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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polyfluorinated Side-Chain Polymer in SILRES BS 38

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1629	3M Australia Pty Ltd Wacker Chemie AG	Polyfluorinated Side-Chain Polymer in SILRES BS 38	ND*	≤ 0.8 tonne per annum	Component of stone and tile sealants

*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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

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

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

However, the notified polymer is a potential precursor for perfluorobutanesulfonic acid (PFBS) in the environment, and PFBS is persistent in the environment. Due to the environmental distribution of PFBS resulting from the use pattern of the notified polymer, secondary human exposure to PFBS via the environment may occur. The notified polymer is replacing a long-chain polyfluoroalkyl polymer, which will result in secondary human exposures to other polyfluoroalkyl chemicals, including perfluorooctanoic acid (PFOA) and other long chain perfluorocarboxylic acids (PFCAs). PFOA and longer chain PFCAs are more hazardous to human health and have higher bioaccumulation potential, compared to PFBS. 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 assumed low hazard and assessed use pattern, the notified polymer itself is not considered to directly pose an unreasonable short-term risk to the environment.

However, degradants of the notified polymer, along with associated impurities and residual monomers of the notified polymer, are potential precursors of the persistent chemical, perfluorobutanesulfonic acid (PFBS). The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of PFBS is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products are unknown.

The notified polymer is a potential precursor for PFBS in the environment. PFBS is an environmentally persistent chemical that has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFBS is considered to be less problematic when compared with long chain (C8 and above) perfluorocarboxylic acids that PFBS is expected to replace, noting that current evidence suggests PFBS is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of chemicals that degrade to release PFBS 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

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed, automated processes, where possible.

- 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:
  - Avoid breathing of vapours, mists and sprays
  - Maintain good hygiene practices

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Gloves
  - Coveralls
  - Safety goggles

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

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

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

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

Environment

- The notified polymer should only be introduced as part of a strategy to phase out the use of long chain perfluoroalkyl chemicals.

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

- The following control measures should be implemented by 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 waste streams that are released to sewer.

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 notified polymer, disposal should be to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds 0.8 tonnes per annum notified polymer;
- the polymer has a number-average molecular weight of less than 1000;
- the use changes from a component of stone and tile sealants;
- the notified polymer is intended for use in spray products for consumers;
- the notified polymer is intended for spray application by professionals using non-automated methods;
- information on the inhalation toxicity of the notified polymer becomes available;
- additional information has become available to the person as to an adverse effect of the polyfluoroalkyl degradation products of the notified polymer (such as perfluorobutanesulfonic acid);
- additional information has become available to the person as to the environmental fate of the polymer or its polyfluoroalkyl degradation products (such as perfluorobutanesulfonic acid) in relation to degradation or partitioning behaviour, including during water treatment processes;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of stone and tile sealants, 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.

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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
3M Australia Pty Ltd (ABN 90 000 100 096)
Building A, 1 Rivett Road
North Ryde NSW 2113

Wacker Chemie AG (ABN 11 607 113 062)
1/35 Dunlop Road
Mulgrave VIC 3170

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, density, vapour pressure, water pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, flammability, autoignition temperature, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA and Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SILRES BS 38 (containing 3-8% notified polymer)

