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

PUBLIC REPORT

Polyfluorinated Side-Chain Polymer ELN101570-18 in Capstone® FS-22

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1539	The Chemours Company (Australia) Pty Ltd	Polyfluorinated Side-Chain Polymer ELN101570-18 in Capstone® FS-22	Yes	< 10 tonnes per annum	Component of paints, oilfield well additives and explosives

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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Toxicity (Category 2)	H330 – Fatal if inhaled
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

- R26 Very toxic by inhalation
- R38 Irritating to skin
- R43 May cause sensitisation by skin contact

Human health risk assessment

Provided that the recommended controls are being adhered to, 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

- The notified polymer should be classified as follows:
 - Acute toxicity (Category 2): H330 – Fatal if inhaled
 - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

Health Surveillance

- As the notified polymer is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

(Material) Safety Data Sheet

- The (M)SDS for products containing the notified polymer should include the following warnings:
 - Avoid breathing of vapours and mists
 - May be harmful 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 as introduced or in formulated products:
 - Enclosed, automated processes, where possible
 - Adequate ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced or in formulated products:
 - Avoid breathing of vapours and mists
 - Maintain good hygiene practices
 - Avoid contact with skin and eyes
 - Avoid inhalation of aerosols
- 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:
 - Impervious 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 MSDS 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 must 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 when used in oilfield wells, 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.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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 chemical;
 - the polymer has a number-average molecular weight of less than 1000 Da;
 - the use changes from a component of paint and film additive, oilfield well additive and explosives products;

- 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;
- the chemical will be used in products that are intended to be sprayed.

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of paints, oilfield well additives and explosives, 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;
 - 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 safe use of the notified polymer were carried out by NICNAS and the Department of the Environment.

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

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: chemical name, other names, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants, import volume and use details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting/boiling point, vapour pressure, flash point flammability, autoignition temperature, hydrolysis as a function of pH, soil adsorption/desorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, China, Taiwan, Europe

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Capstone[®] FS-22 (up to 35% notified polymer)
ELN101570-18

MOLECULAR WEIGHT

$M_n > 10,000$ Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

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

DEGREE OF PURITY $> 90\%$

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: yellow liquid

Property	Value	Data Source/Justification
Boiling Point	Not determined	Expected to be high based on the high molecular weight
Density	1180 kg/m ³	Measured
Vapour Pressure	$< 1.3 \times 10^{-9}$ kPa	Estimated based on the NAMW $> 1,000$ Da (US EPA, 2007).
Water Extractability	3.7 % at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2} > 1$ year at 25 °C, pH 4 to 9	Measured
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, 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.
Particle Size	Effective diameter = 100.2 nm (in dispersion) Polydispersity = 0.15	Measured
Flash Point	Not determined	Expected to be high based on the partial fluorination and the expected low vapour pressure.
Flammability	Not determined	Not expected to be flammable based on the partial fluorination.
Autoignition Temperature	Not determined	Not expected to autoignite based on the partial fluorination.
Explosive Properties	Not expected to be explosive	Contains no explosives.
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. The notified polymer will be imported into Australia at concentrations up to 35%.

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, Brisbane

IDENTITY OF RECIPIENTS

The Chemours Company (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING

The product containing the notified polymer (up to 35% concentration) will be imported by sea in 3.79 kg, 24.64 kg or 1299.76 kg steel 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 (ie. existing polymer). The use categories of the notified polymer are identical to those of the existing polymer it replaces, as outlined below. The proportion of the introduction volume of notified polymer for each use is also noted.

- An oil and water repellent additive for paints and films (< 61%):

- Films (< 1%)
- Paints (industrial) (35%)
- Paints (commercial) (23%)
- Paints (domestic) (< 2%)

- An oilfield well foaming additive (18%)

- Explosives (22%)

OPERATION DESCRIPTION

Paint and film additive use

Manual decanting of the product containing the notified polymer at up to 35% concentration may occur during paint/film 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 1% 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 films containing the notified polymer (up to 1% 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 pad application.

Oilfield well additive

At the drilling site, workers will manually empty the contents (containing the notified polymer at up to 35%) from steel drums and combine with other ingredients into a drilling fluid solution. The drilling fluid will be circulated through the wellbore as the wellbore will be drilled during underbalanced drilling of a small portion of the overall well depth (well below the ground surface). The closed circulation path will extend from the surface of the wellhead down through the drill pipe string to the drilling face and back up through the annular space between the drill pipe string and the wellbore face to the surface. The notified polymer will come into contact with the formation stone substrate but tends to stay in the drilling fluid. Following circulation back to the surface, the drilling fluid will go through a separation system before being circulated back down through the drill pipe string.

Once the underbalanced drilling is complete, the remaining drilling fluid with some formation fluid will come back out of the well hole and into the separation system. Any gas that is obtained will be taken off, recovered and used. The rock cuttings will be removed from the drilling fluid through a vortex system and then disposed of in a landfill. The oil, water, condensate and drilling fluid will be separated by removing the water from the hydrocarbon liquids. The water will be taken to a wastewater treatment plant and the hydrocarbon liquid (expected to contain the notified polymer) will be taken to a refinery and placed in refinery crude storage with other hydrocarbon liquids.

Explosives

Formulation of the final explosive emulsions involves blending fuel oil containing the notified polymer with

concentrated aqueous ammonium nitrate solution to produce a stable water in oil emulsion containing the notified polymer (up to 1% concentration). The finished explosive will be stable unless detonated.

The notified polymer as a mineral oil solution will be transported to batching plants operated by various contracting companies at a number of locations at or near mines throughout Australia. The process would usually involve pumping the imported product containing the notified polymer at up to 35% from the drums or bulk containers (which are stored in banded areas) to a blending tank where it is mixed with fuel oil and other additives. This would then be transferred to a second blending tank where the explosive emulsion is produced by blending the fuel oil mixture (containing the notified polymer) with a concentrated aqueous solution of ammonium nitrate. The blended explosive emulsion will be transported to the blast site by dedicated tanker truck. Short term storage of blended explosives may occur. The emulsions will be poured into bore holes, which are typically 5-23 cm wide and 6-8 metres deep in quarries, or 25-38 cm in diameter and 12-18 metres deep in open pit mines. These dimensions correspond to hole (and hence explosive) volumes of 0.012 m³ to 2.04 m³. The explosive is detonated using a blasting cap. During the explosion, the notified polymer will be destroyed completely.

