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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polyfluorinated Side-Chain Polymer ELN101570-7 in Capstone® LPA and Capstone® ST-200

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:

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Director
NICNAS

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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
LTD/1493	The Chemours Company (Australia) Pty Ltd IMCD Australia Limited California Sport Surfaces Pty. Ltd Laticrete Pty Ltd	Polyfluorinated Side-Chain Polymer ELN101570-7 in Capstone® LPA and Capstone® ST-200	Yes	≤ 10 tonnes per annum	Component of leather and textile treatments and stone and tile products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute toxicity (Category 2)	H330 – Fatal if inhaled

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

However, the notified polymer is a potential precursor 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 polymer, secondary human exposure to PFHxA via the environment may occur. The notified polymer is replacing a long-chain polyfluoroalkyl polymer, which will 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 polymer is less than that of the substance it replaces.

Environmental risk assessment
On the basis of the PEC/PNEC and 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 potential precursors of the very persistent chemical, PFHxA. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment during use and after disposal and there are no adequate long-term environmental effects data for PFHxA. Therefore, the long-term environmental implications are unknown. Consequently, the long-term risk cannot be quantified for the notified polymer and its degradation products. In order to inform a more conclusive assessment of long-term environmental risks further data should be generated. This may include data on longer-term environmental

effects, as well as partitioning behaviour and characterisation of the degradation products, for the notified polymer and/or poly- and perfluoroalkyl degradation products (including PFHxA).

The notified polymer is a potential precursor 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 is 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

- The notified polymer should be classified as follows:
  - Acute toxicity (Category 2): H330 – Fatal if inhaled

  * Classification of products/mixtures containing the notified polymer should be considered based on the concentration of the notified polymer present.

- Aerosol or spray products containing the notified polymer should carry the following safety directions on the label:
  - Avoid breathing of vapours, mists and sprays
  - May be harmful if inhaled
  - 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 polymer should include the following statements or equivalent phrases:
  - Avoid breathing of vapours, mists and sprays
  - May be toxic if inhaled
  - 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 polymer:
  - 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 polymer 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 polymer 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.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer 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 only be introduced as part of a strategy to phase out the use of long chain polyfluoroalkyl chemicals.

- The notifier should seek ways to minimise the level of residual polyfluoroalkyl 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.

- The following control measures should be implemented by users of the notified polymer, or products containing the notified polymer, to minimise exposure of the notified polymer to the environment:
  - Best practice on-site treatment of waste streams should be employed to maximise removal of the notified polymer from wastewaters.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified polymer 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 10 tonnes per annum notified polymer;
  - the polymer has a number-average molecular weight of less than 1000;
  - the use changes from a component of leather and textile treatments, or stone and tile sealants;
  - the notified polymer is intended for use in spray products at > 1.2% concentration outside of automated facilities;
  - further information on the repeated 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 perfluorohexanoic acid);
- additional information has become available to the person as to the environmental fate of the polymer or its polyfluoroalkyl degradation products (such as perfluorohexanoic 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 from a component of leather and textile treatments, and stone and tile sealants, or is likely to change significantly;
- the amount of polymer being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia; or
- additional information has become available to the person as to an adverse effect of the polymer 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 polymer is listed on the Australian Inventory of Chemical Substances (AICS) the 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 the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the 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 polymer 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 polymer were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
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

California Sport Surfaces Pty Ltd (ABN 53 164 522 338)
Unit 4, 149 Pascoe Vale Road
MOONEE PONDS VIC 3039

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, molecular and structural formulae, molecular weight, 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.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2009)
Canada (2013)
China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ELN101570-7
Capstone® LPA (leather and textile treatment, up to 40% notified polymer)
Capstone® ST-200 (stone and tile sealant, up to 40% notified polymer)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference FTIR was provided.

3. COMPOSITION

The notified polymer contains a polyfluoroalkyl carbon side chain with six perfluorinated carbon atoms.

DEGREE OF PURITY > 90%

DEGRADATION PRODUCTS
The notified polymer is a potential precursor 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 ºC AND 101.3 kPa: light yellow liquid (product containing notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	314-319 °C	Measured using DSC.
Boiling Point	Not determined	Expected to decompose prior to boiling.
Density	1150 kg/m^3 at 20 °C	Measured for neat notified polymer.
Vapour Pressure	Not determined	Expected to be low based on high molecular weight.
Water Solubility	0 g/L at 20 °C	Measured. Expected to be low based on the high molecular weight and hydro/lipophobicity of the polymer.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, hydrolysis is expected to occur very slowly under environmental conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	Not determined	On the basis of its hydro/lipophobic tendencies, the notified polymer is expected to partition between the octanol and water phases.
Adsorption/Desorption	Not determined	Generally, non-ionic polymers of high molecular weight are expected to adsorb to soil, sediments and sludge. However, the notified polymer may have low absorption based on the presence of perfluoroalkyl functionalities that have hydro/lipophobic tendencies.
Dissociation Constant	Not determined	Not expected to dissociate based on lack of dissociable functionality.
Flash Point	Not determined	Expected to be high based on the partial fluorination and the low vapour pressure.
Flammability	Not determined	Not expected to be flammable based on the partial fluorination.
Autoignition Temperature	Not determined	Expected to decompose prior to any autoignition.
Explosive Properties	Not expected to be explosive	Contains no explosophores.
Oxidising Properties	Not expected to be oxidising	Estimated based on structure.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified polymer is 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 polymer is 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 polymer will not be manufactured in Australia. It will be imported into Australia at concentrations up to 40% in the products Capstone® LPA (leather and textile treatment) and Capstone® ST-200 (stone and tile sealant).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Sydney, Melbourne and Brisbane.

TRANSPORTATION AND PACKAGING
The products containing the notified polymer (up to 40% concentration) will be imported by sea in 40 kg or 900 kg drums and transported within Australia by road.

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

Leather and textile treatment
The notified polymer will be used as a water, oil and soil repellent for the treatment of leather and textile products such as clothing, footwear and furniture. It will be used for application by professionals (up to 3% concentration) both before and after the leather and textiles are sold to consumers. Products containing the notified polymer (up to 2% concentration) will also be available to consumers for the treatment of leather and textiles. When incorporated in spray products the final concentration will be ≤ 1.2%.

Stone and tile sealants
The notified polymer will be used in stone and tile sealants for application by professionals (up to 3% concentration) both before and after the stone and tiles are sold to consumers and also for use by consumers (up to 2% concentration). Stone and tile sealant products that will be applied by spray will contain the notified chemical at concentration of ≤ 1.2%.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. The notified polymer will be imported at up to 40% concentration.

Reformulation
The notified polymer (up to 40% concentration) will be reformulated into finished leather and textile treatment products and stone and tile sealants (up to 3% for professionals and up to 2% for consumers). The notified polymer (up to 40% concentration) will be pumped into a tank and mixed with other ingredients. The final products (up to 3% concentration) will then be packaged into suitable containers.

Leather and textile treatment
The notified polymer (up to 40% concentration) will be diluted (up to 3% concentration) and applied by professionals in factories and leather tanning facilities to leather products by low pressure spray, brush or foam swab. Professionals and consumers will also apply products containing the notified polymer (up to 3% for professionals and up to 2% for consumers) to existing leather and textile articles by brush or foam swab. Leather and textile treatment products containing the notified chemical at ≤ 1.2% may also be applied by aerosol spray or low pressure spray.

Stone and tile treatment
Application of stone and tile sealant products containing the notified chemical (up to 3% concentration) may

occur prior to the stone and tile being sold to consumers. Professionals and consumers will also apply stone and tile sealant products containing the notified polymer (up to 3% for professionals and up to 2% for consumers) to existing masonry stone and grout and tile articles by brush or foam swab. Stone and tile treatment products containing the notified chemical at concentrations ≤ 1.2% may also be applied by aerosol spray or low pressure spray.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

The notified polymer may undergo slow degradation in the environment. As such, most potential exposure to workers and the public is expected to be to the notified polymer itself, rather than to its degradation products. Exposure to the residual polyfluoroalkyl starting constituents and/or impurities of the notified polymer (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 polymer in the imported products or in end-use products.

