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

PUBLIC REPORT

Polymer in FLOSET™ CAPS 371 L

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

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	APPLICANTS	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1936	SNF (Australia) Pty Ltd and Givaudan Singapore Pte Ltd	Polymer in FLOSET™ CAPS 371 L	ND*	≤ 10 tonnes per annum	Component of liquid laundry products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or 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 polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 polymer has a number-average molecular weight of less than 1,000;
 - the polymer is to be introduced at a concentration more than 1% in products;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of liquid laundry products, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - 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.

(Material) Safety Data Sheet

The (M)SDS of a product containing 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

APPLICANTS

SNF (Australia) Pty Ltd (ABN: 32 050 056 267)
98 Broderick Road
LARA VIC 3212

Givaudan Singapore Pte Ltd (ABN: 87 000 470 280)
Unit 34, 5 Inglewood Place
BAULKHAM HILLS NSW 2153

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

FLOSET™ DP/CAPS 371 L (product containing the notified polymer at ~50% concentration in aqueous solution)

MOLECULAR WEIGHT

$M_n > 1000$ Da

ANALYTICAL DATA

Reference NMR, FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: dark amber liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced in aqueous solution
Boiling Point	Not determined	Introduced in aqueous solution
Density	1000 – 1200 kg/m ³	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on relatively high molecular weight
Water Solubility	> 500 g/L at 20 °C	Based on concentration in aqueous solution
Hydrolysis as a Function of pH	Not determined	The notified polymer has potential to hydrolyse due to the presence of hydrolysable functionalities.

Property	Value	Data Source/Justification
Partition Coefficient (n-octanol/water)	Not determined	Expected to be low based on high water solubility
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on positive charge and large molecular weight
Dissociation Constant	Not determined	The notified polymer is a salt and will ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	Introduced in aqueous solution
Flammability	Not determined	Introduced in aqueous solution
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not determined	Not expected to be explosive based on the chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on the chemical structure

* For the product containing the notified polymer at ~50% concentration in aqueous solution

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 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 polymer will not be manufactured in Australia. It will be imported in formulated fragrance products at $\leq 1\%$ concentration for use in the formulation of consumer liquid laundry products.

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

Year	1	2	3	4	5
Tonnes	5-10	5-10	5-10	5-10	5-10

PORT OF ENTRY

Sydney and Perth

TRANSPORTATION AND PACKAGING

The fragrance products containing the notified polymer at $\leq 1\%$ concentration will be imported in glass, lacquer-lined containers of 1, 5, 10, 25, 100 or 190 kg capacity. The fragrance products will be distributed by road to reformulation sites for formulating into consumer liquid laundry products. Finished laundry products in consumer type packaging (containing the notified polymer at $\leq 0.2\%$ concentration) will be transported by road for distribution to retail outlets.

USE

The notified polymer will be used as a polymeric additive in the imported fragrance products for the reformulation of liquid laundry products, including washing machine detergents and fabric softeners. The finished liquid laundry products will contain the notified polymer at $\leq 0.2\%$ concentration. The finished consumer products containing the notified polymer are expected to be only used within washing machines with no hand-washing anticipated.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. The imported fragrance products containing the notified polymer at $\leq 1\%$ concentration will be distributed to reformulation sites for manufacturing end-use consumer laundry products.

Reformulation

The procedures for incorporating fragrance products containing the notified polymer into end-use products will likely vary depending on the nature of the final products and may involve both automated and manual transfer processes. In general, it is expected that the fragrances products containing the notified polymer will be measured, added to the mixing tank and blended with additional ingredients to form the finished consumer liquid laundry products. This will be followed by automated filling of the finished products into containers of various consumer sizes. The blending and filling operations are expected to be highly automated and use closed systems and/or adequate ventilation. During the reformulation processes, samples containing the notified polymer from various stages will be taken for quality control purposes.

End use

Liquid laundry products containing the notified polymer at $\leq 0.2\%$ concentration will be used by public consumers. Consumers will open the laundry product containers, manually measure out the required volume and add into the washing machine detergent or fabric softener dispensers. The liquid laundry products are expected to be used with episodes of controlled washing procedures. After the washing cycles, consumers will manually remove washed cloths from the machines; however at this stage the laundry products containing the notified polymer are expected to be rinsed off.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****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>
Transport and warehouse workers	1	24
Reformulation workers	8	24
Retail workers	0.2-2	200

EXPOSURE DETAILS

Transport, storage and retail

Transport and storage workers may come into contact with the notified polymer as a component in imported fragrance products (at $\leq 1\%$ concentration) or in finished consumer liquid laundry products (at $\leq 0.2\%$ concentration), only in the unlikely event of accidental rupture of containers.

Reformulation

During reformulation at the consumer product reformulation sites, dermal and ocular exposure of workers to the notified polymer (at $\leq 1\%$ concentration) may occur during measuring, transferring, blending, quality control analysis, and equipment cleaning/maintenance processes. Based on the relatively high molecular weight of the notified polymer, inhalation exposure to the polymer for workers is not expected to be significant unless aerosols and mists are formed. The notifier stated in the submission that the exposure is expected to be minimised by the use of engineering controls including automated and enclosed systems, and by the use of PPE such as coveralls, goggles, impervious gloves and appropriate respiratory protections.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (at $\leq 0.2\%$ concentration) through the use of the consumer liquid laundry products including detergents and fabric softeners. The principal routes of exposure will be dermal, while incidental ocular exposure is possible. Inhalation exposure to the notified polymer for the public is not expected during normal use. Dermal contact with residual notified polymer may continually occur when washed clothes are worn.

