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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Structure Plus

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in Structure Plus

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
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- Other names
- CAS Number
- Molecular formula
- Structural formula
- Means of identification
- Number average molecular weight
- Weight average molecular weight
- Weight percentage of polymer species with MW < 1000 and MW < 500
- Charge density
- Polymer constituents
- Residual monomers and impurities
- Reactive Functional Groups – include FGEW
- Import volumes
- Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Melting point
- Boiling point
- Density
- Vapour Pressure
- Water Solubility
- Hydrolysis as a function of pH
- Partition Coefficient
- Adsorption/Desorption
- Dissociation Constant
- Flash Point
- Flammability Limits
- Autoignition Temperature
- Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Structure ® Plus

3. COMPOSITION

DEGREE OF PURITY
< 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities and residual monomers are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance.

DEGRADATION PRODUCTS
Carbon monoxide, carbon dioxide and other unidentified thermal decomposition products.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer will be supplied in liquid form. Thus, all of the residual monomers can be lost from the notified polymer.

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 205 kg lined drums as an aqueous emulsion containing < 25% solid. The notified polymer will be transported direct from the dockyard to the notifier's warehouse prior to distribution. The product will be sold and the finished products manufactured, such as shower gel and spray hair conditioner, containing the notified polymer at ≤ 2 %.

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

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

USE
The notified polymer will be used as a rheology modifier in personal care products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified polymer will be imported through Melbourne by wharf.

IDENTITY OF MANUFACTURER/RECIPIENTS
Health care product manufacturers.

TRANSPORTATION AND PACKAGING
Aqueous emulsion containing the notified polymer will be imported in 205 kg lined drums. It will be transported by road from wharf to the notifier's warehouse and stored. No repackaging operations will be carried out at the warehouse. Aqueous emulsion containing the notified polymer will then be transported by road unopened to the formulation site.

STORAGE FACILITIES & STORAGE REQUIREMENTS
Store on a wooden pallet. Protect from freezing. Avoid extreme temperatures during storage. Store between 5-30ºC away from heat, sparks or fire.

5.2. Operation description

Importation, Transport and Storage
Structure Plus containing the notified polymer will be imported into Australia in 205 kg lined drums as a white aqueous emulsion. It will be stored at the warehouse from where it will be sold and distributed to formulators into health care products, who subsequently will incorporate the polymer into skin and hair care products.

Formulation – shower gel
Formulation workers are involved in transferring of the material from the import containers into the mixing equipment (1 000 L capacity). The transfer and weighing is performed automatically using pumps and dosing equipment. The notified polymer will then be blended with other ingredients in a batch wise process. Before final packaging of the end product, quality control technicians will be involved in quality control checks on the final product. The samples are taken via a sampling port into sampling jars. Once the batch has received quality assurance approval it will be pumped via an automatic filling line to a multihead filling machine where the final product will be transferred to 300 ml and 500 ml capacity plastic bottles. The final concentration of notified polymer in the end product will be ≤ 2%.

Filling and Packaging
The filling line workers operate and clean the automated guarded filling equipment. The packaging operators will pack the final product containers (300 ml and 500 ml plastic moulded bottles) in cartons ready for distribution to retail market outlets.

Formulation – Spray Hair conditioner
At the formulation site, emulsions containing the notified polymer will be dispensed through an automated pumping system into a 1000 L stainless steel mixing vessel equipped with a mechanical stirrer. Other ingredients will be added to make hair styling formulations, and the mixture stirred until well blended. Manufacturing equipment is cleaned with hot water and rinsed after every batch. The finished product is tested for quality assurance before being filled into 150 ml plastic bottles using automated equipment. The final packaged product containing ≤ 2 % of the notified polymer will be sold to consumers through retail outlets and hair salons.

End-use
The small containers of product will be packed in cardboard cartons and will be distributed by road to retail outlets and hair salons for sale to consumers.