The notified polymer is a potential precursor for perfluorohexanoic acid in the environment. This is likely to lead to secondary human exposure to PFHxA. This exposure is unquantifiable.

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and storage workers

Transport and storage workers will only come into contact with the notified polymer (up to 40% concentration) in the unlikely event of an accident.

Reformulation processes

Dermal and ocular exposure of workers to the notified polymer (up to 40% concentration) may occur 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 polymer 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.

Leather and textile treatment and stone and tile application

Dermal and ocular exposure to the notified polymer (up to 3% concentration) may occur when workers are applying products during pre- and post-market leather and textile treatment and stone and tile use by brush or foam swab, with some potential for inhalation exposure (at ≤ 1.2% concentration) when applying by spray (aerosol or low pressure spraying methods). PPE is expected to be worn, including gloves, safety glasses and respiratory protection when aerosols may be present. Professionals may be exposed on a repeated basis.

6.1.2. Public Exposure

Public exposure to the notified polymer (up to 2% concentration) may occur when leather and textile treatments and stone and tile products are used. Dermal, ocular and inhalation exposure may occur. Consumer exposure is expected to be acute in nature because repeated daily uses are considered unlikely. Exposure is expected to be short-term (i.e., duration of up to 15 minutes). Products may be applied using aerosol cans and the highest exposures will occur when products are sprayed in enclosed settings such as bathrooms. Aerosols of the notified polymer are expected to generate relatively large droplet sizes, given that the target is intended to be well-coated.

The concentration of a polyfluorinated analogue in the air was measured following spraying from aerosol cans at a concentration of 0.9%. The situation was considered a very conservative scenario as up to three cans were used in a short time frame, in a small volume 8 m^3, with the area sealed off so there was no air exchange (DuPont, 2007a). The study determined that concentrations in breathing zone 66" off the floor were from 0.60 – 1.8 mg/m^3. Factoring in concentration differences and the exposure time gives an adjusted value of 0.16 – 0.48 mg/m^3.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B. The toxicology studies were conducted on a formulation containing the notified polymer at up to 40% concentration, with the exception of one acute inhalation study where the notified polymer was tested at up to 1% concentration.

Endpoint	*Result and assessment conclusion*
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; no deaths (equivalent to LD50 > ~2000 mg notified polymer/kg bw)
Rat, acute inhalation toxicity*	LC50 > 20,500 mg/m^3/4 hours; no deaths (equivalent to LC50 > 223 mg notified polymer/m^3/4 hours) LOAEC (histopathology) > 223 mg notified polymer/m^3/4 hours
Rat, acute inhalation toxicity	LC50 ~2,100 mg/m^3/4 hours; 2/5 deaths (equivalent to LC50 290 mg notified polymer/m^3/4 hours) NOEC(death)=71 mg notified polymer/m^3/4 hours NOAEC(histopathology)= 25 mg notified polymer/m^3/4 hours
Rat, acute inhalation toxicity	LC50 >3,100 mg/m^3/4 hour; no deaths (equivalent to LC50 > 70 mg notified polymer/m^3/4 hours)
Rat, acute inhalation toxicity	LC50 > 5,200 mg/m^3/4 hours; no deaths (equivalent to LC50 > 110 mg notified polymer/m^3/4 hours) NOAEC(histopathology) > 15 mg notified polymer/m^3/4 hours
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non-mutagenic

*Test substance contains notified polymer at up to 1% concentration.

Toxicokinetics, metabolism and distribution
The notified polymer is not expected to cross biological membranes (skin or gastrointestinal tract) based on its high molecular weight (> 10,000 Da), the low proportion (< 1%) of low molecular weight species (< 500 Da), and its expected low water solubility. This is supported by the lack of observed systemic toxicity in the acute toxicity studies with the notified polymer. Some accumulation in the respiratory tract may occur from respirable particles (< 10 μm), if present. Alternatively, larger inhalable particles (< 100 μm), if present, are likely to deposit in the nasopharyngeal region and will be coughed or sneezed out of the body or swallowed. Ingestion after swallowing dust or fibres to which the notified polymer is attached is not expected to lead to significant absorption from the GI tract due to the high molecular weight of the notified polymer and its stability to hydrolysis.

Acute toxicity
The notified polymer (up to 40% concentration) 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.

Four acute inhalation studies were conducted with different variants of the notified polymer. In one study, the LC50 for the notified polymer was found to be 290 mg/m^3/4 hours based on 2/5 mortalities at this exposure concentration. Based on this study, the notified polymer is fatal/toxic by the inhalation route. Three of the acute inhalation studies exposed rats to lower concentrations of the notified polymer to explore potential histopathological effects in the lungs and respiratory tract. In one of the studies, no deaths but histopathological effects were observed at the alveolar level and included inflammation, macrophage infiltrates, presence of alveolar blood, perivascular oedema, and perivascular and alveolar mononuclear and mixed inflammatory cell infiltrates. These effects were observed at 223 mg notified polymer/m^3/4 hours and indicate a histopathological LOAEC. Increased breathing frequency, decreased tidal volumes were also observed in rats exposed to 223 mg notified polymer/m^3/4 hour. A histopathological NOAEC for the notified polymer was established at 25 mg/m^3/4 hours (based on consideration of the results from the four studies). This concentration is considered to be

protective of mortality and histopathological respiratory effects in rats and is therefore relevant for the acute inhalation risk assessment of the notified polymer.

No repeated dose inhalation studies with the notified polymer have been submitted and significant uncertainties remain surrounding possible respiratory effects (lung injury and overloading) following repeated exposures to the notified polymer. A safe level for repeated inhalation exposures therefore cannot be determined.

Irritation and sensitisation
The notified polymer (up to 40% concentration) was not a skin irritant in rabbits but was found to be a slight eye irritant in rabbits. The notified polymer (up to 40% concentration) was not a skin sensitiser in an LLNA study.

Mutagenicity/Genotoxicity
The notified polymer (up to 40% concentration) was negative in a bacterial mutation assay.

Health hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute toxicity (Category 2)	H330 – Fatal if inhaled

Toxicology of break down products
The notified polymer contains 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 polymer that is proposed for replacement by the notified polymer is expected to break down to perfluorooctanoic acid (PFOA; CAS No. 335-67-1) (consisting of 7 perfluorinated carbons) and other per- and polyfluorocarboxylic chemicals with longer perfluoroalkyl carbon chain lengths. The toxicokinetic and toxicological properties of the long chain break down products are generally less favourable compared to the short chain break down 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 D for details). It is therefore inferred that the human health hazards associated with the expected break down product of the notified polymer (PFHxA) are likely to be similar or less than the human health hazards associated with the expected break down 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 polymer.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is fatal/toxic by inhalation, with all other toxicology studies indicating low hazard. The notified polymer as imported (up to 40% concentration) is toxic by the inhalation route, however, inhalation toxicity is not of concern during reformulation as aerosols will not be generated. Slight eye irritation may occur during reformulation but automated processes are expected to be in place and PPE (clothing, gloves and goggles) will be worn during reformulation, which will further minimise exposure. The risk to reformulation workers from handling of the notified polymer is therefore not considered to be unreasonable.