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 imported products (up to 0.1%) or in end-use products (up to 0.005%).

The notified polymer is a potential precursor for PFHxA 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 exposure is not likely based on the expected low vapour pressure of the notified polymer and because aerosols are not expected to be generated 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 1% concentration) is expected to be the main route of exposure during paint application with expected PPE in use. Professional painters may be exposed on a repeated basis.

Oilfield

At the end-use sites, dermal, ocular and inhalation exposure of workers to the notified polymer (at concentrations up to 35%) may occur during manual handling of the product and mixing processes. Such operations will be performed in well ventilated areas and it is expected that workers will wear skin, eye and respiratory protection, further reducing exposure to the notified polymer. Worker exposure to drilling fluid containing the notified polymer (concentration is unknown; however, it is expected to be low) may also occur after drilling, when the fluid is returned to the surface for disposal.

Explosive

No details of the number and category of workers were supplied by the notifier. From the details provided, it is evident that one or several workers at each of a large number of sites will be involved in blending explosives and pouring the mixture into bore holes. A large number of transport and storage workers may also be involved in the distribution of the notified polymer.

Transport and storage workers will handle sealed containers of the notified polymer solution, or, in the case of bulk shipments, may be involved in filling and emptying road tankers. If the notified polymer is handled in sealed containers, no exposure of these workers is expected. Tanker drivers may be exposed to drips and spills of the solution of the notified polymer while connecting and disconnecting transfer hoses.

Explosive formulation workers will transfer the notified polymer solution (containing the notified polymer at up to 35%) into blending containers by a variety of means, depending on the storage systems at the individual sites and the quantities involved. There may be widespread dermal exposure and possible accidental ocular exposure depending on the type of transfer operation used. The notified polymer will comprise a low proportion of the finished emulsion (< 1%) and the likelihood of exposure will therefore be reduced following explosives formulation.

The notifier states that workers will wear protective aprons, neoprene or nitrile gloves and boots, also long sleeved shirts and safety glasses, as appropriate.

6.1.2. Public Exposure

Paints containing the notified polymer (up to 1% concentration) will be used by the public. Dermal and ocular exposures may occur when applying paints by brush or roller. 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.

Members of the public are not likely to be exposed to the notified polymer when it is used by workers in the mining and explosive industry.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B. The toxicology studies were conducted on a formulation containing the notified polymer at approximately 30% concentration.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity (2 studies)	LD50 > 5000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	0.054-0.54 mg/L/4 hours (total aerosol concentrations); very toxic
Rabbit, skin irritation	mildly irritating
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation (2 studies)	slightly irritating
Mouse, skin sensitisation – Local lymph node assay (2 studies)	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
<i>In Vitro</i> Skin Sensitisation	weak sensitiser
Mutagenicity – bacterial reverse mutation (2 studies)	non mutagenic

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 (< 1000 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 (approximately 30% concentration) was of low acute oral toxicity in rats. The notified polymer (approximately 30% concentration) was very toxic in an acute inhalation study in rats.

Irritation

The notified polymer (approximately 30% concentration) produced skin irritation effects in rabbits (2 studies). The observed effects warrant classification as a skin irritant according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] in one study. However, according to the GHS these effects are considered mildly irritating, though are not sufficient for classification. The notified polymer (approximately 30% concentration) was found to be a slight eye irritant in rabbits (2 studies).

Sensitisation

The notified polymer (approximately 30% concentration) was a skin sensitizer in two LLNA studies. In the third LLNA study, the notified polymer (approximately 30% concentration) was found not to be a skin sensitizer. In an *in vitro* skin sensitisation study, the notified polymer was found to be a weak skin sensitizer.

Mutagenicity

The notified polymer (approximately 30% concentration) was negative in a bacterial mutation assay (2 studies).

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 table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Toxicity (Category 2)	H330 – Fatal if inhaled
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

- R26 Very toxic by inhalation
- R38 Irritating to skin
- R43 May cause sensitisation by skin contact

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 breakdown products are generally less favourable compared to the short chain breakdown products, with properties becoming less favourable with increasing perfluoroalkyl carbon chain length. In addition, it has been established that the bioaccumulation potential of perfluorocarboxylic acids increases with perfluoroalkyl carbon chain length (Conder *et al.*, 2008; Giesy *et al.*, 2010).

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is expected to be very toxic if inhaled, an irritant and a sensitiser to the skin and it is slightly irritating to eyes. The notified polymer as imported (up to 35% concentration) is very toxic by the inhalation route; however, inhalation toxicity is not of concern during reformulation as aerosols will not be generated. Automated processes are expected to be in place and PPE (clothing, gloves and goggles) will be worn during many of these occupational processes, thus the risk of skin and eye irritation and/or skin sensitisation to reformulation workers is not considered to be unreasonable.

Repeated dermal exposure to the notified polymer may occur during formulation and paint applications (the exposure will be less frequent in oilfield or explosive 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 ($> 10,000$ Da) of the notified polymer and the low proportion ($< 1\%$) of low molecular weight ($< 1,000$ Da) species. Systemic exposure of workers to breakdown 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 ($< 1\%$). 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.

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 1% concentration) and relatively low levels of perfluoroalkyl impurities ($< 0.2\%$) will be available to the public. Paint products will be applied by brush and roller. Public exposure is likely to be less frequent than professional exposure. The risk to public health from use of paints containing the notified polymer is not considered to be unreasonable based on the low concentration (up to 1%) of the polymer in final paint products, and the expected pattern of exposure.

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 of the notified polymer to the environment are not expected from this activity. Accidental spills of notified polymer during import, transport or storage are 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 processes to produce paints and films. Up to 1.21% (121 kg) of the total import volume of the notified polymer is estimated to be released into wastewater as a result of rinsing empty import containers, mixing equipment, transfer lines and filling machines. Wastewater containing the notified polymer may be re-used as the water diluent phase in subsequent reformulation activities. Alternatively, wastewaters may be disposed of through a waste disposal company and be eventually discharged to sewers.

