

File No: LTD/1406

August 2014

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

PUBLIC REPORT

Polyfluorinated Polymer in Capstone® FS-81 and Capstone® TR

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
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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/1406	DuPont (Australia) Pty Ltd	Polyfluorinated Polymer in Capstone® FS-81 and Capstone® TR	No	≤ 7 tonnes per annum	Component of paints and coatings and pre-sale textile/fabric protection products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

Under the conditions of the occupational settings described, the notified 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 polyfluoroalkylpolymer, the latter of 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 ratio and assessed use pattern the notified polymer is not considered to 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, perfluorohexanoic acid (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 the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown. This situation may change if further data on the environmental behaviour of the notified polymer and its poly- and perfluoroalkyl degradation products (including PFHxA) were to become available.

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 that 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

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

(Material) Safety Data Sheet

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified 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.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.

If products and mixtures containing the notified 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 perfluoroalkyl 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 paint reformulators or users of fabric treatment to minimise environmental exposure to the notified polymer:
 - Best practice on-site treatment of aqueous 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 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 7 tonnes per annum notified polymer;
 - the polymer has a number-average molecular weight of less than 1000;
 - the use changes from a component of paint and coatings and a component of pre-sale textile/fabric protection products;
 - the notified polymer is intended for use in spray products at > 2% concentration for consumer or professional use;
 - 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 paint and coatings and a component of pre-sale textile/fabric protection products, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia; 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 Canada and the United States Environmental Protection Agency (US EPA). The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. 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 safe use of the notified polymer were carried out by NICNAS and the Department of the Environment.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

DuPont (Australia) Pty Ltd (ABN 59 000 716 469)
7 Eden Park Drive
MACQUARIE PARK NSW 2113

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: polymer name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physical and chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2008) and Canada (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Capstone® FS-81 (up to 35% notified polymer)
Capstone® TR (up to 35% notified polymer)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR spectra were provided.

3. COMPOSITION

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

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Below concentration cut-offs.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Not expected to occur under normal conditions of use.

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 °C AND 101.3 kPa: Opaque waxy solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	0 °C*	(M)SDS
Boiling Point	Not determined	Expected to decompose prior to boiling.
Density	1100 kg/m ³ at 25 °C*	(M)SDS
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007).
Water Solubility	Not determined	It is expected to have the potential to disperse in water based on its use in aqueous products at up to 35% w/w.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, hydrolysis is expected to occur very slowly under environmental conditions.
Partition Coefficient (n-octanol/water)	Not determined	A low partition coefficient is likely on the basis of its potential to disperse in water. However, it may be present in the form of dispersed particles at phase surfaces/boundaries due to its hydro/lipophobic tendencies.
Adsorption/Desorption	Not determined	Generally, polymers of high molecular weight are expected to adsorb to soil, sediments and sludge. However, it may have low absorption based on its potential to disperse in water and presence of perfluoroalkyl functionalities which have both hydrophobic and lipophobic tendencies.
Dissociation Constant	Not determined	Not expected to dissociate based on the 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 explosives.
Oxidising Properties	Not expected to be oxidising	Estimated based on structure.

* For the product Capstone® FS-81, which contains up to 35% notified polymer in an aqueous dispersion.

DISCUSSION OF PROPERTIES

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 POLYMER (100%) OVER NEXT 5 YEARS

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as an aqueous dispersion at concentrations up to 35%.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	≤ 7	≤ 7	≤ 7	≤ 7	≤ 7

PORT OF ENTRY

Sydney, Melbourne and Brisbane.

TRANSPORTATION AND PACKAGING

The products containing the notified polymer (up to 35% concentration) will be imported by sea in 18 kg or 200 kg steel or high-density polyethylene 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.

Paint additive

The notified polymer (in Capstone® FS-81) will be used as a grease and soil repellent in paint products at up to 2% concentration. Paints will be reformulated in Australia, with approximately 40% used by professionals and 60% by domestic users.

Treatment of textiles

The notified polymer (in Capstone® TR) will be used as a grease and soil repellent treatment for clothing fabrics and furnishings at up to 2% concentration prior to the selling of textiles to consumers. Approximately 80% will be used for clothing, 10% for upholstery, and 10% for treatment of other textile substrates.

Furnishing uses are expected to include indoor home furniture, commercial furniture and outdoor furniture. The notified polymer will be predominantly applied to fabric upholstery and not to leather. Products containing the notified polymer (up to 2% concentration) are suitable for the treatment of several types of fabric. Apparel treated with products containing the notified polymer are expected to include outer wear such as coats, hats, gloves, and footwear. Textile treatment products containing the notified polymer will not be available for sale to the public.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. The notified polymer will be imported at up to 35% concentration, as an aqueous dispersion.