Repeated dermal exposure of workers to the notified polymer may occur during leather and textile treatment and stone and tile application. The repeated dermal toxicity of the notified polymer has not been investigated. In general, systemic exposure to the notified polymer is expected to be low based on the high molecular weight (> 10,000 Da) of the notified polymer and the low proportion (< 2%) of low molecular weight species < 1000 Da. Systemic exposure of workers to break down products (e.g., PFHxA) is not expected based on the stability of the notified polymer. Worker exposure to impurities of the notified polymer is not expected to be significant, given the relatively low levels present. In addition, the use of engineering controls and PPE are expected to further lower exposure to the notified polymer, its 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 polymer 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 overloading. This is of particular concern for workers who may use products containing the notified polymer every day. Based on the uncertainties surrounding repeated inhalation exposure to the notified polymer, measures should be taken to minimise exposure. The risk of inhalation toxicity resulting from repeated exposure to the notified polymer is not considered to be unacceptable provided that users minimise inhalation of the notified polymer.

The risk to professionals of acute inhalation toxicity from the notified polymer 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 starting constituents and/or impurities of the notified polymer at relatively low concentrations during reformulation and end use operations. 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

Leather and textile treatments and stone and tile products containing the notified polymer (up to 2% concentration) will be applied by brush or foam swab. Products containing the notified chemical at concentrations ≤ 1.2% may also be applied by aerosol spray or low pressure spray. Public exposure will be less frequent than that experienced by professional users, and hence the lack of repeated dose inhalation data for the notified polymer is of less concern based on the expected infrequent use of the products. The acute inhalation exposure following spraying from aerosol cans can be estimated, based on data from a polyfluorinated analogue, to be 0.16 – 0.48 mg/m^3. Using the NOAEC (histopathology) from an acute inhalation study in rats which was 25 mg/m^3/4 hours would give a margin of exposure (MoE) of 156 – 52. At the lower end of 52 this MoE would be unacceptable. However, the smaller exposure concentration value (0.16 mg/m^3) and corresponding higher MoE of 156 represents the more realistic but still conservative use of a whole spray can on a small surface area, whereas the higher exposure concentration was for the use of three cans over the same time length. Additionally the exposure was measured in a small volume of air with no air exchange and does not factor in the potential use of PPE. The risk to public health from use of the notified polymer in sprays (up to 1.2% concentration) is not considered to be unreasonable, based on the infrequent and short-term exposure. Additionally, the risk to public health from exposures to perfluoroalkyl impurities is not considered to be unreasonable based on their relatively low concentration (< 0.01%) in end-use products.

The public may also be exposed to the notified polymer and low levels of perfluoroalkyl impurities from direct dermal contact with treated articles (after drying onto the article), such as leather and textile products and stones and tiles. This exposure may be on a long term repeated basis. However, based on the high molecular weight of the notified polymer (> 10,000 Da) and the low proportion of low molecular weight species, dermal absorption of the notified polymer is unlikely to occur. Thus the risk to public health from repeated dermal exposure to the notified polymer from treated articles is not considered to be unreasonable. The risk to public health from long term repeated dermal exposure to perfluoroalkyl impurities of the notified polymer from treated articles may be mitigated by the relatively low concentrations at which they are present.

The public may be exposed indirectly to PFHxA, formed by degradation of the notified polymer 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 break down products of the majority of perfluoroalkyl polymers currently in Australian commerce (such as PFOA). In particular, it is noted that the polymer being replaced contains 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 polymer, on the basis that the notified polymer is intended to replace a currently available “long” chain perfluoroalkyl polymer.

It should also be 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.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Therefore, releases to the environment are not expected from this activity. Releases to the environment may occur following accidental spills during import, transport or storage. Any notified polymer that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

The notified polymer is expected to be imported in products for further reformulation at sites across Australia. The notified polymer may enter the wastewater stream during reformulation as a result of rinsing empty import containers, mixing equipment, transfer lines and the filling machine. The notifier estimates that release of the notified polymer is up to 2.2% of the total import volume for both stone and tile and leather treatment reformulation. Therefore, up to 220 kg of the notified polymer is potentially released to sewer every year from reformulation after wastewater treatment on a nationwide basis.

Notified polymer residues remaining in empty import containers are expected to be minimal as containers will be rinsed prior to disposal, with rinsings expected to be added to the reformulated product. Residues in import containers may be thermally decomposed during metals reclamation of metal containers or enter the wastewater streams following plastic container recycling. Alternatively, empty containers with residues of the notified polymer may be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

When used in stone and tile treatments, the notified polymer may enter wastewater as residues in application equipment washings or rinsings from empty product containers. Wastewater containing the notified polymer that is generated by professional and consumer users may be disposed of to sewers. The notified polymer may also enter sewers from the disposal of water in spray booths when products containing the notified polymer are applied by spray by industrial users, such as original equipment manufacturers.

Limited release of the notified polymer to sewer is expected during its use in leather treatments. Leather treatments will be applied by spray, brush or foam swab in industrial and domestic settings.

It is expected that both uses will generate solid wastes containing the notified polymer. These include residues on rags used to wipe drips, on old applicators (brush, roller, mop heads) and in empty product containers for stone and tile and leather treatments. Solid wastes generated during use are expected to be disposed of in accordance with local regulations, most likely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer applied to treated stone and tile surfaces and leather is expected to adhere to the surface to which it has been applied. However, abrasion of floor surfaces by foot traffic and abrasion of treated leather articles, such as shoes, is expected to result in some loss of the notified polymer. Estimates for losses due to abrasion from these uses are not available. The notified polymer that remains associated with stone, tile and leather is expected to share the fate of these articles. The majority of articles are expected to ultimately be disposed of to landfill.

The notified polymer applied to surfaces may also degrade as a result of weathering upon being exposed to environmental conditions after use and after disposal. Degradation may result in the widespread release of degradation products such as PFHxA to surface waters, landfill and landfill leachates, soils, and other regions where release is not foreseen.

7.1.2. Environmental Fate

For details of the environmental fate studies please refer to Appendix C.

The majority of the notified polymer is expected to adhere to the surface to which it is applied. Treated articles and other dried residues containing the notified polymer are expected to ultimately be disposed of to landfill. When associated with the article to which the notified polymer has been applied, the notified polymer is not

likely to be mobile or bioavailable in landfill.

Some of the notified polymer may be released to sewer during reformulation, use and disposal. Non-ionic polymers with a molecular weight of more than 1000 Da are generally considered to be efficiently removed in sewage treatment plant (STP) processes through adsorption to sludge. 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 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 its potential of being both hydrophobic and lipophobic, the notified polymer, 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 polymer, its 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 polymer is expected to become dissociated from the articles. The product containing the notified polymer has the potential to disperse in water but the notified polymer is not expected to hydrolyse under environmental conditions (pH 4 to 9, 25 ºC) based on structural considerations. A test study indicates that a close analogue of the notified polymer in 75% solvent is not readily biodegradable, achieving 15% degradation in 28 days. The observed degradation is also likely to be contributed to by the high portion of solvent in the test substance. Degradation products are not known for certain as characterisation of the degradation products was not undertaken in the biodegradation test. The notified polymer is expected to have similar primary degradation pathways as standard hydrocarbon based polymers. However, biodegradation of the backbone of the notified polymer is expected to occur slowly under environmental conditions due to its high molecular weight. The notified polymer is a potential precursor for PFHxA in the environment.

In surface waters, agricultural soils and landfill, the notified polymer is expected to eventually degrade to form water, oxides of carbon and nitrogen and degradation products containing polyfluoroalkyl functionality. The expected initial perfluoroalkyl 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 polymer also contains 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 perfluoralkyl functionality to oxides of carbon and hydrofluoric acid. Incomplete combustion of perfluoralkyl 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.

Due to its high molecular weight which limits the ability to cross biological membranes, the notified polymer is 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 (though 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 aquatic biota, there is little evidence of increased bioconcentration of PFOA compared with PFHxA although PFOA may generally be expected to be found in aquatic organisms more often than PFHxA. 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 notified polymer may be released to the aquatic compartment through the disposal of wastewater generated during its reformulation, use and disposal. Under a worst-case scenario, it is assumed that there is no removal of the notified polymer during STP processes.