MOLECULAR WEIGHT
> 10,000 Da

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

3. COMPOSITION

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 perfluorobutane sulfonate (PFBS) in the environment (CAS name for PFBS when present as the acid: 1-Butanesulfonic acid, 1,1,2,2,3,3,4,4,4-nonafluoro-; CAS No.: 375-73-5).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear yellowish solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	33.65 °C	Measured by differential scanning calorimetry
Boiling Point	Not determined	Expected to decompose prior to boiling
Density	900 kg/m^3	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on high molecular weight of polymer
Water Solubility	Not determined	Expected to be low based on the high molecular weight and hydro/lipophobicity of the polymer
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4, 7 and 9	Analogue data
Partition Coefficient (n-octanol/water)	Not determined	On the basis of its hydro/lipophobic tendencies, the notified polymer is expected to partition between the octanol and water phases.
Adsorption/Desorption	Not determined	Generally, non-ionic polymers of high molecular weight are expected to adsorb to soil, sediments and sludge. However, the notified polymer may have low absorption based on the presence of perfluoroalkyl functionalities that have hydro/lipophobic tendencies.
Dissociation Constant	Not determined	Not expected to dissociate based on lack of dissociable functionality
Flash Point	Not determined	Expected to be high based on partial fluorination and the low vapour pressure
Flammability	Not determined	Not expected to be flammable based on the partial fluorination
Autoignition Temperature	Not determined	Expected to decompose prior to any autoignition
Explosive Properties	Not expected to be explosive	Contains no explosophores
Oxidising Properties	Not expected to be oxidising	Estimated based on structure

*(M)SDS for product containing notified polymer at 23-27% concentration.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia in formulated products at up to 8% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.1-0.8	0.1-0.8	0.1-0.8	0.1-0.8	0.1-0.8

PORT OF ENTRY

Melbourne or Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

3M Australia Pty Ltd

Wacker Chemie AG

TRANSPORTATION AND PACKAGING

The notified polymer (up to 8% concentration) will be imported in 350 L or 1 L metal containers and transported within Australia by road or rail.

USE

The notified polymer will be used as a direct replacement of a partially fluorinated polymer containing fluorinated carbon chain lengths of ≥ 6 in various proportions. The use categories of the notified polymer are identical to those of the existing polymer it replaces, as outlined below.

SILRES BS 38 (up to 8% concentration) will be used as a component of stone and tile sealants. The product will be applied in factory settings (33%), by tradesmen (33%) or by the public (34%).

OPERATION DESCRIPTION

Transport and storage

The imported containers will remain closed between the wharf and the notifier's warehouse. Storemen will unpack the delivery containers and store them.

Factory application

Factory workers will manually add the product containing the notified polymer (up to 8% concentration) to a mixing bucket for dilution of 1:5 to 1:10 (up to 0.8-1.6% concentration). The dilution will then be poured into the enclosed reservoir tank and applied in an enclosed spray booth with the substrate entering via conveyor belt. The treated substrate will then be dried using warmed air.

Tradesmen and domestic users

The product containing the notified polymer (up to 8% concentration) will be applied to stone and tiles using brush, roller or mop.

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 (polyfluoroalkyl chemicals containing perfluoroalkyl carbon chain lengths of four) is also possible. Such exposure is limited by the relatively low concentration of polyfluoroalkyl impurities in the notified polymer in the imported and end use products.

The notified polymer is a potential precursor for PFBS in the environment. This is likely to lead to secondary human exposure to PFBS. 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	1-2	10-20
Factory	8	200
Tradesmen	2-4	100

EXPOSURE DETAILS

Transport and storage workers

Transport and storage workers will only come into contact with the notified polymer (up to 8% concentration) in the unlikely event of an accident.

Factory application

Dermal and ocular exposure of workers to the notified polymer may occur during manual transfer of the notified polymer to the mixing bucket (up to 8% concentration) or into the reservoir tank (up to 1.6%

concentration). Exposure may also occur during charging of the spray equipment and cleaning and maintenance operations (up to 1.6% concentration). Exposure will be lowered by the use of PPE such as coveralls, safety glasses and gloves. Inhalation exposure is unlikely during factory application based on the expected low vapour pressure of the notified polymer. Exposure is unlikely during spraying due to the enclosed and automated nature of the spray booth. Once applied, the notified polymer will adsorb to the substrate and exposure is expected to be low.

Tradesmen
Dermal or ocular exposures may occur when tradesmen apply the product containing the notified polymer (up to 8% concentration) by brush, roller or mop. Exposure may be further minimised by PPE such as protective clothing, gloves and safety goggles.