Paint additive use

Manual decanting of the imported product (containing the notified polymer at up to 35% concentration) may occur during paint formulation. This may involve manual measurement or weighing of the required quantities for mixing with other ingredients to make the final paint product. Alternatively, the imported product may be pumped directly from the drums into the mixing tank with other ingredients. Following blending in the mixing tank, the final product (containing the notified polymer at up to 2% concentration) will be filled into 1 and 4 L cans. At the end of the formulation process the mixing tank will be rinsed out and, depending upon whether additional batches are to be formulated, the rinsate may be used in these batches or sent to waste treatment. Quality control staff may test samples of the finished products.

Paints and coatings containing the notified polymer (up to 2% concentration) will be used by both the public and professional painters and are expected to be applied by a variety of methods including brush, roller or low pressure paint sprayers (aerosol containers are not expected to be used).

Treatment of textiles

Reformulation of the imported product (notified polymer at up to 35% concentration) will involve pumping the

product into a mixing tank where it will be further diluted and/or other ingredients added. The diluted product (notified polymer up to 2% concentration) will then be applied to textiles by a spray/dip system that will take place in an enclosed area, which is expected to use airless spray equipment (generating negligible respirable particles). The process is expected to be automated with an operator present to ensure that the system is functioning effectively.

Following application, the textile will transfer into an air dryer to fix the notified polymer to the fibres. After drying the textiles will be rolled and cut ready for storage or dispatch. Once dry, the notified polymer will form a film bound to the textile fibres.

A 'pad and dry' method may also be used for application to textiles, which involves pumping the product containing the notified polymer (up to 2% concentration) to the pad roll trough, where it will be applied to the textile as it passes through the pad roll trough. The textile will then pass through a high temperature dryer where the notified polymer will bond to the textile. The process is expected to be automated.

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 twelve) is also possible. Such exposure is limited by the relatively low concentration of polyfluoroalkyl impurities in the notified polymer in imported products (up to 0.95%) or in end-use products (up to 0.05%).

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 35% concentration) in the unlikely event of an accident.

Reformulation processes

Dermal and ocular exposure may occur when workers manually pour the products containing the notified polymer (up to 35% concentration) into weighing and/or mixing equipment and when connecting or disconnecting transfer hoses. Personal protective equipment (PPE) such as protective clothing, goggles and gloves are expected to be worn during these procedures. Dermal and ocular exposures are also possible during cleaning and maintenance operations. Inhalation exposures are not likely 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.

Paint application

Dermal exposure of workers to the notified polymer (up to 2% concentration) is expected to be the main route of exposure during paint application, with some potential for inhalation exposure when using low pressure sprayers. PPE has not been specified for end use painters. However, it is expected that respiratory protection will be used when spraying. Professional painters may be exposed on a repeated basis.

Treatment of textiles

The spray/dip system will be in an enclosed area. The operator will ensure that the system is functioning effectively. Airless spray equipment producing a coarse non-atomising spray of droplets with negligible respirable particles is expected to be used. If workers are required to intervene in the process dermal and accidental ocular exposure may occur. PPE is expected to be worn, including a splash-proof apron or equivalent, gloves and goggles. Worker exposure to the notified polymer during the pad and dry method is expected to be minimised by the automated nature of the process. Textile workers may be exposed on a repeated basis.

6.1.2. Public Exposure

Paints containing the notified polymer (up to 2% concentration) will be used by the public. Dermal and ocular exposures may occur when applying paints by brush or roller. Additionally, inhalation exposure may also occur when applying paint by low pressure spray. Generally, PPE are not expected to be worn by public users, with the exception of normal clothing and possibly gloves. However, exposure to DIY users is expected to occur less frequently than to professional painters.

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

The public may be exposed to the notified polymer (at up to 2% concentration) through dermal contact to residues in clothing and other fabrics.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on two slightly different versions of the notified polymer are summarised in the Table below. The different versions of the notified polymer are covered by the same chemical identity. The studies were conducted with formulations that are similar to the imported products (containing the notified polymer at up to 35% concentration). Details of these studies can be found in Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
<i>Similar to Capstone® FS-81 (notified polymer at up to 35%)</i>	
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 1363 mg/m ³ notified polymer/4 hr; low toxicity
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
<i>Similar to Capstone® TR (notified polymer at up to 35%)</i>	
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

The notified polymer is not expected to cross biological membranes (skin or gastrointestinal tract) based on its high molecular weight (> 1,000 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 is possible 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

Both tested formulations were of low acute oral toxicity in rats. One of the formulations was of low acute dermal toxicity in rats.

Inhalation toxicity

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. These effects are generally considered to be of most concern when the compound has surface activity (Fischer *et al.*, 2012).

The notified polymer was of low acute inhalation toxicity in rats (LC50 > 1363 mg/m³/4 hours), as there were

no deaths observed at the highest attainable concentration in the study and there were no test substance-related clinical signs of toxicity. Respirable particles were generated during this study. Gross pathological examination was not conducted and therefore any possible pathological effects in the lung would not have been detected. Hence, based on this study, non-lethal lung injury cannot be ruled out following acute exposure. Additionally, the US EPA concluded that they do not have concerns for acute inhalation exposures to the notified polymer, based on the above study.