The predicted environmental concentration (PEC) due to releases from reformulation of stone and tile treatments and leather treatments is calculated assuming a worst-case release from reformulation to an STP with a daily effluent flow rate of 456 ML in a single major city. For this scenario, the notifier's estimate of up to 2.2% of the total import volume of the notified polymer released during reformulation over an average of 80 working days per year is used. The concentration of the notified polymer in STP effluent from point-source releases is estimated as follows:

Predicted Environmental Concentration (PEC) for release to the aquatic compartment during reformulation		
Total Annual Import Volume	10,000	kg/year
Proportion expected to be released to sewer	2.2%	
Annual quantity of chemical released to sewer	220	kg/year
Days per year where release occurs	80	days/year
Daily chemical release:	2.75	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Removal within STP	0%	
Effluent concentration	6.03	µg/L

The PEC due to releases from use in stone and tile treatments is calculated assuming nationwide release over a conservative 260 working days per year. Under a worst-case scenario, it is estimated that 5% of the notified polymer used in stone and tile treatments will be released to sewer during use. For this scenario, it will be assumed that the entire import volume will be used in stone and tile treatments. The resulting concentration in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import Volume	10,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Effluent concentration	0.43	µg/L

Based on the above calculations, the worst-case concentration for the notified polymer in effluent due to the combined releases to STP from reformulation and use is 6.46 µg/L. Therefore, the PEC for the aquatic compartments are calculated as follows:

Predicted Environmental Concentration (PEC) for release to the aquatic compartment during use		
Combined effluent concentration	6.46	µg/L
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River	6.46	µg/L
PEC – Ocean	0.646	µg/L

STP effluent re-use 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 6.5 µg/L may potentially result in a soil concentration of approximately 43 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 220 µg/kg and 430 µg/kg,

respectively.

PEC for PFHxA and long chain perfluoroalkyl substances
The notified polymer is assumed to degrade and ultimately form the persistent degradant, PFHxA. However, the yield and rate of conversion of the notified polymer to PFHxA has not been established as characterisation of the degradation products was not undertaken in the biodegradation study on an analogue polymer. Environmental monitoring data shows that PFHxA and PFOA is 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 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 ($n \geq 60$), 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 polymer 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, such as 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 polymer containing polyfluoroalkyl functionality should not exceed the levels attainable utilising international best practice and that 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 unknown and its partitioning behaviour is uncertain. Further, degradation products of the notified polymer are unknown as characterisation was not undertaken in the biodegradation study. Therefore, a PEC for indirect releases of PFHxA arising from proposed use and disposal of the notified polymer in Australia cannot be determined.

7.2. Environmental Effects Assessment

Ecotoxicological data for the notified polymer are summarised in the table below. Details of the studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Invertebrate Toxicity		

Daphnia magna	48 h EC50 > 37.9 mg/L	At worst, harmful to aquatic invertebrates

Based on the measured data, the notified polymer is considered potentially harmful to aquatic invertebrates on an acute basis. However, as the test was conducted on the product containing the notified polymer at < 40% mixed in solvent, much of the toxicity can be attributed to the solvent which has a reported 48 h EC50 for *Daphnia magna* of 23.7 mg/L (OECD, 2011). As the toxicity to daphnia has not been measured for the notified polymer itself, it is not possible to determine what the effects of the notified polymer are. However, it can be concluded that the EC50 for the notified polymer is most likely > 39.7 mg/L. Therefore, as a definitive measured endpoint is unknown, the notified polymer is not formally classified under the Globally Harmonised System of Classification of Chemicals (GHS, 2009). Polymers without significant ionic functionality are generally of low concern to the environment. However, at worst, it can be considered to be harmful to aquatic invertebrates. As limited toxicity data is available for the notified polymer, it is also not classified under the GHS for long term hazard.

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 the 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 fully characterised.

7.2.1. Predicted No-Effect Concentration

The most sensitive measured ecotoxicological endpoint for the notified polymer was the 48-hour median effect concentration (48 h EC50) for daphnia. The lower limit of this endpoint was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 1000 was used as limited measured ecotoxicological data is available for the notified polymer.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia*; 48 h)	> 37.9	mg/L
Assessment Factor	1000	
PNEC:	> 37.9	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	6.46	> 37□9	< 0.170
Q - Ocean:	0.65	> 37.9	< 0.017

Based on a worst-case scenario, the risk quotients (Q) for river and marine waters are less than 1, indicating the notified polymer will not be present at ecotoxicologically significant concentrations in surface waters. As a polymer with a high molecular weight, it is assumed to persist in the environment but it is not expected to bioaccumulate. However, the notified polymer is 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: $t_{½}$ (hydrolysis) > 200 years; US EPA, 2002) but PFHxA is considered to have 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.

The main environmental risks associated with polyfluoroalkyl polymers relate to the release of 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 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 polymer 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 polymer increases the environmental risk profile of PFHxA. The notified polymer also contains impurities which are assumed to degrade to form PFHxA. Therefore, considering the dispersive use pattern of the notified polymer, it is recommended to reduce the impurities in the notified polymer that breakdown to form PFHxA, to the extent possible.

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

However, degradants of the notified polymer, along with associated impurities and residual monomers of the notified polymer, are potential precursors of the very persistent chemical, PFHxA. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment during use and after disposal and there are no adequate long-term environmental effects data for PFHxA. Therefore, the long-term environmental implications are unknown. Consequently, the long-term risk cannot be quantified for the notified polymer and its degradation products. In order to inform a more conclusive assessment of long-term environmental risks, further data should be generated. This may include data on longer-term environmental effects, as well as partitioning behaviour and characterisation of the degradation products, for the notified polymer and/or poly- and perfluoroalkyl degradation products (including PFHxA).

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 polymer to the extent practicable. Where possible, the total weight of residual monomers and impurities of the notified polymer 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0 g/L at 20 °C (limit of detection = 0.001 g/L)

Method In-house method

Remarks The notified polymer (5 g) was added to water (45 g) and stirred for 2 hours at room temperature. The mixture was gravity filtered through a milk filter. The filtered material was analysed with a moisture analyser to determine the mass of water remaining in the solid. The percentage of solid in the filtrate could then be calculated. An oven test was also used to determine the percentage solids.

It is not clear how the tests were conducted based on the limited detail provided in the experimental method. The water solubility is expected to be low based on the high molecular weight and its hydro/lipophobic functionality. It is not clear from this solubility test whether the notified polymer is water dispersible as a description of the solution before filtration was not provided and filtration may have removed any suspended particles of the notified polymer. As noted in the ecotoxicity test, the notified polymer in approximately 60% solvent formed clear and colourless solutions with water. The notifier indicated that the notified polymer is not water dispersible.

Test Facility DuPont (2010a)

Octanol Solubility 1.8 g/L at 20 °C

Method In-house method

Remarks The notified polymer (5 g) was added to octanol (45 g) and stirred for 2 hours at room temperature. The mixture was gravity filtered through a milk filter. The filtered material was analysed with a moisture analyser to determine the mass of octanol remaining in the solid. The percentage of solid in the filtrate could then be calculated.

It is not clear how the tests were conducted based on the limited detail provided in the experimental method. As the notified polymer contains a portion of hydrophobic functionality, solubility in octanol is expected to be greater than solubility in water. However, the notified polymer also contains hydro/lipophobic functionality that may limit is octanol solubility. Based on these considerations, and the fact the notified polymer is available in a solvent solution, the notified polymer has the potential to disperse in octanol.

