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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Structure 2001

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Modified Acrylate Terpolymer in STRUCTURE 2001

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
National Starch and Chemical Pty Ltd of 9 Stanton Road, Seven Hills NSW (ACN 37 000 351 806)

NOTIFICATION CATEGORY
The notified polymer meets the PLC criteria.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Molecular formula (except for polymer backbone)
Structural formula (except for polymer backbone)
Spectral details
Molecular weight
Polymer constituents
Residual monomers and impurities
Exact Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

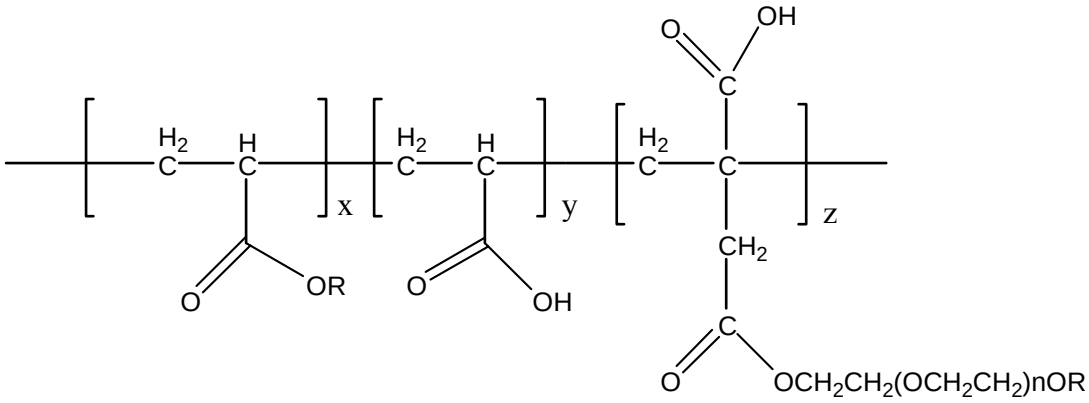
PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Advise of new chemical for cosmetic use introduced at 10 kg or less per 12-month period

NOTIFICATION IN OTHER COUNTRIES
United States, Premanufacture Notice (PMN) 1986
Notification not required in the European Community (Directive 79/831/EEC)
Notification has also been made in Japan and Canada

2. IDENTITY OF CHEMICAL

MOLECULAR FORMULA **Full details are confidential**
$(C_5H_8O_2)_x.(C_4H_6O_2)_y.(C_{63}H_{122}O_{24})_z$ where x=0.5, y=0.4 and z=0.1

STRUCTURAL FORMULA **Full details are confidential**



Details of R groups are exempt from publication

MOLECULAR WEIGHT **Full details are confidential**
Number Average Molecular Weight (Mn) >10 000

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD The notified polymer can be identified by IR spectroscopy

3. COMPOSITION

DEGREE OF PURITY
99.0% on dry basis

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
Concentrations of all residual monomers and impurities in Structure 2001 are less than 1%

POLYMER CONSTITUENTS
STRUCTURE 2001 is manufactured from monomers and reactants already listed on the Australian Inventory of Chemical Substances.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 3	≤ 3	≤ 3	≤ 3	≤ 3

USE
Emulsion thickening agent (rheology modifier) in the formulation of aqueous specialty products in the personal care sector.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Initially, STRUCTURE 2001 will be imported in finished products. National Starch and Chemical will import STRUCTURE 2001 to formulate into other products or to sell to other customers.

TRANSPORTATION AND PACKAGING
STRUCTURE 2001 will be imported as a formulation ingredient in 200 L fibre drums. Cosmetic formulations containing STRUCTURE 2001 will be in consumer-size containers.

5.2. Operation Description

When STRUCTURE 2001 is imported as a component in cosmetic products, it will comprise 0.5% of the product. The concentration of STRUCTURE 2001 in products formulated in Australia will be in the range of 0.2 to 4.0%. Product formulation consists of batch process mixing of various ingredients in a reactor vessel fitted with local exhaust ventilation, automatic dispensing to product containers, lidding, palleting and transfer to designated storage.

5.3. Occupational exposure

Number and Category of Workers
(per company, in not more than eight companies)

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Formulation chemists	2		
Manufacturing personnel	4		
Transport & store personnel	Not known	No exposure expected in routine operations	
Hairdressers, cosmeticians, beauticians	Not known		

Exposure Details
Manufacture
The polymer is not manufactured in Australia.