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

Irritation and sensitisation

The formulation similar to Capstone® FS-81 was not a skin irritant but the formulation similar to Capstone® TR was found to be a slight skin irritant in rabbits. Both products were slight eye irritants in rabbits. The formulation similar to Capstone® FS-81 was not a skin sensitiser in an LLNA study.

Mutagenicity

Two formulations of the notified polymer were negative in bacterial reverse mutation assays.

Health hazard classification

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

Toxicology of break down products

The notified polymer contains perfluoroalkyl side-chains that are potential precursors for 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 substances 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 C 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 formulations tested (containing the notified polymer up to 35% concentration) in the toxicology studies were generally indicative of low hazard. Slight eye and skin irritation may only be of concern when handling the notified polymer as introduced (up to 35% concentration). Automated processes are expected to be in place and PPE (clothing, gloves and goggles) will be worn during many of these processes, thus the risk of skin and/or eye irritation to reformulation workers is not considered to be unreasonable.

Repeated dermal exposure to the notified polymer may occur during fabric/textile application, paint formulation and paint applications. The repeat dose 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 (> 1,000 Da) of the notified polymer and the low proportion (< 2%) of low molecular weight (< 1,000 Da) species. 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 (< 3%). 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 (at up to 2% concentration) may occur during paint spraying operations. The lack of repeat dose inhalation toxicity data is considered to be a data deficiency given the potential for lung injury. 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 unreasonable 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

Paint products containing the notified polymer (up to 2% concentration) and relatively low levels of perfluoroalkyl impurities (< 0.1%) will be available to the public. Paint products will be applied by brush, roller or by low pressure spray. Public exposure is likely to be less frequent than professional exposure.

Lung injury from inhalation exposure to the notified polymer cannot be ruled out. The lack of repeated dose inhalation data for the notified polymer is of less concern for public exposure based on the expected infrequent exposure. Additionally, the notified polymer is present at a relatively low concentration (up to 2%) in final paint products and the expected use of low pressure spray equipment is not likely to generate significant amounts of respirable particles. Based on these considerations, the risk to public health from use of paints containing the notified polymer is not considered to be unreasonable.

The public may also be exposed to the notified polymer and relatively low levels of perfluoroalkyl impurities from direct dermal contact with treated clothing and upholstery. This exposure will be on a long term repeated basis. However, based on the high molecular weight of the notified polymer (> 1,000 Da) and the low proportion of low molecular weight species, dermal absorption is expected to be low. Thus the risk to public health of repeated dermal exposure to the notified polymer from treated clothing and upholstery is not considered to be unreasonable. The risk to public health from long term repeated dermal exposure to perfluorinated 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 Canada and the US 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 these activities. Releases to the environment may occur following accidental spills during import, transport or storage. 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 may enter wastewater streams during reformulation of architectural paints. Up to 2.4 wt% of notified polymer in each batch is estimated to be released as a result of rinsing empty import containers, mixing equipment, transfer lines and filling machines. It is estimated that 79% of the annual introduction volume of notified polymer will be reformulated into paints in Australia. Therefore, up to 133 kg per annum of notified polymer ($2.4\% \times 79\% \times 7$ tonnes) is estimated to be released in aqueous waste streams due to reformulation activities. Aqueous wastes containing the notified polymer may be re-used as the water diluent phase in subsequent reformulation activities. Alternatively, wastewaters may be disposed of to sewer via waste treatment plants.

RELEASE OF CHEMICAL FROM USE

Notified polymer for fabric applications (about 21% of the introduction volume) will be used in treatments during the manufacture of textiles for clothing, drapes and upholstery. Up to 0.7% of the notified polymer used in fabric treatments, equivalent to 10 kg per annum ($0.7\% \times 21\% \times 7$ tonnes), is estimated to enter aqueous waste streams as a result of rinsing empty product containers and reformulation/mixing equipment. A further 0.065 kilograms of notified polymer per day is estimated by the notifier to be released from the cleaning of pad rolls or pad-bath waste disposal during continuous operations in the pad and dry method of application. Wastewater containing the notified polymer may be treated on-site: the removal efficiency of the notified polymer by conventional wastewater treatment processes has not been demonstrated. Any notified polymer removed from wastewater during treatment is expected to be collected and disposed of to landfill. Notified polymer remaining in aqueous waste streams is expected to be released to sewers.