6.1.2. Public Exposure
Public exposure to the notified polymer (up to 8% concentration) may occur when stone and tile sealants are applied by brush, roller or sponge. Dermal and ocular exposure may occur. Consumer exposure is expected to be acute in nature as repeated daily uses are considered unlikely and exposure is expected to be infrequent and short term.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

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 of low molecular weight species (< 500 Da), and its expected low water solubility. In addition, inhalation of the notified polymer itself is not expected to result in significant absorption from the respiratory tract. 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.

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 inhalation toxicity studies are available for the notified polymer.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Toxicology of break down products
The notified polymer contains perfluoroalkyl side-chains that are potential precursors of PFBS in the environment. PFBS is a perfluorosulfonic acid consisting of 4 perfluorinated carbons (a short-chain perfluorinated chemical). The polymer that is proposed for replacement by the notified polymer is expected to degrade to per- and polyfluorocarboxylic substances with a range of perfluoroalkyl carbon chain lengths. The main concern is for the long chain polyfluoroalkyl degradation products, including perfluorooctanoic acid (PFOA; CAS No. 335-67-1) (consisting of 7 perfluorinated carbons) and other longer chain compounds. The toxicokinetic and toxicological properties of the long chain break down products are generally less favourable compared to the short chain break down products, with properties becoming less favourable with increasing perfluoroalkyl carbon chain length. In addition, it has been established that the bioaccumulation potential of perfluorocarboxylic acids increases with perfluoroalkyl carbon chain length (Conder, 2008; Giesy 2010).

In November 2005 NICNAS published a hazard assessment report on PFBS (NICNAS, 2005). In addition, the toxicology of PFOA has been characterised previously (Environment Canada, 2012; Chemical Safety Report, 2009). A comparison of the toxicokinetics and toxicity of PFBS and PFOA indicates the following:

- Excretion of PFBS via the urine was rapid and virtually complete over 24 hours, whereas excretion of PFOA was slower, with only 20% excreted over 24 hours.
- In 90-day repeat dose studies in rats, the LOAEL for PFBS (600 mg/kg bw/day) occurred at higher

doses than for PFOA (0.64 mg/kg bw/day).

- A reproduction study with PFBS showed no effect on reproductive parameters, with a NOAEL of 1000 mg/kg bw/day, while 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.
- A developmental toxicity study in rats with PFBS showed no evidence of developmental effects (NOAEL 1000 mg/kg bw/day). The NOEL for developmental effects for PFOA was 150 mg/kg bw/day in a rat study.

It is concluded that PFBS has a less hazardous human health profile compared to PFOA. It is therefore inferred that the human health hazards associated with the expected breakdown product of the notified polymer (PFBS) are likely to be less than the human health hazards associated with many of the expected breakdown products (PFOA and longer chain perfluorocarboxylic acids) of the perfluoroalkyl chemical currently on the market and that is intended for replacement by the notified polymer.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Repeated dermal and ocular exposure to the notified polymer (at up to 8% concentration) by workers may occur during manual transfer and handling of the imported products containing the notified polymer to the mixing bucket for factory application, or when tradesmen are applying the products by brush, roller or mop. Worker exposure may be minimised by PPE such as protective clothing, gloves and safety goggles. The notified polymer is expected to have a low potential for systemic hazard due to the predicted negligible absorption across biological membranes based on the high molecular weight (> 10,000 Da) and low levels of low molecular weight species. The local effects of the notified polymer are unknown although the lack of reactive functional groups on the polymer and the relatively low concentrations in products will limit its potential for irritancy. Given the expected low hazard of the notified polymer and that the exposure of workers is expected to be minimised through the use of personal protective equipment (PPE), the risk to workers from repeated exposure is not considered to be unreasonable.

Products containing the notified polymer will be applied by spray during factory application but the automated nature of the process that takes place in an enclosed spray booth should mean that there will be no inhalation exposure. Products containing the notified polymer when used by tradesmen will not be applied by spray or aerosolised during application. Due to the high molecular weight of the notified polymer the vapour pressure is expected to be very low and, combined with the lack of aerosolisation the potential for inhalation exposure is expected to be low. Therefore, although lung effects cannot be ruled out, due to the expected low inhalation exposure the risk to workers is not considered to be unreasonable.

