unscheduled deaths during the study. There were no observed adverse clinical signs.

Effects in Organs No adverse macroscopic findings were recorded at necropsy.
 Remarks - Results The body weights increased after dosing.

CONCLUSION The test substance was of low toxicity via the oral route.

TEST FACILITY DuPont (2010a)

A.2. Acute toxicity – inhalation

TEST SUBSTANCE Notified polymer (LTD/1671, < 25% concentration in water)

METHOD Method similar to OECD TG 403 Acute Inhalation Toxicity.
 Species/Strain Rat/Crl:CD(SD)
 Vehicle Test substance administered as supplied.
 Method of Exposure Nose only exposure.
 Exposure Period 4 hours
 Physical Form Liquid aerosol
 Particle Size Mass Median Aerodynamic Diameter = $3.2 \pm 3.3 \mu\text{m}$ and $3.6 \pm 2.8 \mu\text{m}$ for groups 1 and 2, respectively. 83-84% < $10 \mu\text{m}$.
 Remarks - Method No significant protocol deviations. Following exposure, animals had a 14 day recovery period.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration mg/L</i>		<i>Mortality</i>
		<i>Wet weight</i>	<i>Dry weight*</i>	
I	3 per sex	3.2	1.2	0/6
II	3 per sex	5.8	2.0	0/6

*Corresponding to the concentration of notified polymer

LC50 > 2.0 mg notified polymer/L/4 hours

Signs of Toxicity There were no unscheduled deaths during the study. There were no observed adverse clinical signs.

Effects in Organs Two male rats in the high dose group each had a dilated kidney. One of these two rats also had cysts in both kidneys. No effects were seen in any of the other treated animals. The study authors state that “the gross lesions

Remarks - Results

observed occurred in low incidences and were nonspecific changes that are seen spontaneously in rats of this strain and age".
 Minor body weight losses were seen in rats of both sexes in both dose groups. Losses were between 0.03 to 3.4%.
 The study authors considered that the atmospheres generated were respirable to rats.

CONCLUSION

The notified polymer is of low toxicity via inhalation.

TEST FACILITY

DuPont (2011a)

A.3. Acute toxicity – inhalation

TEST SUBSTANCE

Notified polymer (LTD/1671, < 25% concentration in water)

METHOD

Species/Strain

OECD TG 403 Acute Inhalation Toxicity.

Vehicle

Rat/Wistar (CrI:WI[WU], outbred)

Method of Exposure

Water

Exposure Period

Nose-only exposure.

Physical Form

4 hours

Particle Size

Liquid aerosol

$3.4 \pm 2.3 \mu\text{m}$ and $3.9 \pm 1.9 \mu\text{m}$ (low concentration) and $3.9 \pm 2.0 \mu\text{m}$ and $4.1 \pm 2.1 \mu\text{m}$ (high concentration) mass median aerodynamic diameter

Remarks - Method

No significant protocol deviations

In each group, 6 animals (3 per sex) were sacrificed after dosing and an equal number after a 14 day recovery period.

RESULTS

Group	Number and Sex of Animals	Concentration mg/L		Mortality
		Nominal	Actual*	
I	6 per sex	0	0	0/12
II	6 per sex	0.98	0.12	0/12
III	6 per sex	11.2	0.97	0/12

*Corresponding to the concentration of notified polymer

LC50

> 0.97 mg notified polymer/L/4 hours

Signs of Toxicity

There were no unscheduled deaths during the study. There were no observed adverse clinical signs.

Effects in Organs

There was a statistically significant increase in the weight of the lungs relative to body weight in male animals in the high dose group necropsied on day 1. A statistically significant increase in the lung weights relative to the body weights was not seen in any other animals. There were no other effects in the organs noted in the test animals.

Remarks - Results

There were no statistically significant differences in bodyweights between the groups.

CONCLUSION

The notified polymer is of low toxicity via inhalation.

TEST FACILITY

TNO (2011)

A.4. Irritation – skin

TEST SUBSTANCE

Notified polymer (LTD/1671, < 25% concentration in water)

METHOD

Species/Strain

OECD TG 404 Acute Dermal Irritation/Corrosion.

Number of Animals

Rabbit/New Zealand White

Vehicle

3 male

Test substance administered as supplied

Observation Period 72 hours
 Type of Dressing Semi-occlusive.
 Remarks - Method No significant protocol deviations

RESULTS

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

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

Remarks - Results Very slight erythema was noted in one treated animal immediately after patch removal and at the 30-60 minute scoring interval, and had cleared by the 24 hour observation. No signs of irritation were noted in the other animals.

There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.

CONCLUSION

The test substance was slightly irritating to the skin.