RELEASE OF CHEMICAL FROM USE

The notified polymer is intended to be used as an additive for paints and films, a foaming additive in oilfield wells and an explosive additive.

Paint and film additive use (60% of the total import volume)

Paints and films containing the notified polymer will be used by both the Do-It-Yourself (DIY) consumers and professional painters. The products containing the notified polymer are expected to be applied to substrates by a variety of methods including brush, roller or paint pads. Spills and drips during use are expected to be collected by coverings and be disposed of to landfill. It is assumed that 5% of the notified polymer may be released to sewers from cleaning of the application tools. Therefore, up to 3% ($= 60\% \times 5\%$) of the annual import volume of the notified polymer, equivalent to 300 kg per annum ($= 3\% \times 10 \text{ tonnes/year}$), is estimated to enter wastewater streams due to its use as paints and films. Wastewater containing the notified polymer released to sewers is expected to be treated at sewage treated plants (STPs). Any notified polymer removed from wastewater during treatment is expected to be collected and disposed of to landfill. Notified polymer remaining in aqueous streams may be released to surface waters.

Oilfield well additive (18% of the total import volume)

The notified polymer will be used in oilfield wells for on-shore and off-shore drilling operations. During oil well drilling operations, drilling mud containing up to 0.2% of the notified polymer will be pumped down the drill shaft during the drilling of deep wells. The drilling fluids will be circulated through the wellbore as the wellbore is drilled. The notified polymer will come into contact with the formation stone substrate but tends to stay in the drilling fluid. The drilling mud will eventually be pushed out of the well and transferred to the surface separation systems. The rock cuttings will be removed from the drilling fluid and is expected to be disposed of to landfill for the on-shore applications and to the ocean for the off-shore applications. The oil, water, condensate and drilling fluid will be separated by removing the water from the hydrocarbon liquids. The water phase will be directed to a wastewater treatment plant and the hydrocarbon liquid phase (expected to contain the majority of the notified polymer) will be taken to a refinery and placed in refinery crude storage with other hydrocarbon liquids.

After separation, the drill cuttings are estimated to contain up to 5% entrained drilling mud, based on the literature value of 5% for modern practices (Oil & Gas Producers, 2003). Although it is possible for cuttings to be re-injected into the well or collected for re-use as general fill, it would appear that this is not generally practiced in Australia. Consequently, in the case of off-shore drilling, the cuttings (and the entrained mud) will be discharged into the ocean. As the percentages for on-shore and off-shore applications were not indicated by the notifier, for the worst case, it is assumed all of the notified polymer used in oilfield applications (18% of the total import volume) will be used off-shore. Therefore, up to 90 kg of the notified polymer that is used in drilling fluids ($= 10 \text{ tonnes/year} \times 18\% \times 5\%$) may be released into the ocean with drill cuttings during drilling operations off-shore.

Explosives additive (22% of the total import volume)

The product containing the notified polymer will be used as a component in an explosive emulsion for down-hole applications in the mine field. The notified polymer is expected to be destroyed on detonation and no significant release of the notified polymer to the environment is expected from this application.

RELEASE OF CHEMICAL FROM DISPOSAL

Paints and films containing the notified polymer are expected to be applied predominantly to polyurethane, masonry, concrete, stone, plasterboard and timber articles. The notified polymer applied to substrates is expected to adhere to the surface to which it has been applied. The notified polymer that remains associated with the painted articles is expected to share the fate of these articles. The majority of these articles and other dried paint residues are expected to ultimately be disposed of to landfill.

After the completion of drilling operations off-shore, the used drilling mud along with the drilling cutting containing residues of the notified polymer may be discharged into the ocean. Notified polymer associated with

drill cuttings and drilling mud is expected to be disposed of in landfill for the on-shore operations.

Residues remaining in empty containers are expected to be rinsed with water and be discarded to site wastewater or sewers. Empty containers are expected to be sent to landfill via waste collection services.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the introduced notified polymer is expected to be used as an additive in paints and films and consequently, most of the notified polymer is expected to form an inert polymeric matrix adhering to articles following its use. Coated 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.

Notified polymer in rock cuttings and drilling mud is expected to be disposed of to landfill for on-shore applications and directly to ocean for off-shore applications. Notified polymer remaining in the drilling fluids is expected to predominantly partition to hydrocarbon liquid phase. The hydrocarbon liquids phase will be taken to a refinery and placed in refinery crude storage with other hydrocarbon liquids. The notified polymer may either be removed during oil refining and remain in the distillation residues/tar fraction that will be most likely used as road base, or share the fate of the oil product to be eventually thermally decomposed during use. The water phase containing small amounts of the notified polymer is expected to be directed to a wastewater treatment plant (WTP).

The notified polymer used as an explosive is expected to be destroyed on detonation.

Some of the notified polymer is expected to be disposed of to sewers and waste treatment plants as a result of reformulation, use and disposal. Non-ionic polymers with a molecular weight of more than 1000 Da are generally considered to be efficiently removed in treatment plants 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 effluent directly to surface waters or reused in the irrigation of agricultural soils throughout Australia.

The hydrolysis results of Analogue 1 ($t_{1/2} > 1$ year at 25 °C, pH 4 to 9) indicate that the notified polymer is expected to be hydrolytically stable under environmental conditions. Analogue 1 and the notified polymer contain similar functional groups and are expected to have similar chemical-physical properties. Therefore, the analogue data is expected to be representative of the notified polymer for its hydrolysis profile. Investigations of the biodegradation potential of fluoroacrylate polymer and fluorotelomer-based urethane polymer in aerobic soils (Russell *et al.*, 2008; Russell *et al.*, 2010; Washington *et al.*, 2009) indicate very limited degradation of the fluorinated polymers. Biodegradation of the backbone of the notified 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 degradation product, 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 compounds 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 at lower temperatures should only take place at facilities that completely combust 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 perfluoroalkylated compounds, which PFHxA- chemistry is replacing (although PFHxA and PFOA are not considered bioaccumulative). However, both are bioavailable and can be detected in wildlife as demonstrated by monitoring studies (Kumar *et al.*, 2009; Ye *et al.*, 2008a; Ye *et al.*, 2008b; Wang *et al.*, 2008). In general, the available evidence indicates that the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy *et al.*, 2010). Therefore, PFHxA has a lower bioaccumulation potential than PFOA and other long chain perfluoroalkyl substances.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentrations (PECs) due to releases of the notified polymer from its use for off-shore oil/gas applications have been calculated based on the CHARM Model (Thatcher *et al.*, 2005). The PEC due to the release of the notified polymer from its reformulation and use as paints and coatings are calculated using an in-house STP Model. The cumulative worst-case PECs for river and ocean were determined to be 2.47 µg/L and 250.25 µg/L, respectively. For the details of the calculations, please refer to the Appendix C.

