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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DRY-FLO® AF

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Director
Chemicals Notification and Assessment

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DRY-FLO® AF

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
National Starch & Chemical Pty Ltd (ABN: 37 000 351 806)
7 Stanton Road
Seven Hills NSW 2147

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Polymer Constituents, Residual Monomers/Impurities, Use Details, Import Volume, and Site of Reformulation

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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dry-Flo® AF

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia in 45.4 kg net fibreboard drums with metal lid/lever lock as a white powder at <90% concentration. The notified polymer will be transported direct from the dockyard to the notifier's warehouse prior to distribution to personal care product manufacturers. The products will contain <10% notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

USE

The notified polymer will be used as an additive in personal care products.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Importation, transport and storage

Following importation, the imported product, DRY-FLO® AF, containing <90% notified polymer will be stored at the notifier's warehouse from where it will be sold and distributed to cosmetic formulators, who will subsequently incorporate the polymer into personal skin care products.

Formulation

At the formulation site fibreboard drums containing DRY-FLO® AF will be opened and scooped into a stainless steel container for weighing in the designated weighing area. The DRY-FLO® AF is then manually poured into a hopper with other formulation ingredients. Once the dry blending is completed, the formulation is then pumped through a size-screening filter. After the filtration process the final formulation is gravity fed to an automatic, closed filling machine for packaging into 200 g plastic bottles. Prior to final packaging, laboratory technicians will collect samples from the sampling port into sampling jars for quality control checks on the final product.

End-use

The small containers of product will be packed in cardboard cartons and will be transported by road to retail distribution warehouses, who will supply the products to retail outlets for consumer use.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Category of Worker	Number	Exposure (hours/day)	Duration	*Exposure Frequency (days/year)r*
Importation	10	4		40
Storage and transport	3	6		240
Formulation	20	6		240
Quality control	1	6		240
Maintenance	1	6		10
End users	1000	6		240

Importation, transport and storage

Exposure to workers involved in the importation, storage and transport of the notified polymer are not expected. Exposure is only expected in the unlikely event of an accidental spill. No specific controls are required during the above operations. Gloves, coveralls, dust mask and goggles would be used as required.

Formulation

Dermal, ocular and inhalation exposure to the notified polymer is possible when manually weighing and loading the powder into the mixing vessel. The loading operation is carried out under a dust extractor and dry blending occurs in a closed mixing tank under local exhaust ventilation. Personal protective equipment includes coveralls, dust mask, gloves and eye protection when carrying out the above activities. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

Quality Control/Maintenance

Intermittent dermal inhalation and ocular exposure to small quantities of the preparations is possible when collecting samples for quality testing. The laboratory will contain fume hoods and laboratory workers will wear safety glasses, laboratory coats and disposable gloves.

End-Use

Except in the case of accident, workers handling the end-use products during distribution and retail would not be exposed to the notified polymer because of the closed containers, and even in the case of spills, the small packaging size of the notified polymer in the product would limit exposure.

6.2. Summary of Public Exposure

Personal care products (i.e. body powder) containing the notified polymer at <10% concentration will be sold to the public, hence public exposure will be widespread and repeated. Application of the product is likely to occur on a daily basis (twice a day). Exposure during use of body powder will occur primarily via the dermal route, with chances of accidental ocular, oral and inhalation exposure. However, exposure to the notified polymer is considered minimal given the intermittent exposure during use.

The public is unlikely to be exposed to the notified polymer during transport, storage, and reformulation into end use products except in the event of an accidental spillage.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

The notified polymer will be imported and blended into personal care products, which will be sold to the general public. As a result, potential releases to the environment may occur during the reformulation of the imported product into personal care products and use of the personal care products. During reformulation, releases may occur as a result of spill, cleaning of mixing equipment and residues in containers. Spillage is expected to be minimal and contained within the reformulation sites where it will be collected for appropriate disposal. It is estimated that 1% of the notified polymer will remain as residues in the fibreboard drums used to import the polymer and within mixing equipment. At a maximum import rate of 10 tonnes per annum, this would amount to a maximum of 100 kg of the notified polymer, which will be disposed of through the sewer system.