5.3. Occupational exposure

Number and Category of Workers

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

Exposure Details
Importation, Transport and Storage
Exposure to workers involved in the importation, storage and transport of the notified polymer (< 25% concentration of the notified polymer) is only expected in the unlikely event of an accidental spill.

Formulation of shower gel
Typically, the manufacturing operators wear long sleeved overalls, a head covering, safety glasses, safety boots and impervious gloves while handling chemicals. The sampling, dispensing and compounding operations are carried out in an enclosed and automated system designed to not create aerosols or spill hazards, and will further minimise worker exposure. General and local ventilation is used. The maximum exposure level to the notified polymer would be < 25%.

Formulation of hair care products

The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source. However, dermal and limited ocular exposure may occur when opening and closing the 205 kg drums and when adding the notified polymer manually into mixing vessel, and connecting and disconnecting transfer and filling lines. Dermal exposure may also occur due to drips and spills and if containers are overfilled at the filling station. Skin contamination may occur when maintenance workers are cleaning equipment and during maintenance of equipment. Workers involved in the above activities are expected to wear personal protective equipment such as, overalls, safety glasses, safety shoes, gloves hair covering and facemasks. The maximum exposure level to the notified polymer would be < 25%.

Quality Control/Maintenance
Limited dermal and ocular exposure to small quantities of the notified polymer may occur during sampling and testing or during machine maintenance (≤ 2 % concentration of the notified polymer). The laboratory will contain fume hoods and staff will wear safety glasses, laboratory coats and disposable gloves.

End-users
Retail workers (e.g. supermarkets) will unpack the boxes and place the shower gel in 300-500 ml plastic bottles and/or spray hair conditioners in 150 ml plastic bottles containing the notified polymer at ≤ 2% concentration on supermarket shelves. Exposure is only likely to occur in the event of a spill from damaged containers.

Salon workers will open the plastic bottles of lotion/gel. They will spray a small amount of the gel (15 ml) into their hands and apply it to the customer's hair from roots to end with their hands. The product is left in the hair and not rinsed out.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will not be manufactured or repackaged in Australia. The product containing the notified polymer at < 25 % concentration will be imported into Australia in 205 kg lined drums as an aqueous emulsion and will be transported directly to the notifier's warehouse for housing before being distributed to health care product formulators. Release to the environment may occur at the notifier's warehouse in the unlikely event of an accident during transport or if the packaging is damaged.

It is estimated that 1% of the residual polymer would remain in the 205 kg lined drums and in mixing equipment after use. Based on 2 tonnes maximum annual importation of the notified polymer, it is estimated that 20 kg of the notified polymer would remain in the empty drums. The drums along with the residues are sent off site for disposal to landfill. Washings from cleaning of mixing vessels and transfer lines are collected and sent to landfill by waste contractors.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used in body care and hair care products and it is likely that some residue will be left in containers and disposed of with domestic garbage. It is estimated that 5% would be left in empty containers (250 kg notified polymer/year). The garbage will be placed into landfill.

Almost all of the notified polymer will be released to the sewer system, as a consequence of use in personal care products. The notifier indicates that approximately 95% of the notified polymer (annually 1.75 tonnes) may be released to sewer.

5.5. Disposal

Spilled or leaked material will be collected using absorbent material into containers and disposed of by a licensed waste disposal company. Empty import containers and solids removed will be disposed of to landfill. Following use, emptied consumer product containers are expected to be collected through domestic garbage disposal and then disposed of to landfill.

5.6. Public exposure

Personal care products containing the notified polymer at ≤ 2% concentration will be sold to the public. Application of the product is likely to occur on a daily basis (twice a day). Exposure during use of shower gel and hair conditioners will occur primarily via the dermal route, with chances of accidental

ocular, oral and inhalation exposure.

The public is unlikely to be exposed to the notified polymer during transport, storage, and manufacture, except in the case of an accidental spillage.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White liquid emulsion

Freezing Point 0°C

Remarks Cited in MSDS for product containing notified polymer.