Systemic exposure of workers to break down products is not expected based on the stability of the notified polymer. Workers may also be exposed to perfluoroalkyl starting constituents and/or impurities of the notified polymer at relatively low concentrations. 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

Stone and tile products containing the notified polymer (up to 8% concentration) and perfluoroalkyl impurities (up to 0.0048%) will be available to the public. Stone and tile products will be applied by brush, roller or mop. Public exposure is expected to be infrequent and short term. As with use by tradesmen there is expected to be negligible inhalation exposure. The expected low toxicity of the notified polymer means that dermal or ocular exposure to stone and tile products containing it is not expected to lead to adverse health effects. Based on these considerations, the risk to public health from use of stone and tile products containing the notified polymer is not considered to be unreasonable. Additionally, the risk to public health from exposures to polyfluoroalkyl impurities during use of products containing the notified polymer is not considered to be unreasonable based on their low concentration (up to 0.0048%) in end-use products.

The public may also be exposed to the notified polymer from direct dermal contact with tiles or stone that has been treated with products containing the notified polymer. This exposure will be on a long term, albeit infrequent basis. Also, following application the product containing the notified polymer is expected to adhere to stone and tile articles, thereby limiting long term exposure. In addition, based on the high molecular weight of the notified polymer (> 10,000 Da) and the low proportion of low molecular weight species, dermal absorption is unlikely to occur. Thus the risk to public health due to long term exposure to the notified polymer from treated tiles or stone is not considered to be unreasonable. Due to the low level of perfluoroalkyl impurities present in the notified polymer, the risk to public health due to long term exposure to perfluoroalkyl impurities of the notified polymer from tiles or stone is not considered to be unreasonable.

The public may be exposed indirectly to PFBS, formed by degradation of the notified polymer in the environment. Such exposure may increase over time due to the persistence of PFBS in the environment. A quantitative risk assessment for this exposure was not conducted. However, the available data indicates that PFBS 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 used to replace a currently available long chain perfluoroalkyl polymer.

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 or reformulated in Australia. Therefore, no release to the environment is expected from these activities. Releases to the environment may occur following accidental spills during import, transport or storage. Notified polymer that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations, most likely to landfill.

RELEASE OF CHEMICAL FROM USE

Limited release of the notified polymer to the environment is expected during use as a stone and tile treatment. During spray application of the notified polymer in industrial settings, engineering controls are expected to be used to limit release of the notified polymer to the environment. Wastes from overspray are expected to be collected, dried and disposed of according to local regulations, most likely to landfill.

Based on the composition of the formulated product containing the notified polymer, residues on applicators are expected to be cleaned using hydrocarbon-based solvents. Any product that comes into contact with water is expected to potentially solidify. The waste solvents containing the notified polymer are expected to be disposed of in accordance with local regulations. A small proportion of the notified polymer may be released to sewer via improper disposal by do-it-yourself (DIY) users.

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

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer applied to treated stone and tile surfaces is expected to adhere to the surface to which it has been applied. However, abrasion of the floor surface by foot traffic is expected to result in some relocation of the notified polymer. Estimates for losses due to abrasion from these uses are not available. The notified polymer that remains associated with stone and tile is expected to share the fate of articles. The majority of articles are expected to ultimately be disposed of to landfill. The notified polymer applied to surfaces may also degrade as a result of weathering upon being exposed to environmental conditions. Degradation may result in the widespread release of perfluorobutanesulfonic acid (PFBS) 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 polymer is expected to adhere to stone and tile articles following application of the product containing the notified polymer. Treated articles and other dried residues containing the notified polymer are expected to ultimately be disposed of to landfill. When associated with the article to which the product containing the notified polymer has been applied, the notified polymer is not likely to be mobile or bioavailable in landfill.