Formulation
Formulation of products containing Structure 2002 will be carried out in a batch process no more than a few times per year. Structure 2001 is used only once in the batch process. The possibility of dermal exposure due to splashes exists, however exposure becomes less likely as the mixture thickens.

End Use
The frequency and duration of exposure by hairdressers, cosmeticians and beauticians will depend on the type, scope and demands of the particular job, as well as the concentration of the notified polymer in the product being used. Intermitant, short exposure to exposed skin could occur during use of the products. Accidental ocular exposure could also occur.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The majority of the notified polymer will be imported from the USA as the finished product at a concentration of 0.5%. Some reformulation may take place in Australia but the wastes generated from these processes are not expected to be significant.

RELEASE OF CHEMICAL FROM USE
The majority of the notified polymer will be incorporated into hair care products and as such will almost completely be released to the environment after use. It is anticipated that approximately 98% of the import volume of the notified polymer will be released to sewer and the remaining 2% will be sent to landfill as residue in import containers. Thus, based on the maximum import volume, up to 3000 kg/year of the notified polymer will be released to sewer and 60 kg/year sent to landfill.

The notifier has provided the following predicted environmental concentration (PEC) calculation using the assumptions detailed below. Based on annual imports of up to 3 tonnes/annum, and assuming the

majority of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 8.2 kg/day. Assuming a national population of 18,000,000 and that each person contributes an average 100 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 4.6 μg/L.

Amount entering sewer annually	3000 kg
Population of Australia	*8 million*
Amount of water used per person per day	*100 L*
Number of days in a year	*365*
Estimated PEC	4.6 μg/L (4.6 ppb)

5.5. Disposal

The notified chemical will ultimately be disposed of in either the sewer (major) or by landfill. Residues in empty containers will be sent to landfill via household garbage collection.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 KPA: White emulsion in water

FREEZING POINT: 0°C

Remarks: Based on freezing point of water

BOILING POINT: 100°C at 101.3 kPa

Remarks: Based on boiling point of water

DENSITY: 1020 kg/m^3

WATER SOLUBILITY: Not determined

Remarks: Based on its monomer composition, the notified polymer in its protonated form is expected to be insoluble in water. However, under basic conditions such as those commonly found in sewers (pH 8), the water solubility of the notified polymer is expected to increase. This could be appreciable as the carboxylate may contribute up to 50% of the functionality and the polyoxyethylene chain will assist further.

HYDROLYSIS AS A FUNCTION OF PH

Remarks: The notified polymer contains ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.

PARTITION COEFFICIENT (N-OCTANOL/WATER): Not determined

Remarks: Under basic conditions the notifier polymer's expected water solubility is indicative of partitioning mainly into the aqueous phase. However, this will be reduced at low pH.

ADSORPTION/DESORPTION: Not determined

Remarks: The notified polymer may contain up to 50% carboxylate functionality, which under basic conditions will become deprotonated resulting in an increase in the water solubility. Under the basic conditions commonly found in the sewer, the notified polymer is expected to be relatively mobile. However, as a consequence of its polyanionic character, it is expected to chelate with cations on the surface of

soil and sediments and as such its mobility will be reduced.

DISSOCIATION CONSTANT Not determined

Remarks The notified polymer contains carboxylic acid groups that are expected to have typical acidity.

PARTICLE SIZE

Remarks STRUCTURE 2001 is a low viscosity aqueous emulsion (15-30 cps). When used (ie neutralised) it is higher in viscosity.

FLAMMABILITY LIMITS Not applicable

Remarks Water-based emulsion

AUTOIGNITION TEMPERATURE Not applicable

Remarks Water-based emulsion

EXPLOSIVE PROPERTIES Not applicable

Remarks Water-based emulsion

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute oral (OECD TG 401 Acute Oral Toxicity.)	low toxicity LD50 >5000 mg/kg bw
Rabbit, skin irritation (OECD TG 404 Acute Dermal Irritation/Corrosion)	slightly irritating to skin
Rabbit, eye irritation (OECD TG 405 Acute Eye Irritation/Corrosion.)	slightly irritating to eyes
Guinea pig, skin sensitisation – Standard Magnusson and Klingman Guinea Pig Maximisation Method	no evidence of skin sensitisation.
Human, 21-day cumulative skin irritation study –4% un-neutralised.	Possible slight skin irritant in normal use
Human, 21-day cumulative skin irritation study – 1% un-neutralised.	Mild material – very slight experimental irritation
Human, 21-day cumulative skin irritation study – 4% neutralised.	Mild material – no experimental irritation
Genotoxicity - bacterial reverse mutation	non mutagenic