Boiling Point 100°C

Remarks Cited in MSDS for product containing notified polymer.

Density Not determined

Remarks No information was provided

Vapour Pressure 17 kPa at 760 mm Hg at 20°C

METHOD
Remarks Cited in MSDS, for product containing notified polymer.

Water Solubility Not determined

Remarks The notified polymer is water dispersible up to a concentration of 225 g/L. Elsewhere it is claimed to be soluble at this level, which is supported by the extent of hydrophilic groups in the polymer. However, in the fish test, solutions at 6.25 mg/L were not fully soluble.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer contains ester groups, which may undergo hydrolysis under extreme temperature and pH conditions, but not at ambient environmental conditions (pH 4-9).

Partition Coefficient (n-octanol/water) Not determined

Remarks As the notified chemical is dispersible in water, a partition coefficient cannot be obtained. However, it is expected that the notified polymer will partition to the aqueous phase based on its claimed solubility.

Adsorption/Desorption Not determined

Remarks The notified polymer is not expected to bind strongly to organic matter in soil due to its solubility/dispersibility in water. However, the high cationic charge density on the polymer will have affinity to the negatively charge groups present in colloidal organic matter in sediments. Consequently the polymer is expected to become associated with the sediments.

Dissociation Constant Not determined

Remarks The notified polymer has both anionic and potentially cationic functionalities and thus it will have typical acidic and basic properties.

Particle Size Not applicable

Remarks The notified polymer as supplied is in a liquid form.

Flash Point > 100°C

Remarks Cited in the MSDS, for product containing notified polymer.

Flammability Limits Not expected to be flammable.

Remarks Imported as a component of an aqueous formulation.

Autoignition Temperature Not expected to autoignite.

Remarks Imported as a component of an aqueous formulation.

Explosive Properties Not expected to be explosive.

Remarks Imported as a component of an aqueous formulation.

Reactivity Stable under recommended conditions of storage.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test.	no evidence of sensitisation.
Additional Studies	
21-Day Cumulative Irritation Study in Humans	non irritant
Human Repeated Insult Patch Test	non sensitising

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer dispersion (dosage adjusted)

METHOD Method analogous to OECD TG 401 Limit Test
Species/Strain Rat/ Sprague-Dawley (Crl:CD® VAF/Plus®)
Vehicle None
Remarks - Method The test article was administered once as a single dose using a syringe and dosing needle. The dosage level was 2000 mg/kg based on the percent solids (19.86%). The dosage volume was 10.2 mL/kg based on fasted body weight.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
2	5 per sex	2000 (based on percent solids (19.86%)	0

LD50 > 2000 mg/kg bw
Signs of Toxicity All animals survived the 2000 mg/kg oral dose in good health. Some test article-related signs (e.g., increased salivation, hair loss, loose stool, material around the nose, eye and mouth) were observed briefly after dosing. Body weight changes and necropsy results were normal.

Effects in Organs	No macroscopic abnormalities were observed at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	MPI Research (1998a)

7.2. Irritation – skin

TEST SUBSTANCE	Notified polymer 20% dispersion and diluted in distilled water to 5% solids
METHOD	Method analogous to OECD TG 104
Species/Strain	Rabbit/New Zealand White (Hra:SPF)
Number of Animals	6 females
Vehicle	Distilled water (for lower concentration tested)
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The test article (as a dose of 0.5 ml) was applied undiluted as received (19.86% solids) to one site and diluted to 5% solids in distilled water at the other site. Observations were made for 72 h, except that one animal was also scored 7 days after patch removal.