<i>Predicted Environmental Concentration (PEC) for release to the aquatic compartment</i>		
PEC – River	2.47	µg/L
PEC – Ocean	250.25	µg/L

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 substances will become a significant source of persistent poly- and perfluoroalkyl substances in the environment in the future. PFHxA is already being detected in the environment and, as the long chain poly- and perfluoroalkyl substances are phased out in preference for short-chain polyfluoroalkyl chemistry containing a six-carbon perfluorohexyl moiety, the environmental levels of PFHxA are expected to increase.

Half-lives of polyfluoroalkyl polymers in aerobic soil have been found to be indeterminate with calculated half-lives ranging from decades to millennia (Russell *et al.*, 2008; Russell *et al.*, 2010; Washington *et al.*, 2009). The half-lives of PFHxA in various environmental media are also unknown and its partitioning behaviour is uncertain. 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 polymer and Analogue 2 are summarised in the table below. Analogue 2 and the notified polymer are likely to have similar toxicological properties based on their similar structures. Therefore, the results from fish obtained for the Analogue 2 are expected to be representative of the notified polymer. Details of these studies can be found in Appendix D.

<i>Endpoint</i>	<i>Result (mg/L)</i>	<i>Assessment Conclusion</i>
Fish Toxicity (Analogue 2)	96 h LC50 = 500 – 5000	Not harmful to fish
Daphnia Toxicity 1	48 h EC50 > 24	May be harmful to aquatic invertebrates
Daphnia Toxicity 2	48 h EC50 > 115	Not harmful to aquatic invertebrates

Based on the result “daphnia toxicity 1” (48 h EC50 > 24 mg/L), the notified polymer is considered to be potentially harmful to aquatic invertebrates. However, this test was conducted where the highest test concentration for the notified polymer was 24 mg/L. There were not immobilisation nor any sublethal effects observed at any of the test concentrations. The exact EC50 value was unable to be derived. In the most recent test conducted on daphnia (48 h EC50 > 115 mg/L), the highest test concentration for the notified polymer was increased to 115 mg/L and no immobilisation or sublethal effects were observed at any of the test concentrations. Therefore, it is reasonable to conclude that the 48-hour median effect concentration (immobilisation) for daphnia is EC50 > 115 mg/L. On this basis, the notified polymer is not considered to be harmful to aquatic invertebrates under the Globally Harmonised System of Classification of Chemicals (GHS, 2009).

Based on the analogue data, the notified polymer is considered potentially harmful to fish. However, as the test was conducted on a product containing the analogue polymer at < 20%, it is not possible to determine what the effects of the analogue polymer are. Therefore, the notified polymer is not formally classified under the GHS for its acute hazard. Polymers without significant ionic functionality are generally of low concern to the environment. As limited toxicity data is available for the notified polymer, it has not been classified under the GHS for its 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 adequately established and is unknown.

7.2.1. Predicted No-Effect Concentration

The lower limit of the endpoint determined for fish on Analogue 2 (96 h LC₅₀ > 50 mg/L) was used to calculate the Predicted No-Effect Concentration (PNEC) as it represents the most sensitive ecotoxicological endpoint. Although only acute endpoints for daphnia are available for the notified polymer, the analogue data for fish is expected to be representative of the notified polymer based on their structure similarity. Furthermore, the available measured ecotoxicity endpoints for other polyfluoroalkylated polymers indicate that daphnia and fish represent the more sensitive species. Therefore, an assessment factor of 100 was used for the PNEC calculation.

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

EC ₅₀ (Fish)	> 50	mg/L
Assessment Factor	100	
PNEC:	> 500	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	2.47	> 500	< 0.005
Q - Ocean	250.25	> 500	< 0.5

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 perfluorinated 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 perfluorinated 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: PHYSICAL AND CHEMICAL PROPERTIES

Density 1180 kg/m³

Method After the notified chemical (2.35 g) was dropped into 10 mL of water in a graduated cylinder, the meniscus rose to 12 mL. Therefore, the density is calculated to be 1.18 g/mL = 2.35 g ÷ 2 mL.

Water Extractability ~3.7% extractability at 20 °C

Method In house method
 Remarks Flask Method. Water (45 g) was added to 5g of notified polymer. The mixture was stirred for 2 hours and filtered. The solid percentages in the solution were measured using a moisture analyser and an oven test, respectively. The resulting % solid was reported to be < 0% using the moisture analyser method and was calculated to be 0.415%, on average, using the oven test.
 Test Facility DuPont (2011)

Hydrolysis as a Function of pH $t_{1/2} > 1$ year at 25 °C, pH 4, 7 and 9

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2} year
1.2	25	> 1
4	25	> 1
7	25	> 1
9	25	> 1

Remarks The test substance is Analogue 1. The hydrolysis of the test substance was monitored by determining the increase of a degradant “Telomer B Alcohol” (TBA) in solution, instead of by measuring the decrease of the test substance. The observed increase of TBA was approximately two orders of magnitude lower than the concentration of TBA expected if 10% of the test substance hydrolysed. The test substance obtained < 10% hydrolysis over 5 days at 50 °C and therefore is considered to be hydrolytically stable at the test conditions.

