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

PUBLIC REPORT

**LTD/1837: Polymer in RUCO-GUARD AFB6 CONC
LTD/1838: Polymer in RUCO 1046**

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.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1837	R A Piesse Pty Ltd RCA International Pty Ltd Winra Pty Ltd (trading as Oxford Technologies Australia)	Polymer in RUCO-GUARD AFB6 CONC	No	< 25 tonnes per annum	Component of textiles, leather products, carpets, awnings and furnishings
LTD/1838	R A Piesse Pty Ltd RCA International Pty Ltd Winra Pty Ltd (trading as Oxford Technologies Australia)	Polymer in RUCO 1046	No	< 5 tonne/s per annum	Component of textiles, leather products, carpets, awnings and furnishings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

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

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

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

Environmental risk assessment

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

However, degradants of the notified polymers, along with associated impurities and residual monomers of the notified polymers, are potential precursors of the very persistent chemical, PFHxA. The assessed use pattern of the notified polymers does not control the release of breakdown products into the environment during use and after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified polymers and their degradation products are unknown. This situation may

change if further data on the environmental behaviour of the notified polymers and its poly- and perfluoroalkylated degradation products (including PFHxA) become available.

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering control, work practices personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymers 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 polymers should only be introduced as part of a strategy to phase out the use of long chain perfluoroalkyl chemicals.
- The notifier should seek ways to minimise the level of residual polyfluoroalkyl monomers and impurities in the notified polymers. Such levels should be as low as practicable; where possible, the total weight of these constituents should not exceed the levels attainable utilising international best practice.
- The following control measures should be implemented by users of the notified polymers, or products containing the notified polymers, to minimise exposure of the notified polymers to the environment:
 - Best practice on-site treatment of waste streams should be employed to maximise removal of the notified polymers from wastewaters.

Disposal

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

Emergency procedures

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

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymers are 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 Da;
 - the notified polymers are intended for use in spray products;
 - products containing the notified polymers are intended for use by the public;
 - information on the acute or repeated inhalation toxicity of the notified polymers becomes available;
 - additional information has become available to the person as to an adverse effect of the poly- or perfluoroalkyl degradation products of the notified polymers (such as PFHxA);

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymers has changed from component of textiles, leather products, carpets, awnings and furnishings, or is likely to change significantly;
 - the amount of polymers being introduced has increased, or is likely to increase, significantly;
 - the polymers have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymers on occupational health and safety, public health, or the environment.

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

AICS Entry

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

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

R A Piesse Pty Ltd (ABN: 33 060 193 875)
16 North Point Crescent
PELICAN WATERS QLD 4551

RCA International Pty Ltd (ABN: 50 006 843 232)
3 Pilgrim Court
RINGWOOD VIC 3134

Winra Pty Ltd (trading as Oxford Technologies Australia) (ABN: 97 006 583 044)
44 Mickle Street
DANDENONG SOUTH VIC 3175

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

LTD/1837: RUCO-GUARD AFB6 CONC (product containing the notified polymer)
LTD/1838: RUCO 1046 (polymer containing the notified polymer)

MOLECULAR WEIGHT

LTD/1837 and LTD/1838: $> 10,000$ Da

ANALYTICAL DATA

LTD/1837 and LTD/1838: reference IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

LTD/1837 and LTD/1838: $> 95\%$

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

LTD/1837 and LTD/1838: no loss of monomers, other reactants, additives and impurities is expected.

DEGRADATION PRODUCTS

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white solid polymer

Property	Value	Data Source/Justification
Melting Point/Freezing Point	LTD/1837: 37-47 °C LTD/1838: 26-30 °C	Measured
Boiling Point	Not determined	Expected to decompose prior to boiling.
Density	LTD/1837: 1,300 kg/m ³ at 24 °C LTD/1838: 1,320 kg/m ³ at 24 °C	Measured
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	LTD/1837: 0 g/L at 20 °C LTD/1838: 0 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not Determined	Notified polymers are insoluble in water. They contain hydrolysable functionality. However, hydrolysis is expected to occur very slowly under environmental pH of 4-9.
Partition Coefficient (n-octanol/water)	Not Determined	Notified polymers are insoluble in water. On the basis of its hydro/lipophobic tendencies, the notified polymers are expected to partition between the octanol and water phases.
Adsorption/Desorption	Not Determined	Notified polymers are insoluble in water. Polymers similar to the notified polymers are expected to adsorb to soil, sediments and sludge. However, the notified polymers may have low absorption based on the presence of perfluoroalkyl functionalities which have both hydrophobic and lipophobic tendencies.
Dissociation Constant	Not Determined	Notified polymers are insoluble in water. Not expected to dissociate based on the lack of dissociable functionality.
Particle Size	No determined	Imported as a solution with no particles formed upon drying.
Flash Point	> 95 °C (product)	Product (M)SDS*
Autoignition Temperature	Not determined	Expected to be relatively high based on the partial fluorination flash point of the product*.
Explosive Properties	Not determined	Contains no functional groups that would infer explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would infer oxidising properties