RESULTS 5% solids

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	-	0
Oedema	0	0	-	0

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

RESULTS 19.86% solids

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.2	1	<7 days (1 animal) 48 hr (5 animals)	0 (7 days observation) 0 (72 hr observation)
Oedema	0	0	-	0

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

Remarks - Results	All animals survived. No signs of ill health were observed during the study. No erythema or oedema was observed at the 5% solids test sites. Therefore, the primary irritation index for the 5% solids is 0.0. No oedema was observed at the sites for the undiluted test article. Only 2 of 6 animals were observed with slight erythema at the undiluted test article sites. The erythema had cleared by 72 hours post-dose in one animal and by day 7 in the other animal. No other erythema was observed. The primary irritation index for the undiluted test article is 0.3. There was no apparent effect of test article administration on body weight gain.
CONCLUSION	The notified chemical is slightly irritating to skin for undiluted dose (20%) and non-irritating for the dose diluted to 5% solids in distilled water.
TEST FACILITY	MPI Research (1998b)

7.3. Irritation – eye

TEST SUBSTANCE	Notified polymer (20%)
METHOD	Method analogous to OECD TG405
Species/Strain	Rabbit/New Zealand White (Hra:SPF)
Number of Animals	6 Male
Observation Period	96 hours
Remarks - Method	No significant deviations were made from the protocol. Sodium fluorescein examinations were conducted after scoring at 24 h and 48 h. Observations were made at 1, 24, 48, 72 and 96 h after instillation.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.2	1	72hr	0
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0	0	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0.06	1	24hr	0

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

Remarks - Results	All animals survived to study termination. No pain or discomfort was noted during the dosing. No signs of ill health were observed during the study. No corneal opacity was observed in any animal. Only 1 of 6 animals exhibited slight iridal irritation. No conjunctival chemosis was observed in any animal. Slight conjunctival redness was observed in 4 of 6 animals at 1 hour post-dose, which cleared by 96 hours in all animals. Two of 6 animals did not exhibit any conjunctival redness. A single animal had a slight, clear discharge at 1 hour. No other discharge was observed.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	MPI Research (1998c)

7.4. Skin sensitisation

TEST SUBSTANCE	Notified polymer (20% solids)
METHOD	Method analogous to OECD TG 406 (Guinea Pig Maximisation Method)
Species/Strain	Guinea pig/Crl:(HA) BR (Albino Hartley)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5 Vehicle Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 100%
Signs of Irritation	
CHALLENGE PHASE	
1st challenge	intradermal: topical: 100%
2nd challenge	topical: not performed
Remarks - Method	Concentrations above refer to dilutions of the commercial version of the

polymer, which contains 20% solids and is referred to as the 'test substance'. Twenty guinea pigs (10 females and 10 males) were dosed with the test substance and ten (5 females and 5 males) were dosed with distilled water (control). A concurrent positive control was evaluated. The induction phase consisted of two applications. First, animals were injected with 0.1 ml of a 5.0 % solids solution of the test substance with and without Freund's Complete Adjuvant with the application site evaluated 24 and 48 hours after injection. Second, after pretreatment with 10% sodium lauryl sulfate, the test substance was applied topically for 48 hours and the application site evaluated 24, 48, and 72 hours after patch removal. The challenge phase consisted of a saturated 4 cm^2 occlusive application of the test substance for 24 hours with application site evaluations 24 and 48 hours after patch removal.

No deviation from standard protocol.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0	0		
Control Group	-	0	0		

Remarks - Results

A single animal from the test article group died after the injection induction. Reasons for this are unknown.

Scattered mild to moderate diffuse erythema with desquamation, blanching, fissuring, eschar, oedema, scabbing and laceration were present after induction in the positive control animals. Induction with the test article resulted in moderate and diffuse erythema to intense erythema and oedema and the same skin lesions as the positive control plus clear discharge and coriaceousness. One test article treated animal died after injection from an unknown cause. After the challenge exposure, no erythema or oedema was observed at the vehicle or test article application site. The positive control, hexylcinnamic aldehyde (HCA) produced a sensitisation response as expected.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

MPI Research (1998d)