The hydrolysis of the test substance may not be accurately determined based on the increase of the degradant TBA as TBA may not be the unique degradant when the test substance hydrolyses.
 Test Facility Dupont (2003a)

Particle Size Effective diameter = 100.2 nm (in dispersion)
 Polydispersity = 0.15

Method Light scattering
 Test Facility Unspecified (2008)

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

TEST SUBSTANCE	Notified polymer (at approximately 31.96%)
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Crl:CD(SD)
Vehicle	Test substance administered as supplied
Remarks - Method	No protocol deviations.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	No clinical signs were observed in rats from the three lower dose groups.
	In the 5000 mg/kg dose group ataxia, dehydration, hair loss, lethargy, decreased muscle tone, lacrimation, ocular discharge, and/or high posture were observed. No clinical signs were observed after test day 3 except for hair loss.
Effects in Organs	No test substance-related gross lesions were found in the study.
Remarks - Results	No test substance-related or biologically relevant body weight losses occurred in the rats.

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

TEST FACILITY DuPont (2010a)

B.2. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Sprague-Dawley derived, albino.
Vehicle	Test substance administered as supplied
Remarks - Method	No protocol deviations.

RESULTS

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

LD50	> 5000 mg/kg bw
Signs of Toxicity	All animals gained body weight and appeared active and healthy during the study.
Effects in Organs	No gross abnormalities were noted for any of the animals when they were necropsied at the conclusion of the 14-day observation period.
Remarks - Results	No signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour were noted.

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY Eurofins PSL (2009a)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))

METHOD OECD TG 436 Acute Inhalation Toxicity – Acute Toxic Class Method.
 Species/Strain Rats/Crl:CD(SD)
 Vehicle None
 Method of Exposure Oro-nasal exposure.
 Exposure Period 4 hours
 Physical Form Liquid aerosol
 Particle Size MMAD (GSD) = 3.4 – 2.6 (2.3 – 1.9) range across all dose groups.
 Remarks - Method No protocol deviations
 Due to male animals appearing to be more susceptible during the initial two test, a further two tests were undertaken using only male animals.

RESULTS

Group	Number and Sex of Animals	Concentration <mg/L>	Mortality
1	3 per sex	0.58 ± 0.099	2/6
2	3 per sex	1.4 ± 0.14	3/6
3	6 M	0.054 ± 0.0075	0/6
4	6 M	0.54 ± 0.26	3/6

LC50 0.054 - 0.54 mg/L/4 hours (total aerosol concentrations)

Signs of Toxicity In group 1 no abnormalities were detected among the animals until the 4th hour of exposure, at which time they showed no response to sound stimulus. Signs of toxicity following exposure included laboured breathing, low posture, red nasal discharge and facial stains, lethargy, and brown stains in the perineum region. One male died on post-exposure day 1 and a second male on day 2. The surviving rats lost body weight on days 1 and 2 and gained weight thereafter.

In group 2 no response to sound stimulus started to occur from 2 hours onwards. Clinical signs of toxicity observed in males and females included abnormal gait, laboured breathing, breathing with lung noise, red nasal and oral discharge, lethargy, and brown stains in the perineum region. One male was found dead on the same day of the exposure and another male on post-exposure day 1. The remaining male lost 10% of its body weight, displayed laboured breathing and red nasal discharge, and was also found dead on day 1. All females lost < 11% of their body weight each day on days 1 and 2 and gained weight thereafter.

In group 3 all six male rats displayed normal startle responses during the exposure, increased their bodyweights and showed no clinical signs during the 14-day recovery period.

In group 4 after 2 hours of exposure, 4 of 6 male rats had no response to sound stimulus increasing to all rats at the end of the 4 hour exposure. Laboured breathing, high posture, red nasal and oral discharge, and/or lethargy were observed following exposure. One rat was found dead on the same day after exposure and the other 2 on post-exposure day 1. The surviving 3 males lost 4.0-12 % of their body weight each day on days 1 and 2 and demonstrated body weight gains thereafter.

Effects in Organs Gross discoloration of the lungs was present in males exposed to concentrations of 0.54 mg/L or higher, and in females in group 2. Nasal

haemorrhage was observed in one male rat in each of groups 1 and 4, and a large liver in one male rat in group 2. No gross lesions were observed in the male rats in group 3 or the female rats in group 1.

CONCLUSION

The notified polymer is very toxic via inhalation.

TEST FACILITY

DuPont (2013)

B.4. Irritation – skin

TEST SUBSTANCE

Notified polymer (31.96%)

METHOD

OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain

Rabbit/New Zealand White

Number of Animals

1 M, 2 F

Vehicle

Test substance administered as supplied

Observation Period

14 days

Type of Dressing

Semi-occlusive.

Remarks - Method

No protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	2	2.3	2	3	< 14 days	0
<i>Oedema</i>	1	1	1.3	2	< 10 days	0

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

Remarks - Results

All animals gained body weight during the study.

Erythema (scores of 1, 2 and 3) and oedema (scores 1 and 2) were observed on all three rabbits until day 7 with symptoms persisting in one rabbit until day 10. Hyperkeratosis and desquamation became apparent between 72 hours and day 14. Apart from desquamation all animals were free from dermal irritation by study termination (day 14).

CONCLUSION

The test substance is slightly irritating to the skin.

TEST FACILITY

Eurofins PSL (2010a)

B.5. Irritation – skin

TEST SUBSTANCE

Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))

METHOD

OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain

Rabbit/New Zealand White

Number of Animals

1 M, 2 F

Vehicle

Test substance administered as supplied

Observation Period

7 days

Type of Dressing

Semi-occlusive.

Remarks - Method

No protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0.3	2	1	2	< 7 days	0
<i>Oedema</i>	0	1	0	1	< 7 days	0**

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

**Desquamation was present at dose site.

Remarks - Results All animals gained weight during the study, with no signs of gross toxicity, adverse pharmacologic effects, or abnormal behaviour.

Very slight to well-defined erythema and/or very slight oedema were noted for all three treated dose sites within 24-hours after patch removal. The overall incidence and severity of irritation decreased with time. Apart from desquamation, which was present at one site at 48 and 72 hours and at the other two sites on day 7, at the dose site, all animals were free from erythema and oedema by day 7.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Eurofins PSL (2009b)

B.6. Irritation – eye

TEST SUBSTANCE Notified polymer (31.96%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 F
Observation Period Up to 7 days
Remarks - Method No protocol deviations.

RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	Animal No.	1	2			
Conjunctiva: redness	1	0.7	1	2	< 7 days	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	2	1.7	1.7	2	< 7 days	0
Corneal opacity	0	0	0	1	< 24 hours	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results All animals gained weight during the study.

Scattered or diffuse corneal opacity was noted in one treated eye at one hour post-instillation. Conjunctival redness (scores 1 and 2), chemosis (score of 1) and discharge (scores of 1 and 2) were observed in the treated eyes of all rabbits. All animals were free of ocular irritation by day 7.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Eurofins PSL (2010b)

B.7. Irritation – eye

TEST SUBSTANCE Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 2 M, 1 F
Observation Period 72 hours
Remarks - Method No protocol deviations

RESULTS

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

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

Remarks - Results

All animals gained weight during the study, with no signs of gross toxicity, adverse pharmacologic effects, or abnormal behaviour.

There was no corneal opacity or iritis noted in any treated eye during the study. One hour after test substance instillation, all three treated eyes exhibited conjunctivitis (redness and discharge). All animals were free of ocular irritation by the 24 hour observation.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

Eurofins PSL (2009c)

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

TEST SUBSTANCE

Notified polymer (31.96%)

METHOD

OECD TG 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain

Mouse/CBA/JHsd

Vehicle

Acetone:olive oil (4:1)

Remarks - Method

No protocol deviations.

RESULTS

<i>Concentration</i> <i>(% w/w)</i>	<i>Proliferative response</i> <i>(DPM/lymph node)</i>	<i>Stimulation Index</i> <i>(Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	534.35 ± 142.88	-
5	425.55 ± 340.99	0.80
25	931.15 ± 192.82	1.74
50	1734.75 ± 376.08	3.25
100	1726.55 ± 785.12	3.23
<i>Positive Control (hexyl cinnam aldehyde)</i>		
25	4201.55 ± 1972.60	7.86

Remarks - Results

There were no test substance-related effects on body weights. Hair loss was observed in 3/5 mice treated at 50% concentration and 5/5 mice treated with 100% concentration.

The test system was valid for this study with a 25% concentration of the positive control producing a dermal sensitisation response in mice.

The EC3 value for the test substance under the conditions of this study was calculated by the study authors to be 46%.

CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.

TEST FACILITY DuPont (2010b)

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

TEST SUBSTANCE Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))

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

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	1192.05 ± 555.29	-
5	874.85 ± 570.86	0.73
25	1259.45 ± 726.67	1.06
50	3580.45 ± 1643.16	3.00
100	7344.45 ± 2292.90	6.16
<i>Positive Control (hexyl cinnamaldehyde)</i>		
25	4541.45 ± 2262.73	3.81

Remarks - Results There were no test substance-related effects on body weights. Hair loss of the neck was observed in all mice treated with 100% concentration on test days 1, 2 and 5.

The test system was valid for this study with a 25% concentration of the positive control producing a dermal sensitisation response in mice.

The EC3 value for the test substance under the conditions of this study was calculated by the study authors to be 50%.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

TEST FACILITY DuPont (2009a)

B.10. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer (35.37% partially fluorinated acrylic co-polymer)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
 Species/Strain Mouse/CBA/JHsd
 Vehicle Acetone : olive oil (4:1)
 Remarks - Method No protocol deviations
 Each of the test groups used 5 animals.

RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control)	740.40 ± 101.25	-
5	946.80 ± 544.39	1.28
25	760.60 ± 499.90	1.03
50	615.40 ± 164.19	0.83
100	1081.00 ± 445.09	1.46

Positive Control (hexylcinnamaldehyde)

25	3954.80 ± 1244.56	5.34
Remarks - Results	There were no test substance-related effects on body weights. Hair loss on the neck was observed in the 25% and 50% test substance groups. In the 100% test concentration group hair loss was observed on both the head and neck during the study.	
	The test system was valid for this study with a 25% concentration of the positive control producing a dermal sensitisation response in mice.	
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.	
TEST FACILITY	DuPont (2012)	

B.11. In Vitro Skin Sensitisation

TEST SUBSTANCE	Notified polymer (31.96%)
METHOD	The MatTek EpiDerm 3D skin model was used in combination with a direct reactivity test to predict the sensitisation potential.
Remarks - Method	Human reconstructed epidermis (RHE) tissues were treated with the test substance and the induction of genes were monitored. The test substance was also assayed for its ability to react with glutathione in the absence of cells. The gene induction and glutathione reactivity data were used in combination to allow a proprietary algorithm to predict a toxicity index for each substance. Cell viability was determined using a lactate dehydrogenase assay.

RESULTS

Test substance concentration (%)	Viability (%)
0.01	100.4
0.1	100.3
1	100.3
5	100.1
10	98.7
50	55.1

Remarks - Results	The toxicity index for the test substance was calculated to be 2, and under the conditions of the test method it is classed as a weak sensitiser.
CONCLUSION	The test substance was determined to be a weak sensitiser under the conditions of the test.
TEST FACILITY	CeeTox Inc. (2012)

B.12. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (31.96%)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	Plate incorporation procedure
Concentration Range in Main Test	Aroclor 1254-induced rat liver S9
Vehicle	a) With metabolic activation: 50 - 5000 µg/plate b) Without metabolic activation: 50 - 5000 µg/plate
	Acetone

Remarks - Method

Stability data were not provided for the test substance.

RESULTS

Metabolic Activation	Test Substance Concentration ($\mu\text{g}/\text{plate}$) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	> 5000	> 5000	≥ 15	negative
Test 2		> 5000	≥ 150	negative
<i>Present</i>				
Test 1	> 5000	> 5000	≥ 50	negative
Test 2		> 5000	≥ 150	negative
Test 3		> 5000	≥ 500	negative

Remarks - Results

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

No positive mutagenic responses were observed at any dose level or with any tester strain in either the absence or presence of S9 metabolic activation.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

BioReliance (2010)

B.13. Genotoxicity – bacteria

TEST SUBSTANCE

Notified polymer (24.31% fluorinated acrylic polymer (25.7% solids))

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Plate incorporation procedure

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100*E. coli*: WP2uvrA

Metabolic Activation System

Aroclor 1254-induced rat liver S9

Concentration Range in

a) With metabolic activation: 0, 333, 667, 1000, 3333, 5000 $\mu\text{g}/\text{plate}$

Main Test

b) Without metabolic activation: 0, 333, 667, 1000, 3333, 5000 $\mu\text{g}/\text{plate}$

Vehicle

Water

Remarks - Method

No protocol deviations.

