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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Potato Starch Modified

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

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

Unilever Australia Limited (ABN 66 004 050 828)
219 North Rocks Road
North Rocks NSW 2151

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.

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
EU 1997

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Potato starch modified
Structure Solanace

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains potentially cationic functional groups, with a FGEW > 5000.

3. 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. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White to off-white free flowing powder.
Melting Point/Glass Transition Temp	Decomposes from 195°C. Self-ignites at 255°C.
Density	1490 kg/m^3 at 20°C
Water Solubility	83.6 mg/L at 20°C, pH 7 253 mg/L at 37°C, pH 2 235 mg/L at 37°C, pH 9 Determined by a flask stirring method using 5 g of polymer in 500 mL pH adjusted water. The total carbon content of the filtrate was analysed and the water solubility then calculated based on the % carbon content of the polymer.
Dissociation Constant	The polymer contains both acidic and basic functionalities which would be expected to display the typical pKa dependant behaviour.
Particle Size	MMAD = 67 µm 0.6% of the particles have an aerodynamic diameter < 10 µm. 73% of the particles have an aerodynamic diameter <100 µm.
Autoignition Temperature	255°C
Reactivity	Stable under normal conditions of use. Biodegrades when released to the environment. Tests have shown that the notified polymer is thermally stable at room temperature, and neither highly flammable nor explosive.
Degradation Products	None under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes (Unilever)	< 1	< 1	< 1	< 1	< 1
Tonnes (National Starch & Chemical)	0.5	0.5	0.5	0.5	0.5

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a neat powder and as a component (0.1-15%) of finished cosmetic products. The powdered polymer, in 45 kg fibre kegs with fibre lids and packaged on pallets, will be transported from the dock to a warehouse dedicated to the storage of chemical products before dispatch to the customer (cosmetics manufacturer). The finished cosmetic products containing the notified polymer, in plastic bottles (typically < 500 mL), will be transported from the dock to a warehouse dedicated to the storage of personal and household products, before being dispatched to retail customers.

Reformulation/manufacture processes
The notified polymer will not be manufactured in Australia. Reformulation is anticipated to occur at a number of cosmetics manufacturing sites. This will involve blending the notified polymer with other ingredients, and will not involve reaction of the notified polymer.

In a typical process, a compounder will weigh out the notified polymer manually under a dust extract hood, or using a vacuum tube. This will then be manually added to a mixing tank, along with other ingredients. During the blending a chemist may take samples of the product containing the notified polymer using a dip tube. After the blending is complete a packer will supervise the use of a line filler and capper to transfer the finished product into the retail bottles. The packaged cosmetic products will then be stored and handled by a store person.

Use
The notified polymer is used as a viscosity increasing and emulsion stabilising agent in cosmetic products, such as creams, lotions, deodorants and aftershaves at levels of 0.1 to 15%, with a typical concentration being 2%.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE
Transport and storage
Transport and warehousing workers are expected to have dermal and ocular contact with the notified polymer and products containing the notified polymer only in the event of accidental spillages. Inhalation exposure to the polymer powder may also occur if the packaging is breached.

Reformulation
Dermal, ocular and inhalation exposure to the notified polymer powder may occur during weighing out prior to reformulation. However, exposure to significant amounts of the notified polymer is reduced by the use of ventilation at the site of weighing, such as a dust extract hood, or by the use of a vacuum tube. The compounder is also expected to wear personal protective equipment such as glasses, gloves and coveralls. According to EASE (1997) modelling of this work environment (assumed to be a non-dispersive use, with intermittent, direct handling of the polymer powder), dermal exposure during manual weighing of the notified polymer is estimated to be in the range 0.1-1 mg/cm^2/day. Assuming a surface area of 420 cm^2 (half the area of both hands), and a bodyweight of 70 kg this equates to a dermal exposure of 0.6-6 mg/kg bw/day. This is a worst case exposure as it assumes no PPE, or ventilation is used. When effective ventilation is in place the dermal exposure is expected to be very low.

According to EASE (1997) modelling, in the presence of exhaust ventilation, the estimated atmospheric concentration during weighing is 2-5 mg/m^3. Therefore for a 70 kg worker, assuming an inhalation rate of 10 m^3 over an 8 hour exposure time and 100% bioavailability, inhalation exposure is estimated to be 0.29-0.71 mg/kg bw/day.