ADDITIONAL INVESTIGATIONS

7.5 A 21-Day Cumulative Irritation Study In Humans

TEST SUBSTANCE

Notified polymer 20%

METHOD

In-house method.
Twenty-five subjects were exposed topically to the test article (undiluted as received) in the paraspinal region daily for 21 days. The site was occluded for 23 h after each application, then the subjects bathed or showered just after patch removal and then reported immediately to the laboratory for scoring and reapplication of the patches. Scoring for

	cumulative irritation was performed every 24 hours immediately prior to reapplication or until excessive irritation was noted. Distilled water and 0.1% sodium lauryl sulfate (SLS) were used as negative and positive controls respectively. Two different samples of the test substance were also tested. Scoring was by the method of Berger and Bowman.
Remarks – Method	Although not specifically stated in the test report, it is assumed that the commercial form of the notified polymer (20% dispersion in water) was used for testing. It is not known what differences, if any, occurred between the two samples of test substance.
RESULTS	
Remarks – Results	There were no adverse events reported during the conduct of the study. The positive control, 0.1% sodium lauryl sulfate, demonstrated severe irritation potential. The test article was significantly less irritating than water and did not exhibit significant irritation potential.
CONCLUSION	A 20% aqueous dispersion of the notified polymer was not found to be an irritant under the conditions of this study.
TEST FACILITY	Hill Top Research, (1998)

7.6 Human Repeated Insult Patch Test

TEST SUBSTANCE	Notified polymer (20% dispersion). Two different samples tested.
METHOD	In-house method.
Remarks – Method	No clear description of the study protocol was given. It appears that 0.2 ml of the undiluted test article was applied dermally to a non-exclusive panel of 114 people (77 females and 37 males) for nine induction and one challenge exposures. The occluded patch was in contact with the skin for 24 hours and the site was evaluated 48 or 72 hours after the induction application and 48 and 96 hours after the challenge application. The gap between induction and challenge was not stated.
RESULTS	
Remarks – Results	Four subjects showed mild irritation at the 48 hour reading but all scores were zero by 96 hours.
CONCLUSION	Under the described test conditions, a 2% dispersion of the notified polymer did not exhibit evidence of a delayed contact hypersensitivity response in human beings.
TEST FACILITY	Hill Top Research, (1999)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.1.2. Bioaccumulation

The notified chemical's high molecular weight suggests that it is unlikely to cross biological membranes and bioaccumulate (Connell 1989).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static conditions. US EPA Guideline OPPTS 850.1075
Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	150 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	Based on the range-finding test, a definitive test was conducted at nominal test concentrations of 6.3 - 100 mg ac/L. The primary standard of 100 mg/L was prepared by mixing the test substance with the dilution water which was prepared by blending naturally hard well water with well water that was demineralised by reverse osmosis. Prior to use, the dilution water was passed through a sediment filter and UV sterilizer. The test concentrations were prepared by diluting the primary standard with the appropriate amount of dilution water. The test was conducted for 96 h and the process was repeated with each test chamber containing a total of 10 fish resulting in 20 fish per control and test substance treatment. Observations for mortality and sublethal responses were made at 6, 24, 48, 72 and 96 h of exposure.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal	*2 replicates of 10*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
0 (control)	20	0	0	0	0	0
6.3	20	0	0	0	2	20
13	20	0	0	8	11	11
25	20	1	5	11	15	16
50	20	15	19	20	20	20
100	20	20	20	20	20	20

LC50	13 mg/L at 96 hours (CI: 10-16 mg/L).
NOEC (or LOEC)	6.3 mg/L at 96 hours.
Remarks – Results	No analytical confirmation of the test substance concentration was performed during the range-finding or definitive tests. During the test, the control solutions were clear and colourless with no visible particulates or precipitate. All test substance treatment solutions appeared cloudy with cloudiness increasing with concentration. pH, temperature and dissolved oxygen were within acceptable test limits throughout the test. No sub-lethal effects were observed in the control or at 6.3 mg ac/L treatment. For the 13 and 25 mg ac/L treatments, irregular respiration was observed for some of the fish.
CONCLUSION	The notified polymer is considered to be harmful to fish.