A dose-finding study was conducted in the presence and absence of metabolic activation at concentrations of up to 5,000 $\mu\text{g}/\text{mL}$.

RESULTS

Metabolic Activation	Test Substance Concentration ($\mu\text{g}/\text{plate}$) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test	> 5000	≥ 5000	≥ 1000	negative
<i>Present</i>				
Test	> 5000	> 5000	≥ 1000	negative

Remarks - Results

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

No positive mutagenic responses were observed at any dose level or with

any tester strain in either the absence or presence of S9 metabolic activation.

CONCLUSION

The test substance (notified polymer, 24.31% fluorinated acrylic polymer (25.7% solids) was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

DuPont (2009b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Predicted Environmental Concentration from Use as Paints and Films

C.1.1. Predicted Environmental Concentration from Reformulation

It is estimated by the notifier that up to 121 kg of the notified polymer may be released to sewers from reformulation of the notified polymer into paints and films. For a worst case scenario, it is assumed that the reformulation activities occur 120 working days per year and there is no onsite treatment of waste water. The Predicted Environmental Concentration (PEC) due to releases from reformulation is calculated assuming a worst-case release to a single sewage treatment plant (STP) with a daily effluent flow rate of 456 ML and that there is no removal of the notified polymer during STP processes.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Annual quantity of chemical released to sewer	121	kg/year
Days per year where release occurs	120	days/year
Daily chemical release:	1.008	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Removal within STP	0%	
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	2.21	µg/L
PEC - Ocean:	0.22	µg/L

C.1.2. Predicted Environmental Concentration from Use

It is reported by the notifier that up to 60% of the total import volume of the notified polymer will be used for paints and films. It is assumed that 5% of the notified polymer may be released to sewers from cleaning of the application tools. Therefore, up to 3% (= 60% × 5%) of the annual import volume of the notified polymer is estimated to enter to wastewater streams due to its use as paints and films. Assuming a nationwide release over 260 working days per year and there is no removal of the notified polymer during STP processes, the Predicted Environmental Concentration (PEC) from use is calculated as follows:

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	3 %	
Annual quantity of chemical released to sewer	300	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.15	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
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.26	µg/L
PEC - Ocean:	0.026	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 2.47 µg/L (= 2.21 + 0.26 µg/L). Therefore, the PECs for the aquatic compartments are calculated as follows:

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

Combined effluent concentration	2.47	µg/L
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
PEC – River	2.47	µg/L
PEC – Ocean	0.25	µg/L

C.2. Predicted Environmental Concentration from Use in Oilfield Wells

After the completion of drilling operations, the drilling mud will eventually be pushed out of the well and transferred to the surface separation systems. For on-shore applications, notified polymer associated with drilling cuttings and drilling mud is expected to be disposed of to landfill. The oil, water, condensate and drilling fluid will be separated by removing the water from the hydrocarbon liquids. The water phase containing small amounts of the notified polymer will be directed to a wastewater treatment plant where the amount of the notified polymer in water column is expected to be further reduced. The hydrocarbon liquid phase, expected to contain the majority of the notified polymer, will be taken to a refinery and placed in refinery crude storage with other hydrocarbon liquids. Therefore, significant release of the notified polymer from its use for onshore applications is not expected and the PEC from this release has not been calculated.

As the percentages for on-shore and off-shore applications were not indicated by the notifier, for the worst case, it is assumed all of the notified polymer used in oilfield applications (18% of the total import volume) will be used off-shore. The PEC arising from the release of the notified polymer to sea water from offshore applications has been calculated based on CHARM modelling (Thatcher *et al.*, 2005).

The highest concentrations of drilling polymer from water-based mud that occur in the vicinity of off-shore oil and gas production facilities arise from the batch-wise discharge of drilling mud. These discharges occur when drilling mud needs to be diluted, when drilling of a section has been completed and the mud is to be changed, or when drilling at a particular well is complete and the rig is to be moved to a new location. The rate of discharge of mud in the batch-wise disposal method is much larger than the continuous discharges of mud entrained in drill cuttings produced during drilling operations. Hence, the batch-wise disposal method for used drilling mud has the potential to generate higher peak concentrations of the notified polymer in seawater in the vicinity of off-shore drilling sites than the continuous discharge of drilling mud entrained in cuttings.

In the CHARM model (Thatcher *et al.*, 2005, p. 23), the PEC for drilling polymer in seawater resulting from batch-wise discharge of water-based muds ($PEC_{water, batch} / \text{mg L}^{-1}$) is calculated using equation 1:

$$PEC_{water, batch} = \frac{M}{V_m} \times D_{batch} \times 10^3 \quad (1)$$

In this relationship,

$PEC_{water, batch}$ = PEC_{water} for batchwise discharges (mg/L);

M = Amount of the notified polymer discharged (kg);

V_m = Volume of mud discharged for the specific section drilled (m^3);

D_{batch} = Dilution factor for batch-wise discharges;

10^3 = Conversion constant to express PEC as mg/L.

The specific values for volume of mud discharged and the dilution factor have not been provided for operations under Australian conditions. Hence, the default values for V_m (375 m^3 for a 1,500 m drill length) and D_{batch} (7.7×10^{-5}) as specified in the CHARM model for the batch-wise discharge scenario have been used for this calculation (Thatcher *et al.*, 2005, p. 46).