Releases resulting from the use of the personal care products into which the notified polymer has been formulated would include residues in the product packaging, fugitive releases during application and the washing of the products during bathing and clothes washing. Residues remaining in the personal care product packaging are expected to account for a maximum of 5% (up to 500 kg per annum) of the maximum import volume. It is anticipated that this will be disposed of with the containers in domestic garbage and either be sent to landfill or incinerated. Because of the powdery nature of the products and the method of application, fugitive releases during application may account for up to 20% (up to approximately 1800 kg per annum) of the powder applied which is expected to fall to the ground or floor where the majority will be collected via vacuum or sweeping and disposed of with domestic garbage. The remainder of the imported polymer (approximately 7600 kg per annum) will be washed into the sewer as a result of bathing or washing clothes.

6.3.2. Environmental Fate

The notified polymer is expected to be readily biodegradable based on surrogate data for an analogue polymer, 28-1808. The analogue showed 86.7% degradation during a Modified Sturm Test indicating that it was readily biodegradable (Springborn, 2000). The test was verified using a sodium benzoate standard, which showed 98.5% degradation at the end of the study. In addition, a toxicity control

consisting of a mixture of the test substance and sodium benzoate showed 99.8% degradation at the end of the study period.

In landfill and the sewer, the notified polymer is expected to be readily degraded by biotic and abiotic pathways to ultimately yield carbon dioxide and water. Any incineration of the notified polymer would result in its destruction and the formation of carbon dioxide and water.

The notified polymer has a high molecular weight and is expected to be readily metabolised by organism and is therefore not expected to bioaccumulate.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White to off-white free flowing powder with negligible odour
Melting Point/Glass Transition Temp	Not determined.
Density	1500 kg/m^3
Water Solubility	0.798 g/L at 20°C. The water solubility was determined gravimetrically by suspending 5.5 g of test material in 1000 mL of deionised water, mixing for 30 minutes and collecting drying and weighing undissolved material. The soluble fraction was determined by the difference in mass between the initial weight and final dried weight.
Dissociation Constant	The notified polymer contains traces of amino acids, some of which may have groups, which can dissociate.
Particle Size	14 μm (average); fraction <10 μm = 16% (respirable)
Reactivity	Stable under normal environmental conditions
Degradation Products	Carbon monoxide, carbon dioxide and other unidentified thermal decomposition products.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

There are no toxicological data available for the notified polymer. The following toxicological end-points were submitted for a structurally similar material, 73-8050. The material 73-8050 contains the same protein but the ratio of the reactants is higher (contains 8% Dodecenyl succinic anhydride (DDSA) and 2.5% Calcium chloride) compared with the notified polymer.

Endpoint	*Result*	*Classified?*	*Effects Observed?*
Rat, acute oral LD50 5000 mg/kg bw	low toxicity	no	no
Rabbit, skin irritation	slightly irritating	no	yes
Human, 21-day cumulative irritation study		no	yes
Rabbit, eye irritation	slightly irritating	no	yes
Guinea pig, skin sensitisation –non-adjuvant test	no evidence of sensitisation	no	no

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

There was no mortality and all animals appeared normal in a 14-day acute oral toxicity study in rats.

In a skin irritation study in rabbits, one animal treated with 50% test material had very slight erythema at both the intact and abraded dermal site, which cleared by 48 hours. No other dermal reactions were observed.

In an eye irritation study in rabbits, 2 animals showed iridal effects only at 1 hour after test administration. All animals had slight to moderate conjunctival redness, which persisted for 48 hours in 2 animals. There were no eye irritation effects observed on the 72-hour observation.

There was no evidence of skin sensitisation observed in guinea pigs during the skin sensitisation study. Twenty-three subjects completed a 21-day cumulative irritation study in humans. There were no adverse events reported during the conduct of the study. The superficial layer effects ranged from none to glazing with peeling and cracking. The results indicated that the test material at 100% and 50% were classified as mild irritant in normal use conditions.

