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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fluoropolymer in BYK-1798

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 and Energy.

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2047	ResChem Technologies	Fluoropolymer in BYK-1798	ND*	≤ 1 tonne per annum	Component of industrial coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 anticipated to degrade in the environment to release fluorinated degradants similar to perfluorohexanoic acid (PFHxA) that is known to be persistent. Due to environmental distribution of the persistent chemicals, the use of the notified polymer may lead to secondary human exposure to the fluorinated degradants via the environment.

Environmental risk assessment
On the basis of the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

However, the anticipated degradants of the notified polymer include the very persistent chemical, PFHxA. The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment during use and after disposal and 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.

The persistence of PFHxA in the environment is of concern because they have 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, noting that current evidence suggests PFHxA is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of chemicals that release very persistent fluorinated degradants upon degradation should be considered a short-term measure until suitable alternatives, with less persistent chemistry, are identified.

Recommendations

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:
  - Local exhaust ventilation
  - Ventilated spray painting booth

- 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:
  - Avoid breathing in mists, vapours or 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:
  - Respiratory protection

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Environment

- The notified polymer should only be introduced as part of a strategy to phase out the use of long chain perfluorinated chemicals, or chemicals/polymers that degrade to long chain perfluorinated chemicals.

- The notifier should seek ways to minimise the level of residual polyfluoroalkyl monomers and impurities in the notified polymer. Such levels should be as low as practicable. Where possible, the total weight of these constituents should not exceed the levels attainable utilising international best practice.

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

Disposal

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

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000 g/mol;
- products containing the notified polymer are intended for use by the public;
- information on the acute or repeated inhalation toxicity of the notified polymer becomes available;
- additional information has become available as to an adverse effect of the per- or polyfluoroalkyl degradation products of the notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of industrial coatings, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on 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.

Safety Data Sheet
The SDS of the notified polymer and product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
ResChem Technologies Pty Ltd (ABN: 90 315 656 219)
Suite 1103, 4 Daydream Street
WARRIEWOOD NSW 2101

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physicochemical endpoints except hydrolysis.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
USA, China, Japan, Taiwan

2. IDENTITY OF CHEMICAL

MARKETING NAME
BYK-1798 (product containing the notified polymer at 10% concentration)

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference NMR, IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No losses are expected during use.

DEGRADATION PRODUCTS
The notified polymer is a potential precursor for PFHxA (perfluorohexanoic acid – CAS name: Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, with CAS No. 307-24-4) in the environment.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: grey liquid

Property	Value	Data Source/Justification
Melting Point	< 0 °C	SDS*
Boiling Point	Not determined	Expected to decompose prior to boiling
Density	1,050 kg/m^3 at 20 °C	SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight

Property	Value	Data Source/Justification
Water Solubility	Not determined	Not expected to be water soluble based on structural considerations
Hydrolysis as a Function of pH	Does not hydrolyse	Measured
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition into the organic phase based on structural considerations
Adsorption/Desorption	Not determined	Expected to sorb into soil based on structural considerations
Dissociation Constant	Not determined	No dissociable functional groups
Flash Point	105 °C	SDS
Flammability	Combustible liquid[#]	Based on flash point
Autoignition Temperature	> 200 °C	SDS
Explosive Properties	Not explosive	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not oxidising	Contains no functional groups that would imply oxidising properties

* Product (BYK-1798) containing notified polymer at ≤ 10% concentration in organic solvent
[#] Based on *Australian Standard AS1940 definitions*

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 limited physico-chemical data depicted in the above table, the notified chemical cannot be recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The notified polymer has a flash point of 105 °C which is greater than 93 °C. Based on *Australian Standard AS1940 definitions* for a combustible liquid, the notified polymer may be considered a Class C2 combustible liquid.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported into Australia at ≤ 10% concentration in organic solvent for reformulation into industrial coatings immediately prior to end-use.

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

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported at ≤ 10% concentration in 25 kg and 200 kg drums and will be transported by road or rail within Australia.

USE
The solution containing the notified polymer at ≤ 10% concentration will be used as an additive for aqueous and UV-curable industrial coatings at ≤ 0.7% concentration (containing the notified polymer at ≤ 0.07% concentration). The notified polymer will function in these coatings as a defoamer. The coatings will be applied to metal and wood.

OPERATION DESCRIPTION

Reformulation
Professional end users will manually blend the solution containing the notified polymer at 10% concentration with other ingredients to produce finished coatings containing the notified polymer at ≤ 0.07% concentration. This will occur in an industrial setting.

End Use
Finished coatings containing the notified polymer at ≤ 0.07 concentration will be manually transferred into spray guns or paint trays for subsequent application by spray, brush or roller. This will occur within an industrial setting.

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 of the notified polymer is also possible.

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

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	150
Coating production	5	200
Quality control	2	100
Application	4	20

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Reformulation processes
Dermal and ocular exposure to the notified polymer at ≤ 10% concentration may occur during the manual blending process, quality control and cleaning or maintaining equipment. Inhalation exposure to the notified polymer may also occur if aerosols are formed. Exposure should be minimised through the use of local exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respirators) as stated by the notifier.