When used in architectural paints, it is assumed that up to 5% of paint (and therefore 5% of 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. Therefore, up to 276 kg per annum ($5\% \times 79\% \times 7$ tonnes) is estimated to be released in wastewater to sewers around Australia following its use in architectural paints. Dried residues of the notified polymer in empty paint containers or remaining in application equipment and protective barriers (such as newspaper or drop sheets) are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in paints is expected to be applied predominantly to plasterboard and timber articles. Painted articles and other dried paint residues, and thus the notified polymer, are expected to ultimately be disposed of to landfill. The notified polymer may become dissociated from treated fabrics during cleaning activities: the proportion of notified polymer that is released from fabrics due to washing over the useful life of the article has not been estimated, though it is not expected to be significant. Notified polymer in wash water from cleaning activities is expected to be disposed of to sewers. Residual notified polymer on fabrics is likely to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the introduced notified polymer is expected to form an inert polymeric matrix adhering to articles following its use in paints. Painted articles and other dried paint residues, and thus the notified polymer, are expected to ultimately be disposed of to landfill. When associated with the article to which the product containing the notified polymer has been applied, and considering the high molecular weight, the notified polymer is not likely to be mobile or bioavailable in landfill.

Some of the notified polymer is expected to be disposed of to sewers from its 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 compounds such as the notified polymer 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 surface activity and/or high molecular weight results in efficient removal by sorption to sludge during conventional wastewater treatment has not been verified by supporting data for this class of polymer. Thus, noting its potential of being both hydrophobic and lipophobic, the notified polymer, its degradation products and any associated 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.

The notified polymer has potential to disperse in water but it is not expected to hydrolyse under environmental conditions (pH 4 to 9, 25 °C) based on structural considerations. Investigations on biodegradation potential of fluoroacrylate polymer and fluorotelomer-based urethane polymer in aerobic soils (Russell et al., 2008; Russell et al., 2010; Washington et al., 2009) indicate very limited degradation of the fluorinated polymers. The notified polymer contains some end-group functionality that may be susceptible to biodegradation. However, biodegradation of the backbone of the notified polymer is expected to occur slowly under environmental conditions due to its high molecular weight. Thus, the notified polymer is considered to be persistent in the soil and water compartments.

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 polyfluoroalkyl degradation products are assumed to undergo further degradation to form, among other compounds, the very persistent perfluorocarboxylic acid, PFHxA. It is noted that some volatile degradation intermediates have the potential to undergo long range atmospheric transport and thus may result in translocation of PFHxA in the environment. The notified polymer also contains relatively low levels of impurities that may degrade to form perfluorooctanoic acid (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 chemicals (and polymers) due to the environmental persistence characteristics, when it results in mineralisation of the perfluoroalkyl functionality to oxides of carbon and hydrofluoric acid. Incomplete combustion of perfluoroalkyl functionality may produce an array of partially oxidised fluorocompounds. Therefore, disposal of the notified polymer and its degradation products by incineration should only take place at facilities that demonstrate complete combustion of the perfluoroalkyl functionality and have adequate measures in place to control release of hydrofluoric acid.

The notified polymer is not expected to bioaccumulate as, due to its high molecular weight, it is not expected to cross biological membranes. The available laboratory (Higgins et al., 2007; Martin et al., 2003a; Martin et al., 2003b; 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 although neither PFHxA nor PFOA are considered bioaccumulative. However, both are bioavailable and can be detected in wildlife as demonstrated by monitoring studies (Kumar et al., 2009; Ye et al., 2008ab; Wang et al., 2008). In general, the available evidence indicates that the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy et al., 2010). Therefore, PFHxA has a lower bioaccumulation potential than PFOA and other long chain perfluoroalkyl substances.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer may be released to the aquatic compartment through the disposal of wastewater generated during its reformulation, use or disposal. Under a worst-case scenario it is assumed that there is no removal of the notified polymer in the STP.

The predicted environmental concentration (PEC) due to releases from reformulation of paints and use in the manufacture of fabrics is calculated assuming point-source release from site(s). Although four sites of fabric manufacture have been nominated, the worst case PEC calculation assumes that all paint reformulation and fabric manufacture waste waters will be diluted through an STP covering 10% of the Australian population in one geographical area: equivalent to daily effluent production of 452 ML. It is assumed that paint reformulation occurs on 260 days a year and batch processes for fabric treatment occur on 60 days a year. The concentration of the notified polymer in STP effluent from point-source releases is estimated as follows:

<i>Concentration of the Notified Polymer in STP Effluent From Point-Source Releases</i>		
Total Annual Import Volume	7,000	kg/year
Proportion used in paint	79	%
Proportion expected to be released to sewer from reformulation of paints	2.4	%
Annual quantity of chemical released to sewer from reformulation of paints	133	kg/year
Days per year where release occurs for reformulation of paints	260	days/year
Daily release from reformulation of paints:	0.51	kg/day
Proportion used in fabric	21	%
Proportion expected to be released from fabric manufacture batch process	0.7	%
Annual quantity of chemical released to sewer from fabric manufacture batch process:	10	kg/year
Days per year where release occurs for fabric manufacture batch process	60	days/year
Daily release from fabric manufacture batch process	0.17	kg/day
Daily release from fabric manufacture continuous process	0.065	kg/day
Total daily release from fabric manufacture:	0.24	kg/day
Total daily release from all point-sources:	0.75	kg/day
Removal within STP	0%	
Daily effluent production	452	ML
Effluent concentration (point-source releases):	1.7	µg/L