Dermal and ocular exposure to the polymer solutions may also potentially occur during certain processes involving the notified polymer such as sampling, cleaning, maintenance, or by accidental spills during the packing process. However, exposure to significant amounts of the notified polymer is limited because of the largely automated processes, and the engineering controls and personal protective equipment worn by workers.

Beauty Industry
Intermittent, wide-dispersive use with direct handling is expected to occur among cosmeticians and beauticians. According to EASE (1997) modelling of this work environment, dermal exposure in the range of 1-5 mg/cm^2/day of products containing < 15% of the notified polymer could result. Assuming a surface area of 840 cm^2 (area of both hands) and a bodyweight of 60 kg (female workers) this equates to a dermal exposure of 2.1-10.5 mg/kg bw/day. Exposure would be limited by the use of gloves.

Retail Industry
Workers in the retail industry will only be exposed to the notified polymer (< 15%) in the event of packaging breaches or accidental spillages.

PUBLIC EXPOSURE
Since the notified polymer will be in products sold to the general public, widespread public exposure is expected. Exposure to the notified chemical will vary depending on the type of cosmetic product and individual use patterns. Based on exposure estimates for a range of cosmetic products in Europe (SDA, 2005), public exposure (dermal) to the notified polymer in Australia has been estimated using the following assumptions:

- Bodyweight of 60 kg for females, 70 kg for males and 15 kg for babies;
- Typical concentration of notified polymer in products = 2%
- Concentration range of notified polymer in products = 0.1-15%
- 100% retention factor
- 100% dermal absorption
- Product usage is similar in Australia to Europe.

Product(s) used	*Adult/Child*	*Typical Exposure (mg/kg bw/day)*	*Range of exposure (mg/kg bw/day)*
Range of cosmetic products.	Adult female	2.6	0.13-19.4
Skin lotions	Adult female	1.9	0.09-14.2
Facial moisturiser	Adult female	0.53	0.03-4.0
Deodorant (roll-on or stick)	Adult female	0.17	0.008-1.2
Aftershave	Adult male	0.29	0.01-2.1
Baby care products	Child	5.3	0.3-40

The estimate of combined exposure to a range of cosmetic products (skin lotion, facial moisturiser and deodorant) is expected to be an overestimate as it assumes all products used by one person contain the notified polymer and uses the maximum 'product amount used' from the range in the dataset.

Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 5000 mg/kg bw	no	no	OECD TG 401
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	yes	OECD TG 402
3. Rabbit, eye irritation (16.8% aqueous suspension)	slightly irritating	no	yes	OECD TG 405
4. Skin sensitisation - non-adjuvant test (18.5% aqueous suspension).	no evidence of sensitisation.	no	no	OECD TG 406 (Buehler test)
5. Rat, dermal repeat dose toxicity - 28 days- Limit test	NOAEL ≥ 2000 mg/kg bw/day	no	yes	OECD TG 410
6. Genotoxicity – in vitro Mouse Lymphoma Forward Mutation Assay	non genotoxic	no	no	OECD TG 476

Eye irritation
At the 1 hour observation 2/3 animals showed redness of the conjunctivae with vessels definitely injected above normal (grade 1 reaction). At 1 hour observation all three animals showed oedema of the conjunctivae (grade 2, obvious swelling with partial eversion of the lids), as well as conjunctival discharge with moistening of the lids and hairs just adjacent to the lids (grade 2 reaction). These reactions had cleared by 24 hours, except for one animal which still showed slight swelling of the conjunctivae (grade 1). This had cleared by 48 hours.

Skin irritation
In the acute dermal toxicity test (dose of 2 g/kg bw), very slight to well defined erythema and oedema was observed in all test animals after 24 hours. At 48 hours this had reduced to observations of very slight erythema in 5/10 animals and very slight oedema in 3/10 animals. All sites had returned to normal by 72 hours. Due to the difficulty in removing the dressing and test material (caused by adhesion of the test article to the skin and dressing) some of the local irritation observed may have been due to slight mechanical trauma.

In the repeat dose dermal toxicity test (dose of 2 g/kg bw/day) no erythema or oedema was observed at the treatment sites. Small scabs were observed on 5/10 males and 6/10 females. These were attributed to adhesion of the test article to the skin.