Some of the notified polymer may be released to sewer during DIY applications and improper disposal. Predictions of the environmental partitioning behaviour of poly- and perfluoroalkyl polymers, 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 chemical. However, the notified polymer will be incorporated in a product that is expected to potentially solidify upon contact with water, increasing the likelihood that the notified polymer will be removed from the aqueous phase during sewage treatment plant (STP) processes via adsorption to sludge. Therefore, the notified polymer may potentially be present in STP effluent and biosolids that will be reused and applied to agricultural soils throughout Australia.

The notified polymer is not expected to rapidly hydrolyse under environmental conditions. The calculated hydrolysis half-life of an analogue polymer indicates that the half-life is potentially 48 years under environmental conditions (pH 7) with half-lives potentially reduced under more extreme conditions. Investigations submitted by the notifier on the biodegradation potential of PFBS-based urethane and acrylate polymers, such as the notified polymer, indicate similar primary degradation pathways as standard hydrocarbon based polymers. However, biodegradation of the backbone of the notified polymer is expected to occur slowly under environmental conditions due to its high molecular weight. PFBS is expected to be a product of biodegradation of the notified polymer. Studies indicate that the PFBS-based urethane and acrylate polymers also have the potential to undergo weathering via photolysis in the environment. Ultimately, photolysis pathways of these polymers have the potential to form PFBS, perfluorobutanoic acid (PFBA) and nonafluorobutane with half-lives of the polymer being less than two years according to information submitted by the notifier. Thus, the notified polymer is expected to be persistent with the potential to photolyse under environmental conditions.

In surface waters, agricultural soils and landfill, the notified polymer is expected to degrade over extended periods of time to form water, oxides of carbon and nitrogen, and degradation products containing poly- and perfluoalkyl functionality. The expected initial polyfluoroalkyl degradation products are assumed to undergo further degradation to form, among other compounds, the very persistent perfluoroalkyl degradation product of the notified polymer, PFBS. It is noted that some volatile degradation intermediates have the potential to undergo long range atmospheric transport and thus may result in translocation of PFBS in the environment.

PFBS is expected to be recalcitrant in the environment, and potentially undergo long-range transport while mainly staying in the water column (NICNAS 2005). The susceptibility of PFBS for long-range transport is increased compared to long chain perfluoroalkyl compounds, such as perfluorooctanoic acid (PFOA), because its degradation precursors are expected to be more volatile and more likely to enter the atmospheric compartment (NICNAS 2005). PFBS is expected to be very persistent and has limited potential to hydrolyse, photolyse or biodegrade (NICNAS 2005). The increased potential for long-range transport is of concern for PFBS-based compounds as they are increasingly used as replacements for long chain perfluoroalkyl compounds such as those based on PFOA. Increasingly higher use of PFBS-based compounds may result in the accumulation of PFBS in regions where PFBS or PFBS-based compounds have not been intentionally released, including in pristine environments.

By 2005, there was limited detection of PFBS in the environment (NICNAS 2005). However, a recent study detected PFBS in 24% of water samples taken from the Greenland Sea with concentrations ranging from < 51 to 65 pg/L (Zhao 2012). As long chain perfluoroalkyl acids are phased out in preference for short-chain polyfluoroalkyl chemistry containing a four-carbon perfluorobutyl moiety (like the notified polymer), the introduction of chemicals degrading to PFBS may lead to a measurable increase over time of the environmental levels of PFBS. The scale and time frame of such an increase, and its relevance to characterising the long term environmental risk profile of PFBS, currently remain unknown.

Due to its high molecular weight which limits the ability to cross biological membranes, the notified polymer is not expected to bioaccumulate. The available evidence indicates that the assumed major degradation product, PFBS, is expected to have a lower bioaccumulation potential than long chain perfluoroalkyl compounds (C8 and above) as the bioaccumulation potential of perfluoroalkyl compounds is correlated with increasing carbon chain length (Giesy et al., 2010). The reported half-life of PFBS in rainbow trout was 3.3 days in a dietary accumulation study (NICNAS 2005).