The PEC due to releases from use in paints and disposal of wash water from treated fabrics is calculated assuming diffuse release Australia-wide over 365 days per year. Under a worst-case scenario it is estimated that 5% of the notified polymer used in paint will be released to sewers during use, while it is assumed that 100% of the notified polymer on treated fabrics will be released to sewers following washing. The resultant concentration in sewage effluent on a nationwide basis is estimated as follows:

<i>Concentration of the Notified Polymer in STP Effluent From Diffuse Releases</i>		
Total Annual Import Volume	7,000	kg/year
Proportion used in paint	79	%
Proportion expected to be released to sewer from use of paints	5	%
Annual quantity of chemical released to sewer from use of paints:	276	kg/year
Proportion used in fabric	21	%
Proportion expected to be released to sewer from washing of fabric	100	%
Annual quantity of chemical released to sewer from washing of fabrics:	1,470	kg/year
Total annual quantity of chemical released to sewer:	1,746	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	4.78	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 (diffuse releases):	1.0	µg/L

Based on the above calculations, the worst-case concentration for the notified polymer in effluent due to the combined point-source and diffuse releases to STP is 2.7 µg/L. Therefore, the PEC for the aquatic compartments are calculated as follows:

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>	
Combined effluent concentration	2.7 µg/L
Dilution Factor - River	1
Dilution Factor - Ocean	10
PEC - River□:	2.7 µg/L
PEC - Ocean:	0.27 µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 2.7 µg/L may potentially result in a soil concentration of approximately 17.9 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 91.2 µg/kg and 179 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. Environmental monitoring data shows that both PFHxA and PFOA are widely found in the environment, particularly in fresh water close to industrial sources, but also in some biota. Water appears to be the main compartment where PFHxA is found. High measured concentrations of both PFHxA and PFOA in surface waters in Germany have been associated with the legal application of waste materials to agricultural soils (Skutlarek et al., 2006) indicating that these chemicals have the potential to enter the aquatic compartment following initial release into the soil compartment.

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

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

Historically, release of poly- and perfluoroalkyl substances into the environment has been linked to direct releases of low molecular weight poly- and perfluoroalkyl substances, such as poly- and perfluoroalkyl monomers during polymer manufacture and reformulation processes, rather than breakdown of the polymers themselves. In order to limit the extent of direct release of potential PFHxA precursors to the environment, it is recommended that control measures be implemented to minimise the residual weight percentage of unreacted poly- and perfluoroalkyl monomer constituents and impurities in the notified 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 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 will become a significant source of persistent poly- and perfluoroalkyl substances in the environment in the future. PFHxA is already being detected in the environment and, as the long chain poly- and perfluoroalkyl substances are phased out in preference for short-chain polyfluoroalkyl chemistry containing a six-carbon perfluorohexyl moiety, the environmental levels of PFHxA are expected to increase.

Half-lives of polyfluoroalkyl polymers in aerobic soil have been found to be indeterminate with calculated half-

lives ranging from decades to millennia (Russell et al., 2008; Russell et al., 2010; Washington *et al.*, 2009). The half-lives of PFHxA in various environmental media are also unknown and its partitioning behaviour is uncertain. Further, degradation products of the notified polymer are unknown. 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

The results from ecotoxicological investigations conducted on the notified and analogue polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 h LC50 > 2000 mg/L ^a	Not harmful to fish
Daphnia Toxicity	48 h EC50 > 36.2 mg/L	Not expected to be harmful to aquatic invertebrates
Algal Toxicity	96 h ErC50 > 2000 mg/L ^a	Not harmful to algae

^a Test results are for an analogue

The available measured data indicates that the notified polymer is not expected to be harmful to fish, aquatic invertebrates and algae on an acute basis. Therefore, the notified polymer is not formally classified for acute aquatic hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

Effects of PFHxA and long chain perfluorocarboxylic acids

There are only limited available toxicity data for PFHxA to organisms, and these are limited to aquatic organisms. Based on the available literature, the most sensitive trophic level is algae. Latala et al., (2009) reported the 72-hour median effect concentrations (72 h EC50) for three marine species as follows: 1.0 mg/L for blue green algae (*Geitlerinema amphibium*); 1.4 mg/L for diatom (*Skeletonema marinoi*); and, 4.0 mg/L for green algae (*Chlorella vulgaris*). The data indicates that PFHxA is toxic to algae on an acute basis. The study also investigated the toxicity of PFOA to the three marine species: 0.25 mg/L for blue green algae; 0.37 mg/L for diatom; and, 0.98 mg/L for green algae. The data indicates that PFOA is very toxic to algae on an acute basis and demonstrate decreased toxicity of PFHxA compared with PFOA to three species tested.