End-use
Application will be spray, brush and roller. Dermal and ocular exposure to the notified polymer at ≤ 0.07% concentration may occur during manual transfer of the coatings containing the notified polymer to spray guns and paint trays, application of the finished coatings and cleaning of application equipment. Inhalation exposure may also occur during spray application. As stated by the notifier, the potential for exposure should be minimised through the use of PPE (goggles, impervious gloves, protective clothing) by workers, including the use of respiratory protection and spray booths during spray application. Inhalation exposure should be further mitigated through the use of exhaust ventilation, where possible. Once the coating is dried, the notified polymer will be bound into an inert solid matrix and will not be available for exposure.

6.1.2. Public Exposure
Finished coatings containing the notified polymer at ≤ 0.07% concentration will be for industrial use only and are not expected to be sold to the public. The public may come into contact with surfaces that have been coated with products containing the notified polymer. However, once the coating is dried, the notified polymer will be bound into an inert solid matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

The notified polymer is of high molecular weight (> 1,000 g/mol) but contains a moderate percentage (> 10%) of low molecular weight species (< 1,000 g/mol), therefore there is potential for the notified polymer to cross biological membranes.

The notified polymer contains polyfluorinated carbon chains. Fluorinated polymers have been known to cause lung injury, which is characterised by respiratory problems ranging from mild to severe effects associated with acute or repeated exposures. Uncertainties remain surrounding possible acute or chronic respiratory tract effects following acute or repeated exposures to the notified polymer.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Hazard implication of breakdown products

The notified polymer contains polyfluoroalkyl side-chains that are potential precursors of PFHxA in the environment. PFHxA is a perfluorocarboxylic acid consisting of 5 perfluorinated carbons (a short chain perfluorinated chemical). A review of the literature indicates that PFHxA has a less hazardous human health profile, compared to PFOA (NICNAS, a). The toxicokinetic and toxicological properties of fluorinated substances generally become less favourable with increase of perfluoroalkyl carbon chain length. It has also been reported that the bioaccumulation potential of perfluorocarboxylic acids increases with perfluoroalkyl carbon chain length (Conder, 2008; Giesy 2010). It is therefore inferred that the human health hazards associated with the expected breakdown products of the notified polymer (PFHxA) are likely to be similar or less than those associated with PFOA or longer chain perfluorocarboxylic acids, which are known degradants of many perfluoroalkyl polymers currently on the market.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

There are uncertainties surrounding possible acute or chronic respiratory tract effects from the notified polymer when inhaled, because of the presence of perfluorinated alkyl chains in the notified polymer. However, during the reformulation and end use, inhalation exposure of workers to the notified polymer is expected to be minimal due to use of engineering controls such as spray booths and local exhaust ventilation, and use of PPE including goggles, impervious gloves, protective clothing and respirators where required.

Once the final coatings are cured after end use, the notified polymer will be trapped in an inert polymer matrix and will not be available for exposure.

Therefore, under the conditions of the occupational settings described, in the presence of engineering controls and PPE specified, the notified polymer is not considered to pose an unreasonable risk to occupational health.

Workers may also be exposed to per- and polyfluoroalkyl impurities of the notified polymer at low concentrations (≤ 0.1%), during use. It is expected that the PPE utilised during these operations (as outlined above) will mitigate any risk associated with such exposure.

6.3.2. Public Health

The notified polymer is intended for industrial use only and therefore direct exposure of members of the public to the notified polymer is not expected. Once the final coatings containing the notified polymer are cured, the polymer is expected to be bound within inert matrix and will not be available for exposure. Therefore, the notified polymer is not considered to pose an unreasonable risk to public health.

The public may be exposed indirectly to the ultimate break down product of the notified polymer, PFHxA, via the environment. Such exposure may increase over time due to the persistence of PFHxA in the environment. However, the available data indicates that PFHxA has lower bioaccumulation potential than the long chain perfluoroalkyl substances (such as PFOA) that are the ultimate break down products of long chain perfluoroalkyl polymers currently in Australian commerce.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported at ≤ 10% concentration in organic solvent for local reformulation into industrial coatings. The most likely source of release during importation, storage, and transport to the environment will be from an accident during transport. Any release that does occur as a result of an accident is expected to be physically contained, absorbed on inert material such as sand, and sent to a licensed waste management company for disposal.

Reformulation is expected to be conducted following the standard operation procedure within an enclosed and automated system. Therefore, release of the notified polymer from reformulation is not expected to be significant. Solvents used for equipment cleaning are expected to be recycled for reuse on site or disposed of via accredited waste disposal contractors. Wastes containing residues of the notified polymer (up to 1% of annual import volume as estimated by the notifier) are expected to be contained on-site and disposed of in accordance with local regulations. Empty import containers with residues of the notified polymer may be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The coating formulation containing the notified polymer at ≤ 0.07% concentration will be applied to the substrate by spray, roller or brush by professional workers in industrial facilities. The use of roller and brush is expected to be efficient and no significant loss of the products is expected. Any losses from overspray (estimated at 30% of annual import volume) during industrial use are expected to be collected using standard engineering controls such as spray booths. All wastes generated during use, including residues in application equipment washings and empty coating containers are expected to be disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of the substrate to which it has been applied, most often being disposed of to landfill. Residual notified polymer in absorbent material from spills, and that remaining in empty drums, is expected to be present as an inert matrix and likewise disposed of to landfill.