High-temperature incineration is the preferred method of disposal of 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 should only take place at facilities that demonstrate complete combustion of the perfluoroalkyl functionality and have adequate measures in place to control release of hydrofluoric acid.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not calculated as there is expected to be limited aquatic exposure of the notified polymer from the reported use pattern.

The notified polymer is assumed to degrade and ultimately form the persistent degradant, PFBS, which is likely to mostly partition to the aqueous compartment (NICNAS 2005). Historically, release of perfluoroalkyl contaminants into the environment has been linked to direct releases of low molecular weight poly- and perfluoroalkyl chemicals, 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 PFBS 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. Residual polyfluoroalkyl monomer and impurity levels in the notified polymer should be as low as practicable: where possible, the total weight of these constituents should not exceed the levels attainable utilising international best practice.

Efforts have been made globally to control releases of perfluoroalkyl contaminants, such as by reducing the presence of residual polyfluoroalkyl monomers and impurities in polymers. Thus, it is expected that indirect releases from the degradation of polyfluoroalkyl polymers will become a significant source of persistent perfluoroalkyl compounds in the environment in the future. Compared to long chain perfluoroalkyl compounds, there has been limited detection of PFBS in the environment. However, as the long chain perfluoroalkyl compounds are phased out in preference for short-chain polyfluoroalkyl chemistry containing four-carbon perfluorobutyl moieties, the environmental levels of PFBS may increase.

The hydrolysis half-life of the notified polymer is indicated to be approximately 48 years under environmental conditions (3M 2002) and the notified polymer may undergo photolysis with a potential half-life of less than two years, according to information provided by the notifier. However, large uncertainties remain with calculating the contribution of indirect sources to the environmental load of perfluoroalkyl compounds. These uncertainties including determination of the timeframe over which release may occur and global transport mechanisms. Therefore, a PEC for indirect releases of PFBS arising from proposed use and disposal of the notified polymer in Australia cannot be determined.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted. The notified polymer is expected to persist in the environment. However, polymers without significant ionic functionality are generally of low concern to the environment. Therefore, the notified polymer itself is not expected to be harmful to aquatic life.

The persistent degradation product, PFBS, is not considered to be toxic to aquatic organisms (NICNAS 2005). The most sensitive aquatic species was found to be the mysid shrimp, with a 96-hour median effective concentration (EC50) of 372 mg/L. All other aquatic organisms tested (fish, daphnids, alga and sewage microorganisms) were reported to have EC50s >1000 mg/L (NICNAS 2005). Therefore, PFBS is not expected to be harmful to aquatic organisms on a short-term basis. With respect to the long-term hazard to the environment, traditional long-term studies do not adequately represent the potential hazard for very persistent compounds. Test studies are not available for PFBS for periods exceeding 21 days (*Daphnia*: NOEC (21 d) = 502 mg/L). As PFBS is very persistent and there is a potential for it to accumulate in the environment, aquatic organisms will be exposed to PFBS for periods longer than 21 days. Therefore, the long-term hazard to aquatic organisms has not been fully characterised.

The notified polymer contains short-chain polyfluoroalkyl chemistry and consists of a four-carbon perfluorobutyl moiety. Short-chain polyfluoroalkyl chemistry is intended to replace long chain polyfluoroalkylchemistry (C8 and above). Whilst sulphonic acid moieties tend to be more toxic than the carboxylic acid of the same fluorinated carbon chain of the same length, the toxicity of perfluoroalkyl compounds increase with increasing carbon chain length (Giesy et al., 2010). As a comparison, the available data indicate that, for example, PFOA or its salts are, at most, harmful to fish with 96-hour median lethal concentrations (LC50) ranging from 70 to 1550 mg/L (US FDA, 2009; ECHC, 2012). 48-Hour median effect concentrations (EC50) based on immobilisation for *Daphnia magna* ranged from 34 to 1200 mg/L (ECHC, 2012), indicating that PFOA and its salts may be considered toxic to aquatic invertebrates on an acute basis. Reproduction studies on *Daphnia* over 21 days, resulted in NOECs ranging from 13 to 89 mg/L. 96-Hour NOECs, based on growth rate, from algal toxicity studies ranged from 1.0 to 500 mg/L (ECHC, 2012). Therefore, PFBS is expected to have a less problematic ecotoxicological profile than the long chain perfluoroalkyl acids it is expected to replace.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicological data for the polymer were submitted and the notified polymer itself is not expected to be harmful to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer itself has not been calculated as release to the aquatic environment is expected to be limited based on its reported use pattern. As a polymer with a high molecular weight, it is assumed to persist in the environment but it is not expected to bioaccumulate. However, the notified polymer is assumed to eventually degrade to form PFBS which may be delocalised from points of release.