Test Facility DuPont (2010a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (up to 40% concentration)
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure
Species/Strain	Rat/Sprague-Dawley
Vehicle	Butyl acetate
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1F	5000	0/1
2	2F	5000	0/2

LD50	>5000 mg/kg bw (equivalent to 2000 mg/kg bw of the notified polymer)
Signs of Toxicity	None
Effects in Organs	None
CONCLUSION	The notified polymer (up to 40% concentration) is of low toxicity via the oral route.
TEST FACILITY	Eurofins (2010a)

B.2. Acute toxicity – inhalation

TEST SUBSTANCE	Notified polymer (up to 1% concentration)
METHOD	OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Rat/Wistar
Vehicle	n-Octane
Method of Exposure	Nose-only exposure
Exposure Period	4 hours
Physical Form	liquid aerosol
Particle Size	MMAD ± GSD: 1.3 ± 1.9 µm and 1.6 ± 2.0 µm
Remarks - Method	Rats (8/sex/group) were exposed to 20 g/m^3 nominal concentrations of the test substance. Control groups (6/sex/group) were also conducted and were exposed to clean air in the exposure system. The study was conducted according to OECD guidelines, with additional investigations. Respiratory function (breathing frequency, tidal volume and ventilatory flow) was measured on the day prior to exposure, immediately after exposure, day 1, day 3 and the day prior to necropsy. To measure respiratory function, the animals were placed in a restraining tube in a double room plethysmograph. Animals were acclimatised to the restraining tube three times prior to exposure. Measurements were made over 30 seconds and the final measure was taken as the average over a 10 second interval. Half the animals were sacrificed one day post-exposure (3/sex/group for controls and 4/sex/group for the exposure groups). The remainder were sacrificed following the 15 day observation period. The lungs of all animals were subject to histopathological examination.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/m^3)* *Test substance*	*Mortality*
1	6M + 6F	0	0/12
2	8M + 8F	20,500±200*	0/16

*The particulate fraction of the aerosol was measured gravimetrically as 223±9 mg/m^3 corresponding to the concentration of the notified polymer

LC50	>223 mg notified polymer/m^3/4 hours
Signs of Toxicity	Increased breathing rate, piloerection and nasal encrustations were observed in the exposure groups shortly after exposure. Increased breathing rate was observed throughout the exposure period for the exposed groups except for one male for which the breathing rate returned to normal after day 6. Blepharospasm was observed in males and females on day 1. No clinical signs were observed in the control group. There were body weight losses in the exposed animals on day 1. Exposed groups then gained weight but there were statistically significant decreases in absolute body weight compared to control groups. The absolute body weight just prior to sacrifice was decreased in males and females compared to the control groups, but was not statistically significant. Breathing frequency was increased in males and females over the observation period, with statistically significant increases on days 3 and 14 for males and females, and on day 1 for males and day 0 for females, when compared to the concurrent control groups. There was a statistically significant increase in ventilatory flow on day 14 for females, but not in males. Tidal volume was statistically decreased in females on day 0 and on day 1 and 3 in males. Altered breathing patterns were reported just after exposure and on day 1. A slight pause was observed after each exhalation.
Effects in Organs	There were statistically significant increases in absolute and relative lung weights for the groups sacrificed on day 1 and day 15. Gross necropsy in the lungs on day 1 revealed a dark/red appearance and/or petechiae and on day 15 revealed red appearance and the lungs were insufficiently collapsed. Other observations were red appearance of the thymus, skin encrustations and hydrometra of the uterus but were considered a common finding in this species and therefore not treatment related. Histopathological findings were observed in most of the exposed rats at both sacrifice points (see following Table). On day 1, there were observations of alveolar blood, alveolar macrophage infiltrates, alveolitis, perivascular oedema accompanied by mixed inflammatory cell infiltrates. Changes were similar on day 15, but were generally decreased in severity (though not on all occasions).

	Males (mg/m³/4 hours)				*Females (mg/m³/4 hours)*			
	0	*0*	*20,500*		*0*	*0*	*20,500*	
Sacrifice day	*1*	*15*	*1*	*15*	*1*	*15*	*1*	*15*
Lungs *N =*	3	3	4	4	3	3	4	4
Alveolitits, multifocal	0	1 (2.0)	2 (2.0)	4*(1.5)	0	0	4*(1.8)	4*(1.0)
Alveolar macrophage infiltrate, diffuse	0	0	1 (2.0)	4*(1.3)	0	0	2 (1.0)	4*(1.3)
Alveolar blood, focal	1 (3.0)	1 (1.0)	4 (2.3)	0	1 (2.0)	0	4 (2.0)	1 (1.0)
Perivascular oedema, focal	0	0	2 (2.0)	0	0	0	3 (2.0)	0
Perivascular mixed inflammatory cell infiltrate, multifocal	0	0	1 (2.0)	0	1 (2.0)	0	3 (1.7)	2 (1.0)
Perivascular mononuclear cell infiltrate, focal	0	0	0	2 (1.0)	0	0	0	1 (1.0)
Alveolar mononuclear cell infiltrate, focal	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	0	0

( ), Average severity of affected animals: 1=very slight, 2=slight, 3=moderate, 4=severe.
*Statistically significant compared to control (P<0.05).

REMARKS - RESULTS

The histopathological findings in this study are attributed to the notified polymer, as no histopathological findings were observed in an acute inhalation study with n-octane at similar concentrations (Sung *et al.*, 2010). The study authors indicate that the histopathological findings are consistent with responses associated with clearing the lungs following inhalation of aerosol particulates.

CONCLUSION

The histopathological LOAEC for the tested substance (containing the notified polymer at up to 1% concentration) was established at 20,500 mg/m³/4 hours (equivalent to 223 mg notified polymer/m³/4 hours).

TEST FACILITY

TNO (2010)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE

Notified polymer (up to 40% concentration)

METHOD

Similar to OECD TG 403 Acute Inhalation Toxicity

Species/Strain: Rat/Crl:CD(SD)

Vehicle: Butyl acetate

Method of Exposure: Nose-only exposure

Exposure Period: 4 hours

Physical Form: Liquid aerosol

Remarks - Method

In the acute inhalation study, rats (5 males/group) were exposed to nominal concentrations of the test substance of 1200 or 2100 mg/m³. The animals were subject to standard analyses in accordance with the OECD test guideline to determine the LC50.

In the histopathological study, rats (15 males/group) were exposed to nominal concentrations of the test substance of 0, 50, 100 or 200 mg/m³ to determine histopathological effects in the lungs and an acute inhalation NOAEL for the notified polymer. The animals were subject to standard analyses in accordance with the OECD test guideline. Rats (5/group) were sacrificed on days 1, 7 and 14. The lungs, larynx/pharynx, trachea and nose were subject to histopathological examination for the 0 and 200 mg/m³ groups. The test substance for the 50 and 100 groups was diluted 1:1 with butyl acetate, thus these groups were exposed to up to 20% notified polymer.

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/m³)*			*Mortality*
		Nominal (test substance)	*Actual (test substance)*	*Aerosol[1]*	
1	5M	1200	1200*	71	0/5
2	5M	2100	2100**	290	2/5
3	15M	0	0	0	0/15
4	15M	50	70***	14	0/15
5	15M	100	150***	14	0/15
6	15M	200	210***	25	0/15

* MMAD ± GSD: 2.2 ± 2.0 µm
** MMAD ± GSD: 2.3 ± 2.3 µm
*** MMAD ± GSD: 1.2-2.6 ± 1.8-2.4 µm
[1]corresponding to the concentration of the notified polymer

LC50	Although only 40% mortality occurred at 2100 mg/m³/4 hours for the tested substance (equivalent to 290 mg notified polymer/m³/4 hours), the LC50 may be close to this concentration.
Signs of Toxicity	No clinical signs of toxicity were observed and there were no test substance related body weight changes.
Effects in Organs	There were no gross observations at necropsy. There were no treatment related histopathological findings in the 200 mg/m³ exposed group at days 1 or 7. Effects were noted in this group including minimal alveolar histiocytosis (1/5), minimal perivascular inflammation in the lungs (2/5), inflammation of the pharynx/larynx (1/5), and minimal hyperplasia/squamous metaplasia in nasal tissue (1/5), but were not considered treatment related by the study authors as these changes were minimal, focal and consistent with spontaneous changes in this strain of rat.
CONCLUSION	The tested substance is harmful by the inhalation route. However, the notified polymer is fatal/toxic by inhalation, based on the LC50 of 290 mg/m³/4 hours. The NOEC for deaths is 1200 mg/m³/4 hours of the tested substance, equivalent to 71 mg notified polymer/m³/4 hours. The NOAEC for histopathological effects in the respiratory tract for the tested substance was established at 210 mg/m³/4 hours, equivalent to 25 mg/m³/4hr of notified polymer.
TEST FACILITY	DuPont (2010b)

B.4. Acute toxicity – inhalation

TEST SUBSTANCE	Notified polymer (up to 40% concentration)
METHOD	Similar to OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Rat/Crl:CD(SD)
Vehicle	Butyl acetate
Method of Exposure	Nose-only exposure
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	MMAD ± GSD: 2.4 ± 1.6 µm
Remarks - Method	Five male rats were exposed to 3100 mg/m³ of test substance for 4 hours. The animals were observed for 14 days. Post mortem examination was not conducted.