In a skin sensitisation study only very faint erythema (non confluent) was observed in 6/20 animals, following the 2nd or 3rd induction treatments with an 18.5% aqueous suspension.

Dermal repeat dose toxicity
Gross examination of test animals revealed no signs of systemic toxicity.

Statistically lower body weight gain was observed for treated females in the first and fourth weeks, compared to the vehicle control group. Examination of individual body weight data revealed that sporadic gains and losses were observed in both groups, and the weight gain in the fourth week was lower than usually observed for both test and control animals. Food consumption was normal during the test period. The lower body weight gain could therefore be due to the stress associated with the treatment procedure, in which adhesion of the test article to the skin and dressings was a problem.

Clinical biochemical test data revealed a statistical decrease in serum triglycerides and a slight increase in serum calcium, sodium and phosphorous for treated males. However, none of the other test parameters supported these findings and no differences were observed for females.

All other observed effects (decrease in organ weights and differences in hematologic test parameters) were within historical control ranges for this species of rat. The NOAEL is therefore considered to be at or above the highest dose of the given in the study, 2000 mg/kg bw/day.

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Transport, storage and reformulation
The worst case dermal exposure was estimated to be 6 mg/kg bw/day in the absence of ventilation and PPE. This value is over 300 times lower than the worst case NOAEL obtained in the dermal repeat dose animal study (2000 mg/kg bw/day). The risk of systemic toxicity following repeated dermal exposure to the notified polymer is therefore not a significant concern.

The risk to workers from inhalation effects is considered to be low because of the expected low inhalation exposure (due to the use of engineering controls during the reformulation processes) and intrinsic low hazard of the notified polymer. 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.

Due to the slight eye and skin irritation potential of the polymer eye and skin protection should be worn during reformulation processes.

End Use
The worst case dermal exposure was estimated to be 10.5 mg/kg bw/day in the absence of ventilation and PPE. This value is over 190 times lower than the worst case NOAEL obtained in the dermal repeat dose animal study (2000 mg/kg bw/day). The risk of systemic toxicity following repeated dermal exposure to the notified polymer is therefore not a significant concern.

Products containing the higher concentrations of the notified polymer (e.g. 15%) may cause very slight irritation in some individuals. However, products will typically contain only 2% of the notified polymer.

PUBLIC HEALTH
The public will be exposed to the notified polymer during use of cosmetic products. Based on a worst case NOAEL of 2000 mg/kg bw/day, derived from a 28-day rat dermal study, the margin of exposure (MOE) from typical and worst case dermal exposures is calculated as follows:

Product(s) used	*Adult/Child*	*MOE based on typical exposure*	*MOE based on worst case exposure*
Range of cosmetic products.	Adult female	769	103
Skin lotions	Adult female	1053	141
Facial moisturiser	Adult female	3774	500
Deodorant (roll-on or stick)	Adult female	11765	1667
Aftershave	Adult male	6897	952
Baby care products	Child	377	50

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the only MOE not considered acceptable is the worst case exposure of children to baby care products. However as no adverse effects were observed in the repeat dose study the NOAEL may be greater than 2000 mg/kg bw/day. This would be expected based on the high molecular weight of the polymer (MW > 10,000), which would reduce the likelihood of the polymer crossing biological membranes. In addition, the exposure was derived using the highest possible concentration. The MOE is > 350 when the typical concentration of 2% is used.

The risk of eye irritation from the use of cosmetic products containing the notified polymer is considered to be low due to the relatively low concentrations of notified polymer in the products, and the fact that the notified polymer was shown to be only slightly irritating to the eye in more concentrated solutions. Products containing the higher concentrations of the notified polymer (e.g. 15%) may cause slight irritation of the eyes and slight irritation of the skin. It is expected that eyes will

be rinsed following any contact with products containing the notified polymer.

Since products formulated with the notified polymer will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified polymer by accidental ingestion. However, as the notified polymer is considered to be of low acute toxicity and given the relatively low concentration of the notified chemical in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

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 results of spills, cleaning of production equipment and residues in import 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 import containers which will be rinsed prior to disposal via waste contractors. The rinsate will either be used in the product formulation or be disposed of to sewer. Potentially up to an additional 3% of the import volume may be released to sewer due to the cleaning of production equipment. Thus a maximum of 4% of the proposed maximum import volume (1500 kg), which equates to maximum of 60 kg annually of the notified polymer, 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 off of the products during bathing and clothes washing. Residues remaining in the personal care product packaging is expected to account for a maximum of 3% (up to 45 kg per annum) of the 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. The remainder of the imported polymer (~1395 kg per annum) will be washed into the sewer as a result of bathing or washing clothes.