8.2. Human Health Hazard Assessment

By analogy, the notified polymer is of very low oral toxicity. It is a slight skin and eye irritant. It is not a skin sensitiser. The 21-Day Cumulative Irritation Study in humans showed the notified polymer to be a mild irritant in normal use. The notified polymer is not classified as a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004). The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted. However, the ready biodegradation study conducted on an analogue polymer, 28-1808, showed no inhibitory effect on microbial activity. Both the analogue polymer and the notified polymer are starch-based polymers. However, the analogue polymer has higher molecular weight and has different shape of starch particles compared with the notified polymer.

9.2. Environmental Hazard Assessment

No ecotoxicity data were provided for the notified polymer. Non-ionic polymers with a number average molecular weight in excess of 1000 are of low concern for ecotoxicity (Boethling and Nabholz, 1997).

10. RISK ASSESSMENT

10.1. Environment

The notified polymer is to be used as an ingredient in personal care products (body powder) and will be incorporated at <10% by weight. The reformulation of the notified polymer into the personal care products is expected to generate at most 100 kg of waste polymer, which will be discharged into the sewer. Release to sewer of the notified polymer will also result from washing it from the skin or garments. A portion of the notified polymer will be disposed of with domestic garbage as residuals in personal care product containers or from fugitive emissions during application. The residues will either be incinerated or deposited in municipal landfill. Incineration of the notified polymer will result in its destruction and the production of carbon dioxide and water. Given the expected ready biodegradable nature of the notified polymer, mineralisation of the polymer in landfill is expected to produce similar products.

A calculated worst-case scenario daily PEC in the sewer effluent is 6.8 µg/L. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume (10 000 kg) is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20.1 million contributing 200 L of water per person per day to the sewer, (3) there is no adsorption or degradation in the sewer prior to release. Given that the notified polymer is expected to be readily biodegradable, is not volatile and moderately soluble in water, up to 90% of the polymer may be removed through biodegradation as a result of passage through a sewage treatment plant. Hence, the concentration of the notified polymer entering receiving water is expected to be less than 1 µg/L. Given the anticipated low toxicity of the notified polymer at this level, the notified polymer is not expected to have an adverse effect on aquatic organisms.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m^3.

10.3. Public Health

Members of the public will make dermal contact with the personal care products containing the notified polymer. The use of the notified polymer at <10% in personal care products means that a small amount will be applied to the skin for each use. Potential for increased dermal absorption at the different sites of the body is not expected since the notified polymer is of high molecular weight and is unlikely to penetrate biological membranes, suggesting limited systemic absorption following normal use.

Based on the expected low toxicological hazard and limited systemic absorption, the risk to public from normal use of the polymer in personal care products is considered low.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

There is No Significant Concern to public health when used in the proposed manner.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is Low Concern to public health when used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in a powdered form:
  - Enclosed and automated mixing of the notified polymer
  - Exhaust ventilation during weighing and transfer of the notified polymer

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in a powdered form:
  - Personal protective clothing;
  - Gloves;

- Eye protection; and
- Dust mask or respirator when insufficient ventilation is available

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

- Atmospheric monitoring should be conducted to measure workplace concentrations of nuisance dust during formulation of the notified polymer into personal care products.

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of either to landfill or via incineration.

Emergency procedures

- Spills or release of the notified polymer should be handled by containment, collection via vacuum or sweeping, then placing material in sealed labelled containers. The spill area should be cleaned with a minimal amount of water, which is collected via an absorbent material, which will then be disposed of with spilt notified polymer.

13.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under subsection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

14. BIBLIOGRAPHY

Boethling RS and Nabholz JV (1997) "Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act", Chapter 10 (pp 187-234) of Ecological Assessment of Polymers, J. D. Hamilton and R. Sutcliffe (Ed's), Van Nostrand Reinhold.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Springborn (2000) 28-1808 – Determination of the biodegradability by the CO_2 evolution Modified Strum Test. Springborn Study No. 13729.6101. Spring born Laboratories Massachusetts USA. Unpublished.