RESULTS

Group	Number and Sex of Animals	Concentration (mg/m^3)		Mortality
		Tested substance	Aerosol[1]	
1	5M	3100	70	0/5

[1]corresponding to the concentration of the notified polymer

LC50	>3100 mg/m^3/4 hours for the tested substance (equivalent to >70 mg notified polymer/m^3/4 hours)
Signs of Toxicity	A red ocular discharge was observed in two rats immediately following exposure. All rats lost weight on the first day of exposure but continued to gain weight over the recovery period.

CONCLUSION LC50 >70 mg/m^3/4 hours for the notified polymer.

TEST FACILITY DuPont (2010c)

B.5. Acute toxicity – inhalation

TEST SUBSTANCE Notified polymer (up to 40% concentration)

METHOD Similar to OECD TG 403 Acute Inhalation Toxicity

Species/Strain	Crl:CD(SD)
Vehicle	Butyl acetate
Method of Exposure	Nose-only exposure
Exposure Period	4 hours
Physical Form	Liquid aerosol
Remarks - Method	In the acute inhalation study, rats (5 males/group) were exposed to concentrations of the test substance at 720, 1000, 1600 or 5200 mg/m^3/4 hours and then maintained for 14 days. The Mass Median Aerodynamic Diameter was 2.4 - 3.4 ± 1.8 - 2.4 µm (MMAD ± GSD). Post mortem examination was not conducted for these groups. In the histopathological study, rats (15 males/group) were exposed to 0, 45 or 190 mg/m^3/4 hours of the test substance to determine histopathological effects in the lungs and an acute inhalation NOAEC for the notified polymer. The particle size was determined as 3.4-5.0 ± 2.0-2.4 µm (MMAD ± GSD). Rats were (5/group) sacrificed on days 1, 7 and 14. The lungs, larynx/pharynx, trachea and nose were subject to histopathological examination for all animals.

RESULTS

Group	Number and Sex of Animals	Concentration (mg/m^3)		Mortality
		Tested substance	Aerosol[1]	
1	5M	720 ± 150	18	0/5
2	5M	1000 ± 210	24	0/5
3	5M	1600 ± 320	28	0/5
4	5M	5200 ± 650	110	0/5
5	15M	0	0	0/15
6	15M	45 ± 25	6	0/15
7	15M	190 ± 93	15	0/15

[1]corresponding to the concentration of the notified polymer

LC50	>5200 mg/m^3/4 hours for the tested substance (equivalent to >110 mg notified polymer/m^3/4 hours)
Signs of Toxicity	No mortalities were observed in the acute inhalation groups. Rats exposed to 190 mg/m^3/4 hours of the tested substance all lost weight on day one post-exposure with two rats losing weight on day two. All rats

	in this group gained weight normally over the remainder of the observation period. No clinical signs of toxicity were observed in this group.
Effects in Organs	Histopathology findings in the 45 and 190 mg/m^3/4 hour exposure groups were not considered treatment related by the study authors. Generally, findings were observed in the control groups or there was no dose response. Minimal alveolar inflammation was observed in two rats exposed to 190 mg/m^3/4 hours at the day 7 sacrifice point only, with no observations in the controls or the 45 mg/m^3/4 hour exposure group.
CONCLUSION	LC50 >110 mg/m^3/4 hours for the notified polymer. The histopathology NOEC for the tested substance was established at 190 mg/m^3/4 hours (equivalent to 15 mg/m^3/4 hours of the notified polymer).
TEST FACILITY	DuPont (2010d)

B.6. Irritation – skin

TEST SUBSTANCE	Notified polymer (up to 40% concentration in butyl acetate)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	Scores of zero were noted for erythema and oedema for all observations points. Two animals had 2% body weight losses over the study period. The relevance of this effect is unclear but is unlikely to be related to the notified polymer.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	Eurofins (2010b)

B.7. Irritation – eye

TEST SUBSTANCE	Notified polymer (up to 40% concentration in butyl acetate)
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

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1	1	2	<72 hours	0
Conjunctiva: chemosis	0.3	0.3	0.3	2	<48 hours	0
Conjunctiva: discharge	0.7	0.7	0.3	2	<72 hours	0
Corneal opacity	0	0	0	1	<24 hours	0
Iridial inflammation	0.3	0.3	0.3	1	<48 hours	0

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

CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	Eurofins (2010c)

B.8. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified polymer (up to 40% concentration in butyl acetate)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/JHsd
Vehicle	Acetone:olive oil (4:1)
Remarks - Method	No significant protocol deviations

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	882	-
5	1246	1.41
25	833	0.94
50	808	0.92
100	2087	2.37
Positive Control (HCA)		
25	8742	9.91

HCA, hexylcinnamaldehyde.

Remarks - Results	The stimulation index values for the test substance groups were <3, indicating the absence of a skin sensitisation response.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	DuPont (2010e)

B.9. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (up to 40% concentration in butyl acetate)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test – Plate Incorporation Procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33.3-5000 µg/plate b) Without metabolic activation: 33.3-5000 µg/plate
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. A 2-fold increase in the number of revertant colonies in strains TA98, TA100 and WP2uvrA, and a 3-fold increase in strains TA1535 and TA1537 was considered positive. Vehicle and positive controls were used in parallel with the test substance.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>5000	≥333	>5000
Test 2	>5000	≥1000	>5000
Present			
Test 1	>5000	≥667	>5000
Test 2	>5000	≥1000	>5000

CONCLUSION The notified polymer not mutagenic to bacteria under the conditions of the test.

TEST FACILITY DuPont (2010f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue polymer (≤25% in solvent)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Organic and Inorganic carbon content
Remarks - Method	The method was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
3	7	3	64
7	12	7	82
11	12	11	89
14	14	14	90
20	18	20	95
27	15	27	97
28	15	28	98

Remarks - Results	All test validity criteria were met. A toxicity control indicated the inoculum was active and the test substance is not toxic to microorganisms. Characterisation of the degradants was not undertaken. The entire carbon content of the notified polymer is not expected to completely mineralise. However, high molecular weight polymers are generally resistant to biodegradation. As 75% of the test substance is solvent, it is likely that the solvent is the major contributor to the observed biodegradation of the test substance.
CONCLUSION	The test substance, and by inference the notified polymer, is not readily biodegradable.
TEST FACILITY	Elf Atochem (1996)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer (<40% in solvent)
METHOD	Test comparable to OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	100 to 140 mg $CaCO_3$/L
Analytical Monitoring	Not reported
Remarks - Method	The test substance is the product containing the notified polymer at <40% concentration in solvent. The test substance formed clear, colourless test solutions. The method was conducted according to test guidelines using

good laboratory practice (GLP) with no significant deviations.