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

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

7.2.1. Predicted No-Effect Concentration

The most sensitive ecotoxicological endpoint for the notified polymer was the 96-hour median effect concentration (immobilisation, EC50) for daphnia. This endpoint was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as acute endpoints are available for the notified polymer, or an acceptable analogue, for three trophic levels.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
EC50 (Invertebrates)	> 36.2	mg/L
Assessment Factor	100	
PNEC:	> 362	µg/L

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) is calculated for the aquatic compartment in the table below:

<i>Risk Assessment</i>	<i>PEC $\mu\text{g/L}$</i>	<i>PNEC $\mu\text{g/L}$</i>	<i>Q</i>
Q - River	2.7	> 362	< 0.01
Q - Ocean	0.27	> 362	< 0.001

The risk quotients for river and marine waters are both less than 1, indicating that the notified polymer will not be present at ecotoxicologically significant concentrations in surface waters based on its reported use pattern in Australia. The available data indicates that the notified polymer is not harmful to aquatic life. As a polymer with 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 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 and longer chain perfluorocarboxylic acids. Therefore, considering the dispersive use pattern of the notified polymer, it is recommended to restrict the impurities in the notified polymer that breakdown to form PFHxA and longer chain perfluorocarboxylic acids, to the extent possible.

Conclusions

On the basis of the PEC/PNEC ratio and assessed use pattern the notified polymer is not considered to 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, perfluorohexanoic acid (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 the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile of the notified polymer and its degradation products is unknown. This situation may change if further data on the environmental behaviour of the notified polymer and its poly- and perfluoroalkylated degradation products (including PFHxA) were to become available.

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

In order to limit the extent of direct release of potential PFHxA and long chain perfluorocarboxylic acid precursors to the environment, it is recommended that control measures be implemented to minimise the residual weight percentage of unreacted polyfluoroalkyl monomer constituents and impurities in the notified polymer to the extent practicable. Where possible, 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. It is recommended that the levels remain within this range and are further reduced using available technological advances, to the extent practicable.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS**A.1. Acute toxicity – oral**

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35%)

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

RESULTS

<i>Sequence</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	1F	175	0/1
2	1F	550	0/1
3	1F	1750	0/1
4	1F	5000	0/1
5	1F	5000	0/1
6	1F	5000	0/1

LD50 >5000 mg/kg bw
 Signs of Toxicity None
 Effects in Organs None

CONCLUSION The test substance (notified polymer at up to 35%) is of low toxicity via the oral route.

TEST FACILITY DuPont (2008b)

A.2. Acute toxicity – oral

TEST SUBSTANCE Similar to Capstone® TR (notified polymer at up to 35%)

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

RESULTS

<i>Sequence</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	1F	5000	0/1
2	1F	5000	0/1
3	1F	5000	0/1

LD50 >5000 mg/kg bw
 Signs of Toxicity None
 Effects in Organs None

CONCLUSION The test substance (notified polymer at up to 35%) is of low toxicity via the oral route.

TEST FACILITY DuPont (2008a)

A.3. Acute toxicity – dermal

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35% in water)

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test
 Species/Strain Rat/Crl:CD(SD)
 Vehicle None
 Type of dressing Semi-occlusive
 Remarks - Method No significant protocol deviations.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5F	5000	0/5
2	5M	5000	0/5

LD50 >5000 mg/kg bw
 Signs of Toxicity - Local None
 Signs of Toxicity - Systemic None
 Effects in Organs None
 Remarks - Results One male rat exhibited brown-stained fur/skin on the face and chin. This was reported as commonly observed in rats wrapped and was therefore not considered to be related to treatment.

CONCLUSION The test substance (notified polymer at up to 35%) is of low toxicity via the dermal route.

TEST FACILITY DuPont (2008c)

A.4. Acute toxicity – inhalation

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35% in water)

METHOD Similar to OECD TG 403 Acute Inhalation Toxicity
 Species/Strain Rat/Crl:CD(SD)
 Vehicle None
 Method of Exposure Nose-only exposure
 Exposure Period 4 hours
 Physical Form Liquid aerosol
 Particle Size MMAD = 1.6 ± 2.18 and 2.0 ± 2.08 μm for groups 1 and 2, respectively.
 Remarks - Method The actual concentration of 1363 mg/m^3 was reported as the highest achievable airborne concentrations of the notified polymer.

Gross pathology was not conducted.

RESULTS

Group	Number and Sex of Animals	Concentration (mg/m^3)		Mortality
		Nominal	Actual	
1	5 males	1555	108	0/5
2	5 males	12416	1363	0/5

LC50 >1363 mg/m^3 (4 hours)
 Signs of Toxicity Clear material on the trunk, neck, facial area, urogenital area, forelimb and rump was observed mostly in the group treated at 1363 mg/m^3 immediately after dosing. Additionally, several animals were observed to have red material around the nose and eyes, and some had yellow material on the urogenital area. These observations were considered

Effects in Organs common in animals restrained with nose-only inhalation chambers and were therefore not considered to be indicative of test substance related toxicity.
Necropsy not conducted.