TEST FACILITY	ABC Laboratories (2003)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static conditions. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	TOC analysis
Remarks - Method	Following a preliminary range-finding test, twenty daphnids (4 replicates of 5 animals) were exposed to an aqueous solution of the test material at a concentration of 100 mg ac/L and a blank control for 48 h under static conditions. The test solution was prepared by dissolving the test material in deionised reverse osmosis water. Hydrochloric acid was added until the test material was completely dissolved prior to preparing the stock solution. An aliquot (25 mL) of the stock solution was then dispersed in a final volume of 1 L of reconstituted water and the pH adjusted to approximately 7.8. Immobilisation and any adverse reactions to the exposure were recorded after 24 and 48 h. A positive control potassium dichromate was used as the reference material conducted under similar exposure conditions as the definitive test. Analysis of the test preparations was performed by Total Organic Carbon (TOC) analysis due to the dispersive nature of the test material. Samples of the control and the 100 mg ac/L concentrations were taken at 0 and 48 h for the analysis.

RESULTS

Concentration mg/L Nominal	*Number of D. magna 4 replicates of 5 animals*	*Number Immobilised 24 h*	*48 h*
0 (Control)	20	0	0
100	20	0	0

LC50	>100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours
Remarks - Results	There was no immobilisation in 20 daphnids at the nominal concentration of 100 mg ac/L for 48 h exposure. Throughout the duration of the test the test preparations were observed to be slightly opaque homogeneous dispersions/emulsion. The TOC analysis showed measured test concentrations of 92 and 87 mg ac/L for 0 and 48 h, respectively. The results from the positive control were within the normal range for the reference material. The mean 48 h EC50 calculated for the positive control was 0.82 mg/L.
CONCLUSION	The notified polymer is considered to be practically non-toxic to *Daphnia magna*
TEST FACILITY	Safepharm Laboratories Limited (2005)

The notifier has also provided a summary of the following test for *Daphnia magna*. However, no details of the test report were provided.

8.2.2. (b) Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Alcogum L-520 with preservative
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Acute toxicity to *Daphnia Magna*
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	None
Analytical Monitoring	None
Remarks – Method	*Daphnia magna* was incubated with 0.0, 10, 20, 40, 60 and 100 mg Alcogum L-520 solids /L for 48 hours under static conditions. Twenty *Daphnia magna* per concentration were examined at 24 and 48 hours for immobility.
RESULTS	
EC50	41 mg solids/L at 48 hours
NOEC	20 mg solids/L at 48 hours
Remarks – Results	After 48 hours of exposure, the percent immobile was 50% at 40 mg/L and 95% at 80 and 160 mg/L. There were no immobile daphnids observed in the control or 20 mg solids/L or lower treatment concentrations during the exposure period. The calculated 48-hour EC50 was 41 mg solids/L. The 48-hour NOEC was 20 mg solids/L. The slope of the 48-hour concentration-response line was 6.6.
CONCLUSION	The notified chemical is considered to be slightly toxic to *Daphnia magna*.
TEST FACILITY	National Starch & Chemical

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green alga (*Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	Nominal: 0.0 (control), 0.13, 0.25, 0.50, 1.0, 2.0 and 4.0 mg ac/L
Auxiliary Solvent	None
Water Hardness	None
Remarks - Method	Based on the range-finding test, the definitive test was performed with a control and each treatment was replicated three times. The flasks were incubated with *Selenastrum capricornutum* for 72 h. Cell counts were performed using a light microscope and a hemacytometer for each control and test substance treatment replicate once every 24 h. Temperature and pH were measured during the test. No analytical confirmation was performed to measure the concentration of the test substance.