*Containing the notified polymers at individual concentrations < 30%.

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 polymers are not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

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

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

LTD/1837

Year	1	2	3	4	5
Tonnes	< 25	< 25	< 25	< 25	< 25

LTD/1838

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

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING

The products, each containing one of the two notified polymers at < 30% concentration, will be imported by sea in 120 L polyethylene drums and transported within Australia by road. The reformulated products, each containing one of the notified polymers (< 10% concentration) will be transported in 1,000 L intermediate bulk containers (IBCs) by road.

USE

The notified polymers will be used as factory-applied oil and water repellents for textiles, leather products, carpets, awnings and furnishings at < 10% concentration.

OPERATION DESCRIPTION

The notified polymers will not be manufactured in Australia. The notified polymers will be imported each at < 30% concentration, and will be reformulated before products containing them are applied to substrates at industrial sites such as textile mills.

Reformulation

At the reformulation site the imported containers, in which one of the notified polymers is present at a concentration < 30%, will be moved to the blending area, either by forklift or manually. The contents of the imported containers will either be manually poured into the blending equipment, or for larger containers pumped through pipes into the blending tank. Reformulation of the imported products containing the notified polymers will be enclosed and automated with local exhaust ventilation in place. Once reformulation is complete, sampling for quality assurance purposes will take place and the products containing the notified polymers will be pumped to filling machines where will be transferred to 1,000 L intermediate bulk containers.

Application to substrates

At the application sites, formulated products containing the notified polymers at < 10% will be applied to substrates such as textiles, leather or carpets. This may occur by immersing the substrates in a bath consisting of product containing the notified polymers. Any excess liquid will then be squeezed out and the substrates will be dried and cured in an oven which is supplied with local exhaust ventilation. Another method of application involves coating the substrate with the product, with surplus liquid removed with squeegees before the drying/curing process. Spray application will not occur. The concentration of the notified polymer on the finished and dried substrates will be < 2%. It is expected that excess product will be collected and re-used.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

The notified polymers may undergo slow degradation in the environment. As such, most potential exposure to workers and the public is expected to be to the notified polymers themselves, rather than to their degradation products. Exposure to the residual polyfluoroalkyl starting constituents and/or impurities of the notified

polymers (discrete polyfluoroalkyl chemicals containing perfluoroalkyl carbon chain lengths ranging from three to thirteen) is also possible. Such exposure is limited by the low concentration of polyfluoroalkyl impurities in the notified polymers in the imported products and end-use products.

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

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Harbour worker	1	10
Truck driver (to distributor)	1	10
Warehouse staff at distributor	2	30
Workers diluting and filling the dispersion of the polymer	2	10
Truck driver (to textile mill)	1	10
Workers preparing the application liquor at textile mill	1/4	25
Workers cleaning the machinery at textile mill	1/2	25

EXPOSURE DETAILS

Transport and storage workers

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

Reformulation processes

Dermal and ocular exposure may occur when workers manually weigh and pour imported products containing the notified polymers (< 30% individual concentration) into mixing equipment, or when connecting and disconnecting hoses, and during cleaning and maintenance operations. Inhalation exposures are not expected based on the non-spray methods of application, expected low vapour pressure of the notified polymers 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.

Application to substrates

Dermal and ocular exposure may occur when workers manually weigh and pour formulated products containing the notified polymers (< 10% concentration) into the application equipment, or when connecting and disconnecting hoses, during cleaning and maintenance operations, and when handling the treated substrates. Inhalation exposures are not expected unless aerosols are generated during the application and drying processes. PPE is expected to be worn, including gloves, safety glasses, protective clothing and respiratory protection when aerosols or mist may be present.