ENVIRONMENTAL FATE

In a ready biodegradation test the notified polymer showed an 86.87% degradation during a Modified Sturm Test (OECD Test Guideline 301B) indicating that it was readily biodegradable. The test was verified using a sodium benzoate standard which showed 93.77% degradation at the end of the study. In addition a toxicity control consisting of a mixture of the test substance and sodium benzoate showed 83.49% degradation at the end of the study period, indicating that the test material did not inhibit the microbial activity.

The notified polymer does potentially contain cationic and anionic functional groups, however based on the typical dissociation constants for the functionalities and their ratio within the polymer it is expected to have a net anionic charge throughout most of the environmental pH range, becoming slightly cationic only at the low end of the range.

In landfill and the sewer, the notified chemical is expected to be relatively readily degraded by biotic and abiotic pathways to ultimately yield water and oxides of carbon and nitrogen and salts of chlorine and sodium. Any incineration of the notified polymer would result in its destruction and the formation of carbon dioxide and water and ash containing salts of chlorine and sodium.

The notified polymer has a high molecular weight not expected to bioaccumulate.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted, therefore a PNEC can not be determined. The notified polymer does contain a number of potentially cationic and anionic groups. It is expected to be anionic throughout the majority of the environmental pH range and cationic over the lower end of the environmental pH range. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. The toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups. Cationic polymers that are water soluble are known to be toxic to aquatic organisms. However, cationic polymers with FGEW >5000 are not expected to be toxic to aquatic organisms. The aquatic toxicity may be expected to be low.

Exposure levels in the aquatic compartment should be low and dispersed and therefore the overall environmental hazard should be low.

7.3. Environmental Risk Assessment

Release to sewer of the notified polymer will result from reformulation into personal care products and the washing of the product(s) from the skin or garments after application. This will account for up to 1455 kg annually (60+1395 kg). A portion of the notified polymer (up to 45 kg) will be disposed of with domestic garbage in empty personal care product containers which will be disposed of to municipal landfill or possibly via incineration. The notified polymer is ready biodegradable therefore will quickly degrade/mineralise in landfill.

A calculated worst-case scenario daily PEC in the sewer effluent assuming there is no adsorption or degradation in the sewer can be calculated as follows:

Amount released to sewer	1455 kg
Number of days used	365
Australian population	20.1 million people
Amount of water used per person	200 L
PEC_{sewer}	$\frac{1455\ 000\ 000\ 000}{365x200x2010000}$ = 0.99 μg/L
$PEC_{inland\ water}$ (1:1 dilution)	0.99 μg/L
PEC_{ocean} (1:10 dilution)	0.099 μg/L

However, the notified polymer is readily biodegradable (86.87%) and due to its cationic nature, it is expected that 90% will either degrade or partition to the solid phase so that only 10% will be discharged to the aquatic compartment. Thus the $PEC_{inland\ waters}$ will be closer to 0.099 μg/L. While the notified polymer does contain potentially charged functional groups, at this level the notified polymer is not expected to have an adverse effect on aquatic organisms.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

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

8.2. Level of Concern for Public Health

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

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Safety goggles
  - Impervious gloves

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

- 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.

Environment

- The following control measures should be implemented by cosmetic manufacturers and warehouse sites to minimise environmental exposure during personal care product formulation and storage of the notified chemical:
  - All process equipment and storage areas should be bunded.

Disposal

- The notified chemical should be disposed of to landfill for solids and to licensed waste contractors for liquids.

Emergency procedures

- Spills/release of the notified polymer should be contained by soaking up with inert absorbent material and dispose of as special waste in compliance with local and State regulations as recommended in the MSDS.

10.1. 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.

11. BIBLIOGRAPHY

EASE (1997) EASE (Estimation and Assessment of Substance Exposure) for Windows version 2.0; Health and Safety Executive, UK and AIAI, Edinburgh

SDA (2005) Exposure and Risk Screening Methods for Consumer Products Ingredients. Washington, The Soap and Detergent Association.