CONCLUSION The notified polymer is of low toxicity via inhalation.

TEST FACILITY WIL (2008)

A.5. Irritation – skin

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35% in water)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion

Species/Strain Rabbit/New Zealand White

Number of Animals 3 male

Vehicle None

Observation Period 72 hours

Type of Dressing Semi-occlusive

Remarks - Method No significant protocol deviations.

RESULTS

Remarks - Results Scores of zero were observed at all observation points for both erythema and oedema formation.

CONCLUSION The test substance (notified polymer at up to 35%) is non-irritating to the skin.

TEST FACILITY DuPont (2008d)

A.6. Irritation – skin

TEST SUBSTANCE Similar to Capstone® TR (notified polymer at up to 35% in water)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion

Species/Strain Rabbit/New Zealand White

Number of Animals 3 male

Vehicle None

Observation Period 72 hours

Type of Dressing Semi-occlusive

Remarks - Method No significant protocol deviations.

RESULTS

Remarks - Results The mean 24, 48 and 72 hour scores was zero for all animals. Very slight erythema was observed immediately after dosing and at 1 hour.

CONCLUSION The test substance (notified polymer at up to 35%) is slightly irritating to the skin.

TEST FACILITY DuPont (2008e)

A.7. Irritation – eye

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35% in water)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion

Species/Strain Rabbit/New Zealand White

Number of Animals 3 male

Vehicle None
 Observation Period 72 hours
 Remarks - Method The test report did not state whether the eyelids were held shut for approximately one second following instillation of the test substance.

No significant protocol deviations.

RESULTS

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

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

Remarks - Results Conjunctival redness and discharge (up to grade 2), and iritis and chemosis (grade 1) were observed at the 1 hour observation point. Only conjunctival redness and iritis were observed at 24 hours (grade 1) and had cleared by 48 hours.

CONCLUSION The test substance (notified polymer at up to 35%) is slightly irritating to the eye.

TEST FACILITY DuPont (2008f)

A.8. Irritation – eye

TEST SUBSTANCE Similar to Capstone® TR (notified polymer at up to 35% in water)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion

Species/Strain Rabbit/New Zealand White

Number of Animals 3 males

Vehicle None

Observation Period 72 hours

Remarks - Method The test report did not state whether the eyelids were held shut for approximately one second following instillation of the test substance.

No significant protocol deviations.

RESULTS

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

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

Remarks - Results At the 1 hour observation point iritis of grade 1 was observed in one animal and conjunctival discharge of grade 1 was observed in another animal. Conjunctival redness (grade 2) was observed in all three animals at 1 hour but only in one animal (grade 1) at 24 hours. All reactions had cleared by the 48 hour observation.

CONCLUSION The test substance (notified polymer at up to 35%) is slightly irritating to the eye.

TEST FACILITY DuPont (2008g)

A.9. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35%)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
 Species/Strain Mouse/CBA/JHsd (female)
 Vehicle Methyl ethyl ketone
 Remarks - Method No range-finding study was conducted. The study was conducted using 5 mice/group at 0, 5, 25, 50 or 100% concentration. A concurrent positive control group were treated with α -hexylcinnamaldehyde (HCA).

No significant protocol deviations.

RESULTS

Concentration (% w/w)	Proliferative response (DPM/lymph node)	Stimulation Index (Test/Control Ratio)
<i>Test Substance</i>		
0 (vehicle control)	317	-
5	238	0.75
25	363	1.15
50	403	1.27
100	303	0.96
<i>Positive Control (HCA)</i>		
25	3556	11.23

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

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance (notified polymer at up to 35%).

TEST FACILITY DuPont (2008h)

A.10. Genotoxicity – bacteria

TEST SUBSTANCE Similar to Capstone® FS-81 (notified polymer at up to 35%)

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 μ g/plate
 b) Without metabolic activation: 33.3-5000 μ g/plate
 Vehicle Ethanol
 Remarks - Method No significant protocol deviations.

A range finding study was conducted in all strains between 33.3-5000 μ g/plate. Vehicle and positive controls were conducted concurrently.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	>5000	-	>5000	negative
Test 2	-	>5000	>5000	negative
<i>Present</i>				
Test 1	>5000	-	>5000	negative
Test 2	-	>5000	>5000	negative

CONCLUSION The test substance (notified polymer at up to 35%) was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY DuPont (2008i)

A.11. Genotoxicity – bacteria

TEST SUBSTANCE Similar to Capstone® TR (notified polymer at up to 35%)

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 a) With metabolic activation: 1.5-5000 µg/plate

Main Test b) Without metabolic activation: 1.5-5000 µg/plate

Vehicle Ethanol

Remarks - Method No significant protocol deviations.