The amount of the notified polymer discharged (M, kg) can be calculated using equation 2:

$$M = W_t \times V_m \times \rho_m \quad (2)$$

In which,

W_t = Weight percentage of the notified polymer in the mud;

ρ_m = Density of the discharged mud (kg/m^3)

The weight percentage of the notified polymer in the mud (Wt) was indicated to be $\leq 0.2\%$ by the notifier. The default values for ρ_m (1600 kg/m³ for a 1,500 m drill length) as specified in the CHARM model for the batch-wise discharge scenario have been used for this calculation (Thatcher *et al.*, 2005, p. 46). Therefore, the amount of the notified polymer discharged in a single batch of used mud is calculated to be:

$$M = W_t \times V_m \times \rho_m = 0.2\% \times 375 \times 1600 = 1200 \text{ kg}$$

Based on the worst case discharge of 1200 kg of notified polymer in a single batch of used mud, the $PEC_{\text{water, batch}}$ for the notified polymer is calculated using equation 1:

$$PEC_{\text{water, batch}} = \frac{M}{V_m} \times D_{\text{batch}} \times 10^3 = \frac{1200}{375} \times 7.7 \times 10^{-5} \times 10^3 = 0.25 \text{ mg/L} = 250 \text{ }\mu\text{g/L}$$

The PEC in ocean water due to the release of the notified polymer from its use as paints and films was calculated to be 0.25 $\mu\text{g/L}$ in Appendix C1.2. Based on the above calculations, the worst-case concentration for the notified polymer in ocean water is 250.25 $\mu\text{g/L}$ (= 250 $\mu\text{g/L}$ + 0.25 $\mu\text{g/L}$). Therefore, the PECs for the aquatic compartments are summarised as follows:

<i>Predicted Environmental Concentration (PEC) for release to the aquatic compartment</i>		
PEC – River	2.47	$\mu\text{g/L}$
PEC – Ocean	250.25	$\mu\text{g/L}$

The $PEC_{\text{water, batch}}$ calculated above is based on a theoretical worst-case in which all of the mass of notified polymer discharged with a batch of mud is present in seawater within a radius of 500 m from the discharge point. However, based on the low solubility (4.15% by weight) of notified polymer in water, a fraction of the discharged mass of the polymer is expected to remain associated with the insoluble minerals and other solids discharged overboard. This fraction of the notified polymer is therefore expected to deposit on the sea floor beneath the discharge point along with the mud and cuttings. The concentration of the notified polymer in sediment (PEC_{sediment}) was not calculated in this assessment report as there is no standard effect data to allow for determination of the corresponding risk quotient.

APPENDIX D: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

D.1. Ecotoxicological Investigations

D.1.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 2
METHOD	Not reported
Species	Fathead minnows (<i>Pimephales promelas</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks – Method	There was no full study report available. It was indicated in the provided study summary that fish were exposed to the test media under static conditions. Based on visual observations, the test substance was soluble in water at 0.5 and 1.0 mg/L. The other three higher test concentrations appeared cloudy. The study was not conducted according to formal regulatory good laboratory practices standards.

RESULTS

<i>Concentration mg/L</i>		<i>Number of Fish</i>	<i>Mortality (%)</i>
<i>Nominal</i>	<i>Actual</i>		<i>96 h</i>
control	-	Not available	0
0.50	-	Not available	0
1.0	-	Not available	0
50	-	Not available	0
500	-	Not available	0
5000	-	Not available	100

LC50 500-5000 mg/L at 96 hours.

Remarks – Results The study was not conducted according to formal regulatory good laboratory practices standards. The validity and reliability of the results is undetermined and the results should be treated with caution.

CONCLUSION The analogue polymer and, by inference, the notified polymer is not harmful to fish.

TEST FACILITY DuPont (1992)

D.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Product containing the notified polymer (24%)
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test - Static
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	100-140 mg CaCO ₃ /L
Analytical Monitoring	Not applicable
Remarks - Method	A stock solution of 100 mg/L test solution was prepared by directly adding 100 mg of the test substance into water. The lower concentrations were prepared by dilution of the stock solution. The test solutions at all nominal concentrations were clear and colourless with no visible particle present at the start of the test. The OECD test guideline was followed. There is no significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	10	1	1
0.1	-	10	0	0
1.0	-	10	0	0
10	-	10	0	0
100	-	10	0	0

EC50 > 24 mg/L at 48 hours

NOEC Not reported

Remarks - Results All validity criteria for the test were satisfied.

The actual concentrations of the active ingredient in the test media were not measured and the results above were based on the nominal concentration for the test substance. The test substance contains 24% of the active ingredient. Therefore, the EC50 was re-calculated based on the purity of the test substance. The 48 hours EC50 was originally reported to be > 100 mg/L in the test report.

No sub-lethal effects were observed in the control and in the 0.1, 1.0 and 10 mg/L test concentrations. Two floating daphnids were observed at the concentration of 10 mg/L.

CONCLUSION

The notified polymer may be harmful to aquatic invertebrates.

TEST FACILITY

Dupont (2009c)

D.1.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Product containing the notified polymer (32%)

METHOD

OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 100 - 140 mg CaCO₃/L

Analytical Monitoring Not applicable

Remarks - Method The test solutions were prepared by directly adding amounts of the test substance into water. Undissolved particles were observed in the test solutions at all nominal concentrations at the start of the test.

The OECD test guideline was followed. There is no significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	10	0	0
3.6	-	10	0	0
12	-	10	0	0
36	-	10	0	0
120	-	10	0	0
360	-	10	0	0

EC50 > 115 mg/L at 48 hours

Remarks - Results All validity criteria for the test were satisfied.

The actual concentrations of the active ingredient in the test media were not measured and the results above were based on the nominal concentrations for the test substance. The test substance contains 32% of the active ingredient. Therefore, the result for EC50 was corrected based on the purity of the test substance. The 48 hours EC50 was originally reported in the test report to be > 360 mg/L.”

One floating daphnid was observed in the control and in the 36 mg/L test solutions at the end of the test.

CONCLUSION

The notified polymer is not harmful to aquatic invertebrates

TEST FACILITY

Dupont (2010c)

APPENDIX E: 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 *et al.*, 2009a; Gannon *et al.*, 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, 2003b).
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 *et al.*, 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 *et al.*, 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 *et al.*, 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, with the NOAEL for maternal and reproductive effects being 100 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 a NOAEL of 100 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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