6.1.2. Public Exposure

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

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

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer (LTD/1837) at concentrations of < 30% are summarised in the following table. For full details of the studies, refer to Appendix B. No toxicological studies were provided on the other polymer (LTD/1838); however, LTD/1837 is considered to be

an acceptable analogue for the other polymer.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw, low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

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

Acute toxicity

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

Inhalation toxicity

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

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

Mutagenicity/Genotoxicity

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

Health hazard classification

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

Toxicology of breakdown products

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

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Toxicological studies on the notified polymers were generally indicative of low hazard. During reformulation automated processes are expected to be in place and PPE (gloves, safety glasses and protective clothing) is expected to be worn. The risk to reformulation workers handling the notified polymers is therefore not considered to be unreasonable.

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

There are uncertainties surrounding possible acute or chronic respiratory tract effects from the notified polymers. However, the risk to professionals of acute or repeated inhalation toxicity from the notified polymers is not considered to be unreasonable, as the products containing them will not be sprayed and the potential for aerosol and mist exposure to workers during use is low.

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

6.3.2. Public Health

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

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymers will be imported at concentrations of < 30% into Australia, and reformulated prior to use.

During this process any spilled material will be recycled where possible or collected for disposal to landfill. Empty containers, mixing vessels and transfer lines will be cleaned with water and recycled into subsequent batches where possible. Waste water controls will be established both at the facility for reformulating and at the customer facilities for application. Prior to release the waste water is expected to be tested and reported to regulatory authorities.

RELEASE OF CHEMICAL FROM USE

The majority of the imported notified polymers will be adsorbed onto the surface or incorporated into the surface matrix of the treated substrates after application. The application methods include immersing the substrates in a

bath consisting of product containing the notified polymers. Any excess liquid will then be squeezed out and the substrates will be dried and cured in an oven which is supplied with local exhaust ventilation. Another application method is coating the substrate with the product, with surplus liquid removed with squeegees before the drying/curing process. Spray application will not occur. Sources of potential release will be residues in empty containers (factory and site use), splashes and drips during decanting, mixing and loading into application equipment, cleaning of equipment. The residual application bath solution (approximately 60 L including maximum 2 kg per notified polymer) will be collected as "Hazardous Waste" by licensed waste collectors and disposed of, if not reused for further applications. The empty application bath and the equipment will be rinsed with water, which will be collected in large holding tanks and taken off site as "Hazardous Waste" by licensed waste collectors. It is estimated that per year approximately 1000 L in sum will be collected as waste water after several cleansings of the equipment. It is estimated that these 1000 L will include a maximum 7 kg of the residual notified polymers combined. During drying and condensation all volatile components (water and dipropylene glycol) are expected to evaporate.

Depending upon the equipment of the customers the exhaust air will be either released directly to the environment via an exhaust air unit or passed on to an exhaust air washer meeting the national requirements on emission.

RELEASE OF CHEMICAL FROM DISPOSAL

The empty IBC/drums will be cleaned with several washings, with almost the entire remaining product trapped and transferred to reformulation. It is estimated that 0.1% of the import volume of the notified polymers will remain in the IBC/drums, which will be reused for reformulated product or collected by an approved drum recycling facility. The drums/IBC and residues will be treated according to the national regulations.

The notified polymers are expected to adhere to the substrate's surface to which they have been applied. However, the use in textiles, leather products, carpets, awnings and furnishings is expected to result in some relocation of the notified polymers. Estimates for losses due to abrasion from these uses are not available. The portion of the notified polymers that remains associated with the textiles, leather products, carpets, awnings and furnishings is expected to share the fate of the associated articles. The majority of the articles are expected to ultimately be disposed of to landfill. The notified polymers applied to surfaces may also degrade as a result of weathering upon being exposed to environmental conditions. Degradation may result in the widespread release of perfluorohexanoic acid (PFHxA) to surface waters, landfill and landfill leachates, soils, and other regions where release is not foreseen.

7.1.2. Environmental Fate

No environmental fate data were submitted.

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

Some of the notified polymers may be released to sewer during reformulation, use and disposal. In general, cationic polymers have the potential to be removed from influent in sewage treatment plants (STP) via sorption to sludge. However, predictions of the environmental partitioning behaviour of polyfluoroalkyl polymers remain uncertain based on current knowledge because of limited data and their unique properties. In particular, the usual predictive models for partitioning during sewage treatment are inapplicable for chemicals containing perfluoroalkyl functionality as they assume lipophilicity for hydrophobic functionality, whereas the perfluoroalkyl functionality is both hydrophobic and lipophobic. The assumption that cationicity and/or high molecular weight results in efficient removal by sorption to sludge during conventional wastewater treatment has not been verified by supporting data for this class of chemical. Thus, noting the potential for the notified polymers formulations to disperse in water, the notified polymers, and any associated degradation products and/or impurities/residual monomers of poly- or perfluoroalkyl compounds, may remain in the aqueous phase following wastewater treatment. As such, the notified polymers, the degradation products and the poly- or perfluoroalkyl impurities/residual monomers in wastewater have the potential to be released in STP effluent directly to surface waters or reused in the irrigation of agricultural soils throughout Australia.