6.2. Human Health Effects Assessment

No toxicological information on the notified polymer was provided. Based on the high molecular weight of the notified polymer ($> 1,000$ Da), the potential for the polymer to be absorbed through skin contact is expected to be limited. However, the notified polymer contains a small portion ($< 10\%$) of low molecular weight species (< 500 Da) that may be able to cross biological membranes.

The notified polymer contains quaternary ammonium functional groups that are known to be a structural alert for skin corrosion and sensitisation (Barrett et al., 1994; Hulzebos et al., 2005). Given the high molecular weight of the notified polymer and low percentage (< 10%) of low molecular weight species < 1000 Da, the potential for irritation and sensitisation is expected to be limited. However, at high concentration, the potential for the notified polymer to cause adverse skin effects cannot be ruled out.

Health hazard classification

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the notified polymer may have potential to cause adverse skin effects at high concentrations.

Reformulation

Workers may come into contact with fragrance or laundry products containing the notified polymer at $\leq 1\%$ or $\leq 0.2\%$ concentration, respectively. However, significant exposure of workers to the notified polymer is not expected based on the control measures in place. At this low use concentration, adverse skin effects are not expected from the notified polymer.

Therefore, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Laundry products containing the notified polymer at $\leq 0.2\%$ concentration will be used by the public. The main route of exposure is expected to be dermal with potential for incidental ocular exposure. The potential for the notified polymer to cause adverse skin effects at high concentration cannot be ruled out; however at the proposed low end-use concentration adverse skin effects are not expected for the notified polymer.

Based on the available information and proposed use scenario, the risk to the public from use of the notified polymer at $\leq 0.2\%$ in laundry products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component of a fragrance formulation for reformulation into finished liquid laundry products. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the product containing the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. The process will be followed by automated filling of the formulated products into containers of various sizes suitable for retail and use. Wastes containing the notified polymer generated during reformulation include equipment wash water, residues in empty import containers and spilt materials. It is estimated by the notifier that up to 0.2% of the import volume of the notified polymer (or up to 20 kg) may be released from reformulation processes. These will be released to sewers in a worst case scenario, or be collected and disposed of to landfill in accordance with local government regulations. Empty import containers are expected to be recycled or disposed of through licensed waste management services.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer across Australia as a result of its use in liquid laundry products. A small proportion of the notified polymer is expected to be disposed of to landfill as residues in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion of the notified polymer may remain in end-use containers once the consumer products are used up. Wastes and residues of the notified polymer in empty containers are likely either to share the fate of the container and be disposed of to landfill, or to be released to sewer when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. Based on its chemical structure, the notified polymer is not expected to be readily biodegradable. However, the notified polymer is not expected to cross biological membranes and be bioaccumulative based on its large molecular size and high water solubility.

Following its use in liquid laundry detergents, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on its amphoteric properties and high molecular weight, up to 90% of the notified polymer is expected to bind to sludge and sediment (Boethling and Nabholz, 1997). A proportion of the notified polymer may be applied to land when effluent is used for irrigation, when sewage sludge is used for soil remediation, or disposed of to landfill as collected spills and empty container residue.

In landfill, soil or water, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated by assuming that 100% release of the notified polymer into sewer systems nationwide. Based on its amphoteric properties and high molecular weight, up to 90% of the notified polymer is expected to be removed from the effluent at sewage treatment plants by binding to sludge and sediment (Boethling and Nabholz, 1997). Therefore, the PEC is calculated as the table below:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.06	µg/L
PEC - Ocean:	0.61	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 6.06 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Ecotoxicological endpoints for aquatic organisms for the notified polymer were calculated based on structure-activity relationship (SAR) equations, assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The acute and chronic endpoints are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u>Acute Toxicity</u>		
Fish	96 h LC50 = 3.99 mg/L	Predicted to be toxic to fish
Daphnia	48 h EC50 = 18.20 mg/L	Predicted to be harmful to aquatic invertebrates
Algae	96 h EC50 = 1.25 mg/L	Predicted to be toxic to algae
<u>Chronic Toxicity</u>		
Fish	ChV = 0.22 mg/L	Predicted to be toxic to fish
Daphnia	ChV = 1.01 mg/L	Not predicted to be harmful to aquatic invertebrates
Algae	ChV = 0.50 mg/L	Predicted to be toxic to algae

The notified polymer is predicted to be toxic to fish and algae, and harmful to aquatic invertebrates on an acute basis. The notified polymer is also predicted to be toxic to fish and algae on a chronic basis, but is not predicted to be harmful to aquatic invertebrates on a chronic basis. The SAR estimation procedure used here is a standard approach, and is considered reliable to provide general indications of the likely environmental effects of a chemical. However, this method is not considered sufficient to formally classify the acute and chronic hazards of the notified polymer to aquatic life under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for algae. The endpoint for algae was therefore selected for the calculation of the PNEC below. An assessment factor of 10 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae, 96 h)	0.22	mg/L
Assessment Factor	10	
Mitigation Factor	1.00	
PNEC:	22	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	6.06	22	0.27
Q – Ocean	0.061	22	0.027

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified polymer is not expected to be readily biodegradable, it is expected to have a low potential for bioaccumulation based on its high water solubility and high molecular weight.

On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

- Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994) An Expert System Rulebase for Identifying Contact Allergens. *Toxicology In Vitro*, 8(5), 1053-1060.
- Boethling, RS and Nabholz, JV (1997) "Environmental Assessment of Polymers under the US Toxic Substances Control Act", in: Hamilton, JD, Sutcliffe, R (ed). *Ecological Assessment of Polymers: Strategies for product stewardship and regulatory programs*. Van Nostrand Reinhold, New York.
- Hulzebos E, Walker JD, Gerner I and Schlegl K (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. *QSAR Combinatorial Science*, 24:332-342.
- NOHSC (2004) *Approved Criteria for Classifying Hazardous Substances*, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- United Nations (2009) *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.