A range finding study was conducted in all strains between 33.3-5000 µg/plate. Vehicle and positive controls were conducted concurrently.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	>5000	-	>5000	negative
Test 2	-	>5000	>5000	negative
<i>Present</i>				
Test 1	>5000	-	>5000	negative
Test 2	-	>5000	>5000	negative

Remarks - Results

CONCLUSION The test substance (notified polymer at up to 35%) was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BioReliance (2008)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 1 (40% solids)
METHOD	US EPA EG-9 Fish Acute Toxicity Test – Static (1982).
Species	<i>Pimephales promelas</i> (fathead minnow)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	65 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks – Method	A definitive test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol. The concentrations in the table below were adjusted to take into consideration the concentration of the analogue in solution (40%).

RESULTS

Concentration mg solids/L <i>Nominal</i>	Number of Fish	Mortality			
		24 h	48 h	72 h	96 h
Control	20	0	0	0	0
125.2	20	0	0	0	0
250	20	0	0	0	0
500	20	0	0	0	0
1000	20	0	0	0	0
2000	20	0	0	0	0

LC50	> 2000 mg/L at 96 hours.
NOEC	2000 mg/L at 96 hours.
Remarks – Results	The dissolved oxygen content decreased below 60% saturation at 96 hours in the highest test concentration. This was not considered to affect the results of the test as no mortality was observed in the controls or any test concentration over the duration of the test. Further, as there was no mortality, a qualified median lethal concentration (LC50) could not be determined. The concentration of the test substance in test solutions was not verified over the duration of the test. Thus, the above results are based on the nominal concentration of the test substance corrected for solids content.

CONCLUSION	Analogue 1 and, by inference, the notified polymer are not harmful to fish.
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TEST FACILITY	Haskell (1990)
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B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Product similar to Capstone® FS-81 (30.2% solids)
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test Test – Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	119-122 mg CaCO ₃ /L
Analytical Monitoring	High performance liquid chromatography with detection by mass spectrometry (limit of detection: 0.4 mg/L; limit of quantitation: 2.49 mg/L).
Remarks - Method	After a range finding test, a definitive limit test, with a nominal

concentration of 36.2 mg/L (solids), was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol. The concentrations in the table below are corrected for the concentration of the notified polymer in the test substance.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	Not detected	20	0	0
36.2	36.0	20	0	0

LC50 > 36.2 mg/L at 48 hours
 NOEC 36.2 mg/L at 48 hours
 Remarks - Results The validity criteria were met. No immobilisation was observed in the dilution water control or tested concentration. The above results are based on the nominal concentration of the notified polymer in the test substance.

CONCLUSION The notified polymer is not expected to be harmful to aquatic invertebrates.

TEST FACILITY DuPont (2008j)

B.1.3. Algal growth inhibition test

TEST SUBSTANCE Analogue 1 (40% solids)

METHOD Based on US EPA 40 CFR Part 797 (1987).

Species *Selenastrum capricornutum* (green algae)

Exposure Period 96 hours

Concentration Range Nominal: 126, 250, 500, 1000, 2000 mg/L

Actual: not determined

Auxiliary Solvent None

Water Hardness 14.7 mg CaCO₃/L

Analytical Monitoring None

Remarks - Method After a range finding test, a definitive test was conducted in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol.

The 96-hour test was conducted under static conditions using sterile enriched media as the dilution medium. A dilution water control was run in conjunction with 5 test concentrations (in triplicate) in a geometric series with a factor of 2.

Test conditions were: 23.2 °C to 24.2 °C; pH 7.5 to 9; 24 hour light photoperiod; 24 µE/m².s; initial cell density 10 000 cells/mL; shaking speed 100 rpm.

The concentration range was adjusted to take into consideration the concentration of the analogue in solution (40%).

RESULTS

<i>E_rC50</i> mg/L at 96 h	<i>E_rC10</i> mg/L at 96 h
> 2000	> 2000

Remarks - Results Water quality parameters were within acceptable limits for the tested

species. In the controls, exponential growth was maintained over the first 72 hours of the test and cells counts increased by at least a factor of 100 over 96 hours. The concentration of the test substance in test solutions was not verified.

Statistical methods were not used to interpret the results because cell growth at the highest test concentration was greater than 50% of control growth. Determination of the median effect concentration (E_rC_{50}) and was by inspection of the percent of control growth data. The above results are based on the nominal concentration of the test substance corrected for solids content.

CONCLUSION

Analogue 1, and by inference the notified polymer, is not harmful to algae.

TEST FACILITY

Resource Analysts, Inc (1991)

APPENDIX C: TOXICOLOGY OF PERFLUOROHEXANOIC ACID (PFHxA)

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

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

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

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

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

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

- The acute toxicities of PFHxA and PFOA were low.
- No data were available to compare eye and skin irritation or sensitisation.
- In 90-day repeat dose studies in rats, 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).

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