Over time, the notified polymers are expected to become dissociated from the articles. The notified polymers are insoluble in water and they are not expected to rapidly hydrolyse under environmental conditions (pH 4 to 9, 25 °C) based on structural considerations. Investigations of the biodegradation potential of short-chain

polyfluoroalkyl acrylic polymers based on 6:2 fluorotelomer chemistry (ENVIRON, 2014) showed very limited degradation of the fluorinated polymers. Biodegradation of the backbone of the notified polymers is expected to occur slowly under environmental conditions due to their high molecular weight. Thus, the notified polymers are considered to be persistent in the soil and water compartments (i.e., half-lives >> 10-100 years).

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

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

No studies were available that evaluated the bioaccumulation potential of short-chain polyfluoroalkyl acrylic polymers based on 6:2 fluorotelomer chemistry. However, it could be expected that polymer molecules are typically too large to cross biological membranes and do not bioaccumulate. For example, molecules with molecular weights of more than 700 g/mol to 1,000 g/mol cannot be absorbed through respiratory membranes of aquatic organism and are less likely to bioaccumulate (European Commission 2003; Boethling and Nabholz 1997). Although variable, depending on polymer length, the molecular weight of short-chain polyfluoroalkyl acrylic polymers is approximately 40,000 Da. This indicates that these short-chain short-chain polyfluoroalkyl acrylic polymers are unlikely to be bioaccumulative (ENVIRON, 2014). It has been reported that PFHxA has a lower bioaccumulation potential than PFOA and other long chain perfluoroalkyl substances.

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

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) from this process is calculated assuming a worst-case scenario that there is no removal of the notified polymers during STP processes. Around 0.4 % of the notified polymers that corresponds to 100 kg (polymer 1) and 20 kg (polymer 2) are expected to be released to sewer per year.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	0.4%	
Annual quantity of chemical released to sewer	120	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.46	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.10	µg/L
PEC - Ocean:	0.01	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.102 µg/L may potentially result in a soil concentration of approximately 0.68 µg/kg.

Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.402 µg/kg and 6.804 µg/kg, respectively.

PEC for PFHxA and long chain perfluoroalkyl substances

The notified polymers are assumed to degrade and ultimately form the persistent degradant, PFHxA. However, the yield and rate of conversion of the notified polymers to PFHxA has not been established. Environmental monitoring data shows that PFHxA, and PFOA (which PFHxA-chemistry is replacing) is widely found in the environment, particularly in fresh water close to industrial sources, but also in some biota. Water appears to be the main compartment where PFHxA is found. High measured concentrations of both PFHxA and PFOA in surface waters (Hansen *et al.*, 2010) indicate that these chemicals have the potential to enter the aquatic compartment following initial release into the soil compartment.

The distribution coefficient (K_d) values of selected perfluorinated compounds (PFC) in primary, secondary and digested sludge indicate longer PFCAs and PFOS exhibited high K_d values, indicating that PFCs' sorption on sludge occurs due to hydrophobic interactions. Assuming that PFCs are neither volatile nor degraded in STP and target compounds' formation due to precursors is negligible, K_d values were used to evaluate the fate of PFCs in a typical STP. According to the results, PFCs with short chain length are expected to be detected mainly in treated wastewater, while longer compounds will be removed via sludge disposal (Arvaniti *et al.*, 2014).

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 (ENVIRON, 2014). The half-lives of PFHxA in various environmental media are also unknown and its partitioning behaviour is uncertain. Further, degradation products of the notified polymers are unknown. Therefore, a PEC for indirect releases of PFHxA arising from proposed use and disposal of the notified polymers in Australia cannot be determined.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. However, typically nonionic polymers have low solubility and are too large to cross biological membranes and are therefore low in toxicity. However, polymers with monomers that are blocked for use as a surfactant or dispersant, may exhibit some aquatic toxicity (Boethling and Nabholz 1997).