RESULTS

Concentration mg/L *Nominal*	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	10	0	0
0.12	10	0	0
1.2	10	0	0
12	10	0	0
120	10	10	10

EC50	37.9 (12 to 120) mg/L at 48 hours
NOEC	12 mg/L at 48 hours
Remarks - Results	All relevant test validity criteria were met. The geometric mean of the nominal concentrations was used to calculate the EC50. The 95% fiducial limits are 12 to 120 mg/L. As the test substance is the notified polymer (<40%) in solution with solvent, the observed immobilisation of the daphnia is potentially due to the effects of solvent and not necessarily the notified polymer. The lowest reported 48 h EC50 for solvent to *D. magna* is 23.7 mg/L (OECD 2011), which is approximately 60% of the EC50 for the test substance. As the concentration of the solvent in the test substance is also approximately 60%, the majority of the toxicity could be attributed to the solvent. Polymers without significant ionic functionality are generally of low concern to the environment. However, the toxicity to daphnia has not been measured for the notified polymer itself. Therefore, it is not possible to determine what the effects of the notified polymer are. As it has not been demonstrated that the notified polymer is not harmful to aquatic invertebrates, the EC50 for the notified polymer is ≥ 39.7 mg/L.
CONCLUSION	The notified polymer is, at worst, harmful to aquatic invertebrates.
TEST FACILITY	DuPont (2010g)

APPENDIX D: 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, 2007b, 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, 2007b).
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, 2007c). 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, the LOAEL for PFHxA (100 mg/kg bw/day) occurred at higher doses than for PFOA (0.64 mg/kg bw/day).
- In chronic toxicity studies in rats, the LOAEL for PFHxA (100/200 mg/kg bw/day [m/f]) was higher than for PFOA (14.2/16.1 mg/kg bw/day [m/f]).
- 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 is “likely to be carcinogenic to humans” (US EPA, 2012).

BIBLIOGRAPHY

AGC Chemicals (2010) A 24-month oral (gavage) combined chronic toxicity/carcinogenicity study of perfluorohexanoic acid (PFHxA) in rats (Study no. WIL-534009) Ahiba, Japan. AGC Chemicals, Asahi Glass Company (Unpublished report provided by the notifier).

Ahrens L, Felizeter S, Sturm R, Xie Z and Ebinghaus R (2009) Polyfluorinated compounds in wastewater treatment plant effluents and surface waters along the River Elbe, Germany. Marine Pollution Bulletin, 58(9):1326-33.

Arp H, Niederer C and Goss K (2006) Predicting the Partitioning Behaviour of Various Highly Fluorinated Compounds. Environmental Science and Technology, 40(23): 7298-304.

Chemical Safety Report (2009) Risk assessment of perfluorooctanoic acid (PFOA) as part of a strategic partnership between German authorities and industry. (Unpublished report provided by the notifier).

Chengelis CP, Kirkpatrick JB, Myers NR, Shinohara M, Stetson PL and Sved, DW (2009a) Comparison of the toxicokinetic behaviour of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. Reprod Toxicol, **27**(3-4):342-351.

Chengelis CP, Kirkpatrick JB, Radovsk Ann and Shinohara, M (2009b) A 90-day repeated dose oral (gavage) toxicity study of perfluorohexanoic acid (PFHxA) in rats (with functional observational battery and motor activity determinations). Reprod Toxicol, **27**:400-406.

Conder JM, Hoke RA, De Wolf W, Russell MH and Buck RC (2008) Are PFCAs Bioaccumulative? A Critical Review and Comparison with Regulatory Criteria and Persistent Lipophilic Compounds. Environmental Science and Technology, 42(4):995-1003.

ConsExpo (2006) Consumer Exposure and Uptake Model, ConsExpo, version 4.1. National Institute for Public Health and the Environment, The Netherlands.

Daikin Industries (2011). Oral (gavage) combined developmental and perinatal/postnatal reproduction toxicity study of PFH ammonium salt in mice (study no. UZS00010). Osaka, Japan (unpublished report provided by the notifier).

Danish EPA (2008) Survey and environmental/health assessment of fluorinated substances in impregnated consumer products and impregnating agents, <www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/Publications/2005/87-7614-668-5/html/default_eng.htm> (accessed 20 May 2013).

DuPont (2003). Hexanoic acid, undecafluro-: (Biopersistence) Screening-10-dose oral gavage study in rats (Study No. 11560, April 2003) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2006a) Sodium perfluorohexanoate: Bacterial reverse mutation test (Study No. 20947, October 2006) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2006b) Sodium perfluorohexanoate: *in vitro* mammalian chromosome aberration test in human peripheral blood lymphocytes (Study No. 20880, November 2006) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2006c) Sodium perfluorohexanoate: Repeated-dose oral toxicity-two weeks gavage study in rats and mice (Study No. 18510, June 2006) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2007a) Air Monitoring Studies ES-07-155 and ES-07-85 (29 August 2007 and 16 May 2007) DuPont Facilities Services (Unpublished report submitted by the notifier).

DuPont (2007b) Sodium perfluorohexanoate: 90-Day gavage study in rats with one-generation reproduction evaluation (Study No. 19715, July 2007) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2007c) Sodium perfluorohexanoate: developmental toxicity in rats (Study No. 20639, April 2007) Delaware, USA. E.I. du Pont de Nemours and Company (Unpublished report provided by the notifier).

DuPont (2010a) Testing for the Solubility of [Notified Polymer] in Octanol and Water (Study No. D100197-1749, June, 2010). DuPont (Unpublished report submitted by the notifier).

DuPont (2010b) [Notified Chemical]: Inhalation Acute Exposure with Anatomic Pathology Evaluation in Male Rats (Study No. 18309-723, July, 2010). Delaware, USA, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

DuPont (2010c) [Notified Chemical]: Inhalation Approximate Lethal Concentration (ALC) in Male Rats (Study No. 18310-700, August, 2010). Delaware, USA, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

DuPont (2010d) [Notified Chemical]: Inhalation Acute Exposure with Anatomic Pathology Evaluation in Rats (Study No. 18308-723, August, 2010). Delaware, USA, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

DuPont (2010e) [Notified Chemical]: Local Lymph Node Assay (LLNA) in Mice (Study No. 18309-1234, April, 2010). Delaware, USA, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

DuPont (2010f) [Notified Chemical]: bacterial Reverse Mutation Test (Study No. 18309-500, May, 2010). Delaware, USA, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

DuPont (2010g) [Notified Polymer]: Static, Acute, 48-Hour Toxicity Screening Test with *Daphnia magna* (Study No. 18309-296, May, 2010). Wilmington, Delaware, United States, DuPont Haskell Global Centers for Health & Environmental Sciences (Unpublished report submitted by the notifier).

Elf Atochem (1996) [Analogue Polymer]: Détermination de la Biodégradabilité Facile Essai de Dégagement de CO_2 (Study No. 4178/96/A, December, 1996). Levallois-Perret, France, Centre d'Application de Levallois, Service Analyse Environnement (Unpublished report submitted by the notifier).

Environment Canada (2012) Screening Assessment Report – Perfluorooctanoic Acid, its Salts, and its Precursors. Government of Canada, August, 2012, <www.ec.gc.ca/ese-ees/default.asp?lang=En&n=370AB133-1>.

Eurofins (2010a) [Notified Chemical]: Acute Oral Toxicity – Up-And-Down Procedure in Rats (Study No. 18309-834, May, 2010). New Jersey, USA, Eurofins PSL (Unpublished report submitted by the notifier).

Eurofins (2010b) [Notified Chemical]: Primary Skin Irritation in Rabbits (Study No. 18309-1008, May, 2010). New Jersey, USA, Eurofins PSL (Unpublished report submitted by the notifier).

Eurofins (2010c) [Notified Chemical]: Primary Eye Irritation in Rabbits (Study No. 18309-602, May, 2010). New Jersey, USA, Eurofins PSL (Unpublished report submitted by the notifier).