Comments on Toxicology

Acute Oral Toxicity

Five male and five female Wister Albino rats were dosed with the notified polymer emulsion at 5000 mg/kg bw. The rats were observed 1, 2, and 4 hours post dose and once daily thereafter for 14 days for toxicity and pharmacological effects, and twice daily for mortality. Body weights were recorded pretest, weekly and at termination. All animals were examined for gross pathology. All animals survived the 5000 mg/kg bw oral dose. Instances of diarrhea and soiling of the anogenital area were noted during the observation period. Body weight changes and necropsy were normal.

(MB Research Laboritories, 1996a)

Dermal Irritation

Six female New Zealand White rabbits were exposed to the notified polymer emulsion for four hours on intact and abraded skin using an occluded dressing. The animals were observed daily for evidence of systemic toxicity and/or ill-health. Initial and final body weights were also obtained. No signs of systemic toxicity were observed during the test. The averaged irritation scores are given in the following table.

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar (Intact)	0.27	1	24	0
Oedema (Intact)	0	0	0	0
Erythema/Eschar (abraded)	0.44	1	48	0
Oedema (abraded)	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

(Unilever Research US, 1996a)

Eye Irritation

The eyes of six New Zealand White rabbits were instilled with 0.1 mL of the notified polymer emulsion and the animals observed at 1, 24, 48 and 72 hours. Redness of the conjuctiva, chemosis and discharge was observed in all animals at the one hour observation, in four animals at 24 hours and two animals at 48 hours. No opacity of the cornea or iridial inflammation was observed in any animals, and all animals were without signs at the end of the observation period. The observation scores are given in the following table.

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*

Conjunctiva: *redness*	0.44	2	48	0
Conjunctiva: chemosis	0.22	1	48	0
Conjunctiva:discharge	0.11	1	24	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.
(MB Research Laboratories, 1996b)

Skin sensitisation
The standard Magnusson and Kligman Guinea Pig Maximisation Method was used with twenty female guinea pigs to test for skin sensitisation. Following intradermal injection during the induction phase, systemic effects including lethargy, anorexia, weight loss and nasal discharge were observed. No positive responses were observed following the challenge phase.
(Unileaver Research US, 1996b)

21-day Cumulative skin Irritation Study
The potential of the notified polymer emulsion for human skin irritation was tested by repetitive topical application over a 21-day period for 23 ± 1 hr/day. Twenty-six of a total of 33 subjects completed the study. Reapplication and scoring of the test materials – 4% unneutralised, 1% unneutralised, 4% neutralised and 1% neutralised – occurred every 24 hours until excessive irritation was noted at any scoring session. No adverse events were reported during the course of the study.
(Hill Top Research Ltd, 1997)

Genotoxicity
The mutagenic activity of the polymer emulsion was tested using the *Salmonella – Escherichia coli*/Mammalian-microsome Reverse Mutation Assay. The strains used in the assay were *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* strain WP2uvrA. A rangefinding study was conducted using tester strains TA100 and WP2uvrA and 10 doses ranging from 5000 µg to 6.67 g per plate with and without Aroclor™-induced rat liver S9 and with one plate per dose. The main study used five doses – 5000, 3300, 1000 333 and 100 µg per plate, with and without S9 and with three plates per dose. The test article did not cause a positive increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes.
(Lawlor, 1996)

8. ECOTOXICOLOGICAL INVESTIGATIONS

No ecotoxicological data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Exposure

The intended use pattern is expected to result in the majority of the notified polymer being eventually released to the aquatic environment. However, this will be in diluted manner as the notified polymer contained within the hair care products will be released from domestic use at low concentrations.