The notified polymers do not contain any functional groups which may undergo rapid hydrolysis within the environmental pH range of 4 – 9. Additionally, significant exposure of the notified polymer to aquatic organisms is unlikely based on the reported use pattern. The majority of the notified polymer will be bound within an inert matrix of cured substrates and is not expected to be bioavailable.

Effects of PFHxA and long chain perfluorocarboxylic acids

There are only limited available acute ecotoxicity data for PFHxA to organisms, and these are limited to aquatic organisms. Based on the available literature, the most sensitive trophic level is algae. The long-term hazard to aquatic organisms has not been adequately established and is unknown.

7.2.1. Predicted No-Effect Concentration

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

7.3. Environmental Risk Assessment

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for the notified polymer has not been calculated because release to the aquatic environment in ecotoxicologically significant quantities is not expected based on their reported use pattern as oil and water repellents for textiles, leather products, carpets, awnings and furnishings. The majority of

the environmental release of the notified polymers will be disposal of the cured substrates to landfill. In cured substrates the notified polymers are bound within the inert matrix and are unlikely to leach or be bioavailable.

Conclusions

On the basis of the assumed low hazard and assessed use pattern, the notified polymers are not considered to pose an unreasonable short-term risk to the environment.

However, when the notified polymers are disposed of to landfill, it is expected to very slowly degrade and, potentially, form the persistent chemical, perfluorohexanoic acid (PFHxA). The assessed use pattern of the notified polymers does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of PFHxA is currently unknown. Consequently, the long-term risk profile for the notified polymers and their degradation products is unknown. This situation may change if further data on the environmental behaviour of the notified polymers and their poly- and perfluoroalkylated degradation products (including PFHxA) become available.

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

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** 37-47 °C (RUCO-GUARD AFB6 CONC, LTD/1837)

Method Similar to OECD TG 102 Melting Point/Melting Range.
Remarks Determined by differential scanning calorimetry.
Test Facility Unspecified (2011)

Melting Point/Freezing Point 26-30 °C (RUCO 1046, LTD/1838)

Method Similar to OECD TG 102 Melting Point/Melting Range.
Remarks Determined by differential scanning calorimetry.
Test Facility Unspecified (2011)

Density 1,300 kg/m³ at 24 °C (RUCO-GUARD AFB6 CONC, LTD/1837)

Method Similar to OECD TG 109 Density of Liquids and Solids.
Remarks Measured using a pycnometer.
Test Facility Universität Osnabrück (2011)

Density 1,320 kg/m³ at 24 °C (RUCO 1046, LTD/1838)

Method Similar to OECD TG 109 Density of Liquids and Solids.
Remarks Measured using a pycnometer.
Test Facility Universität Osnabrück (2011)

Water Solubility 0 g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. In a stepwise procedure, increasing volumes of water was added at room temperature to approximately 0.1 g of the sample. Due to the insolubility of the substance in water, only the preliminary test was carried out.
Test Facility Rudolf GmbH (2015)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	RUCO-GUARD AFB6 CONC (LTD/1837)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar (RccHan TM :WIST)
Vehicle	Arachis oil BP
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	3 F	2,000	0/3
2	3 F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed expected bodyweight gain.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Harlan (2013a)
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B.2. Genotoxicity – bacteria

TEST SUBSTANCE	RUCO-GUARD AFB6 CONC (LTD/1837)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Test 1: Plate incorporation procedure/Test 2: Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from Phenobarbitone/β-Naphthoflavone induced rat liver
Concentration Range in Main Test	Test 1: with and without metabolic activation: 0, 3, 10, 33, 100, 333, 1,000, 2,500 and 5,000 µg/plate Test 2: with and without metabolic activation: 0, 10, 33, 100, 333, 1,000, 2,500 and 5,000 µg/plate
Vehicle	DMSO (at ratio 1:1)
Remarks - Method	No protocol deviations

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>		
	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	> 5,000	≥ 1,000	negative
Test 2	> 5,000	≥ 1,000	negative
<i>Present</i>			
Test 1	> 5,000	≥ 1,000	negative
Test 2	> 5,000	≥ 2,500	negative

Remarks - Results	No visible reduction in the growth of the bacterial background lawn was caused by the test substance at any dose level. Precipitation of the test
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substance in the overlay agar on the incubated agar plates observed in the tests did not prevent the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

The positive controls produced satisfactory responses, thus confirming the activity of S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

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

TEST FACILITY

Harlan (2013b)

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