RESULTS

Biomass		*Growth*	
EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
0.3 (CL: 0.28 – 0.33 mg/L)	0.13	1.2 (CL: 0.82 – 1.5 mg/L)	0.13

Remarks - Results	The control and all test solutions were clear and colourless with no visible precipitate or surface film at test initiation. The control and treatments ≤0.25 mg/L were green in colour after 48 h of exposure. The control and

	all treatments ≤2.0 mg/L were green in colour after 72 h of exposure. The green colouration was resulted from an increase in algal biomass. The 4.0 mg/L treatment remained clear and colourless with no visible precipitate or surface film for the duration of the experiment. No significant reduction in algal growth was detected in the 0.13 mg/L treatment after 72 h of exposure. All results were based on the nominal concentrations. pH and temperatures were within the acceptable limits during the course of the exposure.
CONCLUSION	The notified polymer is considered to be highly toxic to alga.
TEST FACILITY	ABC Laboratories Inc. (2002)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is to be used in body care and hair care products and is dispersible up to a concentration of 225 g/L in water. No biodegradation data are available. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified polymer disposed of directly through normal garbage.

Assuming a worst-case scenario that all of the notified polymer is eventually released to sewer, a calculated daily PEC in the sewer effluent as a continental release in Australia was 1.4 µg/L. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume of 2 tonnes is evenly distributed over a 365 day period; (2) usage is nationwide with a population of 20 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.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified polymer in rural areas and coastal water may approximate 1.4 and 0.14 µg/L, respectively.

SIMPLETREAT modelling is not possible due to the lack of Kow and vapour pressure results. However, its high dispersibility in water suggests the majority will be retained in the water column.

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 2.72 mg/kg (dry wt), assuming 20% attenuation in sludge during the STP process. This is based on the assumption that 0.1 tonne of biosolids is generated for each ML of STP effluent and the consumption of 4000 ML/day for total population per year (20% X 2 tonnes/4000 X 0.1 X 365 = 2.72 mg/kg). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1000 kg/m^3 and a soil mixing zone of 0.1 m, the concentration of the notified polymer may approximate 0.272 mg/kg in the applied soil, assuming accumulation of the notified polymer in soil for 10 years under repeated biosolids application.

The effluent re-use (eg. irrigation purposes) concentration of the notified polymer may potentially approximate 1.12 µg/L, assuming 80% remains in solution during the STP process. STP effluent re-use for irrigation in Australia occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 1.12 µg/L may potentially result in a soil concentration of approximately 112 µg/kg assuming accumulation of the notified polymer in soil for 10 years under repeated irrigation.

The worst-case PECs values are summarised below:

Sewage effluent/coastal city = 0.14 µg/L

Sewage effluent/rural areas = 1.4 µg/L.

Soil concentrations after 10 years application of biosolids = 0.272 mg/kg

Soil concentrations following 10 years irrigation with effluent = 112 µg/kg.

In the case of landfill, the notified chemical is likely to be slowly degraded by biotic and abiotic processes. Based on the high molecular weight, the notified polymer is not expected to bioaccumulate.

9.1.2. Environment – effects assessment

The most sensitive species is algae with 72 h EbC50 of 0.3 mg/L. A predicted no effect concentration (PNEC) of 3.0 µg/L has been derived by dividing this end point of 0.3 mg/L by a safety factor of 100 as three trophic levels are available.

9.1.3. Environment – risk characterisation

Location	PEC (µg/L)	PNEC (µg/L)	Risk Quotient (RQ)
Australia-wide STPs (worst case)			
Ocean outfall	0.14	3	0.05
Inland river	1.4	3	0.5

The risk quotients indicate an acceptable risk for both marine and freshwater organisms. This is without taking movement to sludge into account, which is expected to remove some chemical from the water column.

Given the low volume usage and the disperse use, the notified chemical is unlikely to pose a significant environmental risk under the proposed use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The worst-case scenario is exposure due to formulation processes. Dermal and occasional ocular exposure to the notified polymer may occur when opening and closing drums, during manual addition to mixing vessels, and when connecting and disconnecting transfer and filling lines. Mixing vessels are enclosed and the filling machines automated and fitted with local exhaust ventilation. Workers are provided with personal protective equipment for use during these operations. The maximum level of worker exposure to the notified polymer would be < 25%.