The PEC calculation of 4.6 µg/L would seem to be an overestimation of the realistic effluent concentration due to the low assumption of water used per person per day. However, it serves as a worst-case scenario. When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, so that the PEC is approximately 0.46 µg/L. This concentration may be further reduced through removal from the aquatic compartment resulting from association between the notified polymer and cations on the surface of sewage sludge.

Fate

After release to the aquatic compartment, the notified polymer, as a consequence of its polyanionic character, is expected to chelate with cations on the surface of sediments. Here it will slowly degrade through biological and abiotic processes to water and oxides of carbon. In landfill, the notified polymer is not expected to escape from the hair product containers and if this was to occur it is expected to associate with the soil matrix and slowly decompose by the processes described above.

The polymer is not expected to cross biological membranes, due to its high molecular weight and predicted low water solubility, and as such is not expected to bioaccumulate (Connell 1990).

9.1.2. Environment – effects assessment

Polycarboxylic acids such as the notified polymer are considered to be of moderate concern to algae with 96 h EC 50 values ranging from 1-100 mg/L (Nabholz 1993). The toxicity exhibited seems to result from overchelation of nutrient elements needed by the algae for growth.

9.1.3. Environment – risk characterisation

Since the notified polymer will be used in shampoos, most will eventually be released into domestic sewage systems as a consequence of product use.

A Predicted No Effects Concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, *Daphnia*, algae). The PNEC is calculated by taking the EC50 value of the most sensitive species, and dividing this value by an assessment safety factor of either 100 (OECD) or 1000 (EU). If the above data is used as a surrogate, the worst case EC50 value to algae is 1 mg/L and using a worst case scenario safety factor of 100, gives a PNEC of 10 µg/L.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.05. This value is less than 1, indicating no immediate concern to the aquatic compartment. As noted above, the notified polymer is expected to chelate with cations which will be removed from the water column.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal and ocular exposure can occur during certain formulation processes, such as when opening drums, transferring to the mixing vessel, blending and packaging. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls (local exhaust ventilation) personal protective equipment worn by workers, and the viscous nature of the formulation. During formulation, exposure to the notified polymer is expected at 10-30% concentration.

Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE modelling of this work environment, exposure in the range of 1-5 mg/cm^2/day of products containing 0.5-4% of the notified polymer could result.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

9.2.2. Public health – exposure assessment

The potential for public exposure to the notified polymer during transport, manufacture, use and disposal is assessed as negligible. Cosmetic products containing the notified polymer are for sale to the general public. Members of the public will make dermal contact (dispersed over the skin) and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the notified polymer is present at low concentrations.

9.2.3. Human health - effects assessment

The notified polymer is slightly irritating to the skin and eye. It caused slight irritation to human skin in a 21-day cumulative study. It is not classified as an irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The notified polymer meets the PLC criteria and therefore low hazard is expected due to the lack of reactive groups and the inability of the polymer to penetrate biological membranes. Slight skin irritation may occur following exposure to the un-neutralised STRUCTURE 2001, due to its low pH (2.2 to 3.5). However, the neutralised product at 4% notified polymer was not an irritant.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified polymer is expected to be low. During reformulation processes when the concentration of the notified polymer is high, gloves and glasses may be worn to protect against skin and eye irritation. 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.

9.2.5. Public health – risk characterisation

The risk to public health will be no significant concern because the notified polymer is present at low concentrations and is unlikely to be bioavailable. At 4%, the notified polymer is not expected to be a skin or eye irritant.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer in STRUCTURE 2001 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label Needs contact details

The label for the notified polymer in STRUCTURE 2001 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Personal protective equipment is required for the safe use of the notified polymer in STRUCTURE 2001 during charging to the reformulation process
  - Chemical resistant gloves, glasses.
- No specific engineering controls, work practices or personal protective equipment are required for the safe use of products containing the notified polymer, 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 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.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - The concentration of the notified polymer in products should not exceed 4%

Environment

Disposal

- The notified polymer should be disposed of by landfill or by discharge to the sewer.

Emergency procedures

- Spills/release of the notified polymer should be handled as outlined in the MSDS for STRUCTURE 2001. Absorb spillages onto sand, earth or any suitable absorbent material. Sweep up and shovel into waste drums. Wash the spillage area with water. Disposal should be in accordance with local, state or national legislation.

12.1. 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 Section 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 Section 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.

No additional secondary notification conditions are stipulated.

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