Perfluoroalkyl compounds are expected to be very persistent in the environment (for example, PFOA: $t_{½}$ (hydrolysis) > 200 years; US EPA 2002) but PFBS is considered to have low potential for bioaccumulation. PFBS is not considered to be harmful to aquatic organisms at concentrations less than 372 mg/L on an acute basis. There is no available data on the long-term aquatic effects of PFBS beyond the limits of traditional long-term ecotoxicity tests.

The main environmental risks associated with polyfluoroalkyl polymers relate to the release of poly- and perfluoroalkyl degradation products, such as PFBS. However, it is not possible to quantify the long-term risks of PFBS to the environment due to knowledge gaps both in predicting environmental concentrations from indirect sources of release and the uncertainty surrounding long-term environmental effects. To date, the available data on environmental concentrations of PFBS indicate a low risk of environmental toxicity. However, the long-term environmental risk profile of PFBS is currently unknown, and further long term research should ideally be undertaken to characterise this risk.

There has been limited detection of PFBS in the environment. However, as the long chain perfluoroalkyl compounds are phased out in preference for short-chain polyfluoroalkyl chemistry containing four-carbon perfluorobutyl moieties, the environmental levels of PFBS are expected to increase. Continuing release of PFBS is expected to 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 over significant periods of time. In this eventuality, precursors of PFBS such as the notified polymer cannot be recalled after release and are a potential source of PFBS in the environment even long after their use ceases. Thus, use and disposal of the notified polymer increases the environmental risk profile of PFBS over time. Considering the potential for widespread release of PFBS from unreacted monomers in polymeric material, it is recommended to reduce the levels of impurities in the notified polymer, to the extent practicable.

Conclusions

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

However, degradants of the notified polymer, along with associated impurities and residual monomers of the notified polymer, are potential precursors of the persistent chemical, perfluorobutanesulfonic acid (PFBS). The assessed use pattern of the notified polymer does not control the release of breakdown products into the environment after disposal and the long-term environmental risk profile of PFBS is currently unknown. Consequently, the long-term risk profile for the notified polymer and its degradation products is unknown.

The notified polymer is a potential precursor for PFBS in the environment. PFBS is an environmentally persistent chemical that has potential to be globally distributed. However, the ecotoxicological profile and bioaccumulation potential of PFBS is considered to be less problematic when compared with long chain (C8 and above) perfluorocarboxylic acids that PFBS is expected to replace, noting that current evidence suggests PFBS is not bioaccumulative in aquatic ecosystems. Nonetheless, the introduction and use of chemicals that degrade to release PFBS 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 PFBS 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 these constituents should not exceed the levels attainable utilising international best practise. 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

Hydrolysis as a Function of pH $t_{½}$ > 1 year at pH 4, 7 and 9

Method In-house method comparable to OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$*
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks The test was conducted on an analogue polymer with identical functionality, but of lower molecular weight than the notified polymer. Calculated estimates for the half-lives of the analogue were greater than 19.65, 48.53 and 29.62 years at pH 4, 7 and 9 respectively. However, considering the test is conducted over a period of 5 days, calculation of the half-lives in excess of one year is expected to result in a significant statistical error. Therefore, the results have been reported as $t_{½}$ > 1 year at pH 4, 7 and 9 as the extrapolated results should be treated with caution.

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