TEST FACILITY

DuPont (2010b)

A.5. Irritation – eye

TEST SUBSTANCE

Notified polymer (LTD/1671, < 25% concentration in water)

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion.
 Species/Strain Rabbit/New Zealand White
 Number of Animals 3 female
 Observation Period 72 hours
 Remarks - Method No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0	0	0.3	1	< 48 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	-	0
<i>Conjunctiva: discharge</i>	0	0	0	2	< 24 hours	0
<i>Corneal opacity</i>	0	0	0	0	-	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks - Results A single application of 0.1 mL of the test material to the non-irrigated eye of three rabbits produced conjunctival irritation in all animals. Two treated eyes appeared normal at the 24 hour observation, with the remaining eye showing no signs of irritation at the 48 hour observation. There were no effects from the test substance on the cornea or iris. There were no signs of systemic toxicity and bodyweight gains were within the normal range.

CONCLUSION

The test substance was slightly irritating to the eye.

TEST FACILITY

DuPont (2010c)

A.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer (LTD/1671, < 25% concentration in water)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
 Species/Strain Mouse/CBA/JHsd
 Vehicle Dimethyl sulfoxide
 Remarks - Method No significant protocol deviations.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	897.5	-
5	749.7	0.84
25	1076.5	1.20
50	1068.3	1.19
100	768.1	0.86
<i>Positive Control (hexylcinnamaldehyde)</i>		
25	6627.1	7.38

Remarks - Results There were no treatment related clinical signs of toxicity or statistically significant changes in body weights. The stimulation index was similar in treated and control groups and was below the threshold for a positive response (< 3).

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.

TEST FACILITY DuPont (2010d)

A.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer (LTD/1671, < 25% concentration in water)

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: WP2uvrA
 Metabolic Activation System Rat S9 fraction from Aroclor 1254 induced rat liver
 Concentration Range in Main Test a) With metabolic activation: 50 – 5,000 µg/plate
 b) Without metabolic activation: 50 – 5,000 µg/plate
 Vehicle Water
 Remarks - Method In the main assay the positive control value for TA100 was too low and subsequently this strain was retested.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	> 5,000	> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative
<i>Present</i>				
Test 1	> 5,000	> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative

Remarks - Results	The positive controls performed as expected. No significant increase in revertants was seen in any strain, in the presence and absence of metabolic activation.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	DuPont (2010e)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer (LTD/1671, < 25% concentration in water)
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test - static. American Society for Testing and Materials (ASTM) (1988) Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. E 729-88a. Annual Book of ASTM Standards, Vol. 11.04.
Species	<i>Daphnia magna</i> (less than 24 hours old)
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	100-140 mg/L as CaCO ₃
Analytical Monitoring	No analysis of the test concentration has been reported.
Remarks - Method	<p>This is a screening test conducted according to the guideline above. No information about the good laboratory practice (GLP) principles was provided. Only one test vessel using 10 animals was established for each test level. No other significant deviations from the test guideline OECD TG 202 were reported.</p> <p>One test chamber was used per test concentration with 10 test organisms in each chamber. Based on visual observations, the dilution water control and 0.6, 6.0, 60, and 600 mg/L test concentrations (or 0.12, 1.2, 12, and 120 mg notified polymers/L) were clear and colourless with no visible precipitate at test start.</p>

RESULTS

<i>Concentration mg/L Nominal</i>	<i>Number of D. magna</i>	<i>Number Immobilised 48 h</i>
0 (control)	10	0
0.12	10	0
1.2	10	0
12	10	0
120	10	0

LC50	> 120 mg/L at 48 hours (nominal)
NOEC	120 mg/L at 48 hours (nominal)
Remarks - Results	Only 10 animals were used for each test level. However, this is considered acceptable considering no effects were observed. Also the test concentration was not analysed for the notified polymers, which is acceptable considering the notified polymer is expected to be stable and dispersible in water under the test conditions.

CONCLUSION The notified polymers are not harmful to aquatic invertebrates

TEST FACILITY DuPont (2010f)

APPENDIX C: TOXICOLOGY OF PERFLUOROHEXANOIC ACID (PFHxA)

The following conclusions can be drawn from the data on PFHxA to assess health effects:

1. Absorption of PFHxA in mice and rats was rapid, with C_{max} achieved within 1 hour. Systemic exposure (AUC) was higher in males than in females in both mice and rats, probably as a result of the more rapid clearance in females than in males. Low levels of PFHxA were found in various rat tissues; these decreased rapidly and could not be detected in most tissues by 24 hours. Excretion of unchanged PFHxA was rapid and was largely via the urine. Most of the PFHxA was excreted via the urine within 24 hours, indicating almost 100% bioavailability. There was no evidence of bioaccumulation following repeat exposure in rats. Similar kinetics were observed in monkeys, with rapid absorption, similar exposure for males and females, and rapid and comprehensive urinary excretion of unchanged PFHxA. The volume of distribution in rats and monkeys indicates distribution mainly to extracellular fluid. The serum half-lives were 2.4/5.3 hours (male/female) in monkeys and 1/0.42 hours (male/female) in rats (Chengelis, 2009a; Gannon, 2011).
2. In a study comparing the toxicokinetics of PFHxA to PFOA following repeated oral exposure for 10 days, results indicate that the AUC was 9 times lower for PFHxA, which is attributed to the more rapid excretion of PFHxA. The half-life for PFHxA was 3 times lower than PFOA and persistence in the liver was much lower for PFHxA than PFOA (DuPont, 2003).
3. During seasonal use of ski wax, PFHxA levels in the blood of workers increased during the ski season, then decreased to below the detection limit following cessation of exposure. PFOA levels in blood were also monitored and were found at mostly stable concentrations before, during and after the ski season (elevated compared to the general population). These data suggest that clearance of PFHxA from blood occurs soon after cessation of exposure (Nilsson, 2010).
4. The acute toxicity of PFHxA was low, with an LD_{50} value of > 1750 mg/kg bw and < 5000 mg/kg bw in female rats. Males are expected to be more sensitive to PFHxA based on higher exposure (AUC) and an expected lower LD_{50} for males (Loveless, 2009). No information was available to assess acute dermal toxicity or acute inhalation toxicity.
5. In repeat dose oral toxicity studies in rats (14 days, 90 days), there was evidence of effects on the liver and decreased haematological parameters at 500 mg/kg bw/day, with liver effects in males at 100 mg/kg bw/day. Nasal lesions (degeneration and atrophy of the olfactory epithelium) were observed at 100 mg/kg bw/day and above in the 90-day study and the NOAEL was 20 mg/kg bw/day in both sexes (DuPont, 2006c; DuPont, 2007a, Chengelis, 2009b).
6. In a 2-year chronic toxicity/carcinogenicity study in rats, there were treatment-related systemic effects (increased incidence of struggling, and papillary necrosis and tubular degeneration of the kidneys) at 100/200 mg/kg bw/day (male/female). The NOAEL for non-neoplastic effects was 15/30 mg/kg bw/day (male/female). There was no evidence of carcinogenicity in either male or female rats (AGC Chemicals, 2010).
7. NaPFHx showed no effect on fertility parameters in a one-generation reproduction study in rats. The NOAEL for maternal systemic toxicity in the P1 animals was 100 mg/kg bw/day based on excessive body weight gain during lactation. There were no biologically significant adverse effects on pups (DuPont, 2007a).
8. In a developmental toxicity study with NaPFHx in rats, there was evidence of maternal (reduced body weight and body weight gain) and foetal toxicity (reduced neonatal bodyweight) at 500 mg/kg bw/day (DuPont, 2007b). In a second developmental toxicity study in mice with ammonium PFHx, foetal toxicity (increased incidence of still births, perinatal death, and microphthalmia and corneal opacity) was noted at 175 mg/kg bw/day in the absence of maternal toxicity. There was no toxicity in pups post-weaning. The NOAEL was 35 mg/kg bw/day (Daikin Industries, 2011).
9. No evidence of genotoxicity was observed in an *in vitro* mutagenicity assay in bacteria (DuPont, 2006a) or in a test for chromosome aberrations in human peripheral blood lymphocytes (DuPont 2006b).

The toxicology of PFOA has been characterised previously (Environment Canada, 2012; Chemical Safety Report, 2009). Comparative analysis of the toxicokinetics of PFHxA and PFOA indicated the following:

- Bioavailability of PFHxA and PFOA after oral administration was high.

- In repeat oral exposure studies, PFHxA showed no evidence of bioaccumulation, whereas PFOA showed some evidence of bioaccumulation.
- Excretion of PFHxA via the urine was rapid and virtually complete over 24 hours, whereas excretion of PFOA was slower, with only 20% excreted over 24 hours.
- Half-lives of excretion of PFHxA after oral exposure were 2–3 hours, whereas the excretion half-life of PFOA was 4.8 days.

Comparative analysis of the toxicity of PFHxA and PFOA indicated the following:

- The acute toxicities of PFHxA and PFOA were low.
- No data were available to compare eye and skin irritation or sensitisation.
- In 90-day repeat dose studies in rats, for PFOA, effects were observed at 0.64 mg/kg bw/day (LOAEL), while for PFHxA, no effects were observed at 10 mg/kg bw/day with a LOAEL of 100 mg/kg bw/day.
- In chronic toxicity studies in rats, for PFOA, effects were observed at 14.2/16.1 (m/f) mg/kg bw/day (LOAEL), while for PFHxA, no effects were observed at 15/30 (m/f) mg/kg bw/day with a LOAEL of 100/200 (m/f) mg/kg bw/day.
- Reproduction studies with PFHxA produced no effect on reproductive parameters with a NOAEL of 500 mg/kg bw/day, whereas PFOA produced increased mortality, decreased bodyweight and delayed sexual maturity in the F1 generation with a NOAEL of 10 mg/kg bw/day in females.
- The LOAEL was 175 mg/kg bw/day for developmental effects in a rat study with ammonium PFHx. The NOEL for developmental effects for PFOA was 150 mg/kg bw/day in a rat study.
- There was no evidence of genotoxicity for PFHxA or PFOA.

A carcinogenicity study in rats with PFHxA produced no evidence of a treatment-related increase in tumours, whereas a study in rats with PFOA produced an increased tumour incidence in males. The US EPA considers PFOA to be “likely to be carcinogenic to humans” (US EPA, 2012).

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