Falandysz J, Taniyasu S, Gulkowska A, Yamashita N and Schulte-Oehlmann U (2006) Is Fish A Major Source of Fluorinated Surfactants and Repellents in Humans Living on the Baltic Coast? Environmental Science and Technology, 40(3):748-51.

Falandysz J, Taniyasu S, Yamashita N, Rostkowski P, Zalewski K and Kannan K (2007) Perfluorinated compounds in some terrestrial and aquatic wildlife species from Poland. Journal of Environmental Science and Health. Part A, Toxic/Hazardous Substances and Environmental Engineering, 42(6):715-9.

Furdui V, Stock N, Ellis D, Butt C, Whittle D, Crozier P, Reiner E, Muir D and Mabury S (2007) Spatial Distribution of Perfluoroalkyl Contaminants in Lake Trout from the Great Lakes. Environmental Science and Technology, 41(5):1554-9.

Gannon SA, Johnson T, Nabb DL, Serex TL, Buck RC and Loveless SE (2011) Absorption, distribution, metabolism and excretion of [1-^{14}C]-perfluorohexanoate ([^{14}C]-PFHx) in rats and mice. Toxicology 238(1):55-62.

Giesy JP, Nail JE, Khim JS, Jones PD and Newsted JL (2010) Aquatic Toxicology of Perfluorinated Chemicals. Reviews of Environmental Contamination and Toxicology, 202:1-52.

Higgins C, McLeod P, Macmanus-Spencer L and Luthy R (2007) Bioaccumulation of Perfluorochemicals in Sediments by the Aquatic Oligochaete Lumbriculus variegatus. Environmental Science and Technology, 41(13):4600-6.

Huset C A, Barlaz M A, Barofsky D F and Field J A (2011). Quantitative Determination of Fluorochemicals in Municipal Landfill Leachates. Chemosphere, 82(10):1380-6.

Kumar K, Zushi Y, Masunaga S, Gilligan M, Pride C and Sajwan K (2009) Perfluorinated Organic Contaminants in Sediment and Aquatic Wildlife, Including Sharks, From Georgia, USA. Marine Pollution Bulletin, 58:601-34.

Latala A, Nedzi M & Stepnowski P (2009) Acute Toxicity Assessment of Perfluorinated Carboxylic Acids Towards the Baltic Microalgae. Environmental Toxicology and Pharmacology, 28:167-71.

Loveless SE, Slezaka B, Serex T, Lewisa J, Mukerji P, O'Connor JC, Donnera EM, Frame SR, Korzeniowski SH, and Buck RC (2009) Toxicological evaluation of sodium perfluorohexanoate. Toxicology, **264**:32-44.

Martin J, Mabury S, Solomon K and Muir D (2003a) Bioconcentration and Tissue Distribution of Perfluorinated Acids in Rainbow Trout (Oncorhynchus mykiss). Environmental Science and Technology, 22(1):196:204.

Martin J, Mabury S, Solomon K and Muir D (2003b) Dietary Accumulation of Perfluorinated Acids in Juvenile Rainbow Trout (Oncorhynchus mykiss). Environmental Toxicology and Chemisty, 22(1):189-95.

McLachlan M, Holmstrom K, Reth M and Berger U (2007) Riverine Discharge of Perfluorinated Carboxylates from the European Continent. Environmental Science and Technology, 41(21):7260-5.

Nakayama S, Strynar M, Helfant L, Egeghy P, Ye X and Lindstrom A (2007) Perfluorinated Compounds in the Cape Fear Drainage Basin in North Carolina. Environmental Science and Technology, 41(15):5271-6.

Nilsson H, Karrman A, Westberg H, Rotander A, van Bavel B and Lindstrom G (2010) A Time Trend Study of Significantly Elevated Perfluorocarboxylate Levels in Humans after Using Fluorinated Ski Wax. Environmental Science and Technology 44(6): 2150-2155.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

OECD (2011) The OECD (Q)SAR Toolbox for Grouping Chemicals into Categories, version 2.2.1.1120 Laboratory of Mathematical Chemistry, Bourgas University, Bulgaria. <www.oecd.org/document/54/0,3343,en_2649_34373_42923638_1_1_1_1,00.html> (accessed 2013, May 21).

RIVM (2006) Cleaning Products Fact Sheet (Report No. 320104033/2006). Centre for Substances and Integrated Risk Assessment, RIVM, The Netherlands.

RIVM (2007) Paint Products Fact Sheet (Report No. 320104008/2007). Centre for Substances and Integrated Risk Assessment, RIVM, The Netherlands.

Russell M, Berti W, Szostek B and Buck R (2008) Investigation of the biodegradation potential of a fluoroacrylate polymer product in aerobic soils. Environmental Science and Technology, 42(3):800-7.

Russell M, Berti W, Szostek B, Wang N and Buck R (2010) Evaluation of PFO formation from the biodegradation of a fluorotelomer-based urethane polymer product in aerobic soils. Polymer Degradation and Stability, 95:79-85.

SWA (2012) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating>.

Skutlarek D, Exner M & Färber H (2006) Perfluorinated Surfactants in Surface and Drinking Waters. Environmental Science and Pollution Research, 13(5):299-307.

So M, Miyake Y, Yeung W, Ho Y, Taniyasu S, Rostkowski P, Yamashita N, Zhou B, Shi X, Wang J, Giesy J, Yu H and Lam P (2007) Perfluorinated compounds in the Pearl River and Yangtze River of China. Chemosphere, 68(11):2085-95.

Sung JJ, Choi B, Kim HY, Baek M, Ryu HY, Kim YS, Choi YK, Yu IJ and Song KS (2010) Acute and Subchronic Inhalation Toxicity of n-Octane in Rats. Safety and Health at Work, 1(2):192-200.

TNO (2010) An Augmented Acute (4-hour) Inhalation Toxicity Study with [Notified Chemical] (Diluted in n-Octane) in Rats (Study No. 8401/06, July, 2010). Netherlands, TNO Quality of Life (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <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 (2012) Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers – Risk Assessment. <http://www.epa.gov/opptintr/pfoa/pubs/pfoarisk.html>.

US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program, <www.epa.gov/oppt/newchems/pubs/hmwtpoly.htm>.

US FDA (2009) Environmental Assessment. US Food and Drug Administration, 22 April, 2009. Available at: <www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM176786.pdf>.

Washington J, Ellington J, Jenkins T, Evans J, Yoo H and Hafner S (2009) Degradability of an Acrylate-linked, Fluorotelomer Polymer in Soil. Environmental Science and Technology, 43(17):6617-23.

Wang Y, Yeung L, Taniyasu S, Yamashita N, Lam J and Lam P (2008) Perfluorooctane Sulfonate and Other Fluorochemicals in Waterbird Eggs from South China. Environmental Science and Technology, 42(21):8146-51.

Woodcroft M, Ellis D, Rafferty S, Burns D, March R, Stock N, Trumpour K, Yee J and Munro K (2010) Experimental Characterization of the Mechanism of Perfluorocarboxylic Acids' Liver Protein Bioaccumulation: The Key Role of the Neutral Species. Environmental Toxicology and Chemisty, 29(8):1669-77.

Ye X, Strynar M, Nakayama S, Varns J, Helfant L, Lazorchak J and Lindstrom A (2008a) Perfluorinated Compounds in Whole Fish Homogenates from the Ohio, Missouri and Upper Mississippi Rivers, USA. Environmental Pollution, 156(3):1227-32.

Ye X, Schoenfuss H, Jahns N, Delinsky A, Strynar M, Varns J, Nakayama S, Helfant L and Lindstrom A (2008b) Perfluorinated Compounds in Common Carp (Cyprinus carpio) Fillets from the Mississippi River. Environmental International, 34(7):832-8.

Zhao L, Folsom, PW, Wolstenholme BW, Sun H, Wang N, Buck R (2013) 6:2 Fluorotelomer Alcohol Biotransformation in an Aerobic River Sediment System. Chemosphere, 90:203-9.