7.1.2. Environmental Fate

The majority of the notified polymer is expected to be cured within an inert polymer matrix adhering to articles following its use in coatings. As the notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied, there should be no significant release to the aquatic compartment. Further, the results from submitted hydrolysis and biodegradability tests (see Appendices A and B) strongly suggest that in landfill the notified polymer is unlikely to be bioavailable or biodegradable.

In landfill, the notified polymer is expected to eventually degrade through biotic and abiotic processes to form mainly water and oxides of carbon and silicon, and per- and polyfluoroalkyl degradation products, such as perfluorohexanoic acid (PFHxA), which is likely to be highly resistant to degradation in the environment. Such chemicals may potentially undergo long range transport while staying largely in the water column. Some of these chemicals have the potential to be classified as PBT chemicals (NICNAS, d), but their fluorinated shorter degradation products are not considered to be PBT chemicals (NICNAS, e).

7.1.3. Predicted Environmental Concentration (PEC)

The PEC has not been calculated for the notified polymer because, based on its reported use pattern (including during reformulation), significant quantities are not expected to be released to the aquatic environment.

PFHxA and other poly- and perfluoroalkyl compounds have 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 compounds, landfills have the potential to continue to release PFHxA and homologous perfluorinated carboxylic acids well into the future.

The lifetime of PFHxA in the aquatic environment is unknown, but is expected to be comparable to the very long lifetimes established for homologous perfluorinated acids such as PFOA and PFOS (NICNAS, b and c).

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted.

Effects of PFHxA and other perfluorocarboxylic acids

The current available data, summarised in the NICNAS IMAP Environment Tier II Assessment for Short-Chain Perfluorocarboxylic Acids and their Direct Precursors, indicate that PFHxA and other short-chain perfluorinated acids (i.e. those with five or fewer perfluorinated carbon atoms) have low toxicity to aquatic life (NICNAS, d and e) compared to PFOA and perfluorooctanesulfonic acid (PFOS) (NICNAS, b and c). However, no long-term intergenerational studies were identified for PFHxA and other short chain PFCAs. Emerging evidence suggests that the most significant aquatic toxicity effects of PFOA and PFOS may manifest in offspring when the parent generation is exposed to PFOA or PFOS (NICNAS, b and c).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated because release to the aquatic environment in significant quantities is not expected based on its use pattern in industrial coatings.

On the basis of the assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment. However, the notified polymer contains fluorinated carbon groups that have the potential to degrade to the exceptionally persistent short-chain perfluorinated carboxylic acid, perfluorohexanoic acid (PFHxA).

The environmental degradation of the notified polymer is expected to contribute to the cumulative emissions of perfluorohexanoic acid to the environment. Based on the currently available evidence, the concentrations of PFHxA and other short-chain perfluorinated carboxylic acids are not considered to pose a concern for the environment. However, if additional hazard information becomes available to indicate that short-chain perfluorinated carboxylic acids have hazard characteristics of high concern for the environment (such as PBT properties), then the risks posed by industrial uses of precursors to these environmental degradants may need to be re-assessed.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Hydrolysis as a Function of pH

METHOD	OECD TG 111 Hydrolysis as a Function of pH
TEST SUBSTANCE	Notified polymer
REMARKS	The test substance and a blank were examined in three buffer solutions (pHs 4, 7 and 9) at three different temperatures (22 °C, 42 °C, 60 °C) over five days. Tests for hydrolysis were those for perfluorinated surfactants, fluoride and semi-volatile organic compounds, together with a NMR analysis of the test item before and after hydrolysis. Perfluorinated surfactants, fluoride and semi-volatile organic compounds that were tested for in the buffer solutions could not be detected at the detection limits of 1.0 µg/L, 0.1 mg/L and 1 µg/L, respectively.
CONCLUSION	The notified polymer does not hydrolyse.
TEST FACILITY	Leeder Analytical (2016)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 310 Ready Biodegradability: CO2 in sealed vessels (headspace test) (2014)
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	GC-TCD
Remarks - Method	As per OECD test guidelines. No deviations were noted. Samples were also analysed for perfluorinated surfactants at each time point (0, 7, 14, 22 and 28 days)

RESULTS

Test Substance		*1-octanol*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	49
14	0.29	14	63.45
28	0.59	28	84.45

Remarks - Results	The results are considered valid as 60% of the control was degraded in 14 days and the mean amount of inorganic carbon in the blank was < 3 mg C/L (as per the validity criteria of OECD TG 310). No perfluorinated surfactants were detected at the detection limit of 1.0 µg/L.
CONCLUSION	The notified polymer is not considered readily biodegradable
TEST FACILITY	Leeder Analytical (2016)

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