Exposure during filling and packaging operations is likely to be minimal, due to the use of an automatic filling machine. The maximum level of worker exposure to the notified polymer would be ≤ 2%.

Dermal exposure of the notified polymer to salon workers will occur during the application of final product (≤ 2%) to the hair of customers by spraying a small amount of the gel (approx. 15mL) into their hands and applying it to the hair.

9.2.2. Public health – exposure assessment

Exposure will be principally by the dermal route, with the potential for occasional accidental ocular exposure. Inhalation exposure could also occur when the products are applied by spraying. The “leave-on” spray hair conditioner products are expected to have the greatest potential for dermal exposure, because they would be in contact with the scalp for a longer period.

9.2.3. Human health – effects assessment

The notified polymer was of low acute oral toxicity in rats (LD50 > 2000 mg/kg bw). It was found to be slightly irritating to the skin and eyes of rabbits, though non-irritating to the skin of humans. At a diluted concentration of 5%, the notified polymer was non-irritating to the skin of rabbits. There was no evidence of skin sensitisation in guinea pigs and it was found to be non-

sensitising to humans. No data on the mutagenicity of the notified polymer were submitted. However, a Canadian assessment report indicated that a polymer of similar chemical composition was non-mutagenic in vitro.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The data provided suggest that the notified polymer is of low acute oral toxicity, and is not a skin sensitiser. It has the potential to cause slight skin and eye irritation but, as importation is at concentrations < 25%, adverse effects are not expected. Reformulation is largely automated and enclosed so that the risk of adverse health effects would be limited to drips and spills associated with transfer operations. Given the chemical nature of the polymer (NAMW > 10000 and low level of low molecular weight species), the risk of adverse health effects can be considered to be low.

Salon workers will handle the final products at a concentration of ≤ 2%. Based upon the high molecular weight and the low levels of low molecular weight species, the notified polymer is not expected to cross biological membranes. As such, the risk of adverse health effects from inhalation exposure is considered acceptable.

Overall, the risk of the notified polymer is acceptable during formulation and end use considering the concentrations of the notified polymer and its toxicological properties.

9.2.5. Public health – risk characterisation

The data available on the health effects of the notified polymer indicate a low hazard. The public will be exposed to the notified polymer on the skin, scalp or by inhalation at concentrations of ≤2%. However, the notified polymer should not be absorbed due to its high molecular weight and low levels of low molecular weight species. Therefore, there is negligible likelihood of systemic effects and a low likelihood of irritant or sensitising effects even on repeated or prolonged exposure.

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

10.1. Hazard classification

Based on the available data (acute oral, skin irritation, eye irritation, skin sensitisation, human irritation and human repeated insult patch test), the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

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

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 No Significant Concern to public health when used as a component of personal care products at ≤ 2%.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of Structure Plus, provided by the notifier was assessed in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). 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

The label for Structure Plus, provided by the notifier was assessed in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed and automated systems, and general and local ventilation during the formulation of shower gel products (sampling, dispensing and compounding operations).
  - Fume hoods during quality control testing.
  - Enclosed mixing vessels and automated filling machines fitted with local exhaust ventilation during formulation of hair care products.

- Employers should implement the following safe work practices to minimise occupational exposure during formulation of the notified polymer:
  - Prevent splashes, spills and overfilling of containers.
  - Prevent aerosol formation.
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Long sleeved overalls, safety glasses, safety boots, impervious gloves, head coverings, and facemasks during formulation of personal care products.
  - Laboratory coats, enclosed footwear, safety glasses, and gloves during quality control procedures.

  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 chemical 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

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

- Collect with absorbent material such as sand, earth or appropriate commercial absorbent. Shovel up and place into suitable containers.

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 used in personal care products at > 2%.

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.

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