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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of Solamer GR8 (Polyamide-2)

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nalco Australia Pty Ltd (ABN 41 000 424 788)
3 Anderson Street
Banksmeadow NSW 2019

NOTIFICATION CATEGORY
Limited: Synthetic 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, Structural formula, Molecular weight, Spectral data, Degree of purity, Polymer constituents, Hazardous impurities and residues, Non Hazardous impurities and residues, Use, Identity of manufacturer/recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Boiling point, Hydrolysis, Adsorption/Desorption, Dissociation constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Not known

2. IDENTITY OF CHEMICAL

MARKETING NAME
Solamer GR8 (60-70% notified polymer)

OTHER NAME
Polyamide-2 (INCI Name)

MOLECULAR WEIGHT
M_n > 1,000 Da

ANALYTICAL METHOD
Reference IR, UV/VIS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa
Amber light orange liquid

Property	Value	Data Source/Justification
Melting Point	Not determined	The notified polymer is imported only as an aqueous solution.
Density	1160 kg/m^3 at 15.6^{o}C	MSDS (Solamer GR8)
Vapour Pressure	Not determined	Based on the high molecular weight, the notified polymer is expected to have a low vapour pressure.
Water Solubility	> 700 g/L at 20^{o}C	MSDS
Hydrolysis as a Function of pH	Not Determined	The notified polymer contains potentially hydrolysable groups. However, hydrolysis was said not to be not observed in the environmental pH range as the notified polymer and marketed forms of the same are stable at pH values between 4 – 9
Partition Coefficient (n-octanol/water)	log Pow = -3.2	Measured
Adsorption/Desorption	Not Determined.	Although the chemical is highly water soluble the potentially cationic sites are expected to bind to the negative sites in soils. Adsorption properties were demonstrated for the notified polymer by the reduction of aquatic toxicity in the presence of humic acid. A reversal of adsorption is not expected to occur readily with the notified polymer.
Dissociation Constant	pKa ~ 10	The polymer contains potentially cationic groups. The dissociation constant of these groups is expected to be approximately 10. Accordingly the polymer is expected to be mostly in its cationic form in the environmental pH range.
Particle Size	Not applicable	The notified polymer is imported as a liquid.
Flash Point	>93°C	MSDS (Solamer GR8)
Flammability	Not determined	Imported only as an aqueous solution. Based on the flash point, the notified polymer as introduced is not expected to be a flammable liquid.
Autoignition Temperature	Not determined	The notified polymer is imported only as an aqueous solution.
Explosive Properties	Not determined	The notified polymer does not contain functional groups which may infer explosive properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
Under normal conditions, the notified polymer does not react in water or in the air.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be introduced in liquid products (up to 3%) in 400 g bottles and 375 g tubes, which are further packaged into boxes.

In the future the notified polymer may be introduced in the product Solamer GR8 (60-70% notified polymer).

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

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

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The marketed product containing the notified polymer will be imported into Australia in boxes of 24 x 400 g bottles shampoo and 30 x 375 g tubes of conditioner and transported by road to a central warehouse facility. From the warehouse, the marketed product containing the notified polymer is distributed nationally to retail outlets.

In the future the notified polymer may be imported as a 60-70% solution in 200 L drums or 20 L pails. The polymer solution will be transported by road from the dock to warehouses, and then to customer reformulation sites.

USE
The notified polymer is used as a component (up to 3%) of hair care products, such as shampoos, conditioners and styling products. The polymer is designed to be UV absorbing.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. The notified polymer may be reformulated in the future.

Reformulation
The notified polymer solution (60-70% concentration) will be transferred from the imported drums and/or pails directly into a blender, or into a storage vessel where it is then piped to a blender. This process requires connection and disconnection of piping to the drum or pail. Once in the blender the notified polymer is mixed with other cosmetic ingredients to a final concentration of up to 3%, and then the finished product is automatically dispensed into bottles for retail sale. Samples will be taken for quality control analysis. The blending and dispensing process is generally enclosed and automated.

End Use
Small cardboard cartons containing up to 30 units of product will be distributed by road to retail outlets for consumer use.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Toll container loading	10	1-2	12
Truck drivers	6	1-2	12
Forklift Drivers	2	4-5	12
Warehouses – Australia wide	500	0.5-1	12
End use	>10000	0.08-0.17	365

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

Reformulation
Inhalation exposure during reformulation processes is expected to be minimal, based on the expected low vapour pressure of the notified polymer and the largely enclosed nature of the process. Dermal and accidental ocular exposure to the notified polymer may occur due to splashes, drips and spills during connection/disconnection of piping to the drum or pail, and during quality control sampling and analysis. This exposure will be incidental and minimised by the use of personal protective equipment, including impervious gloves, protective clothing and safety glasses.

Retail

Retail workers (e.g. supermarket personnel) will unpack the boxes and place the product on the supermarket shelves. Exposure is only likely in the event of a packaging breach.

Hair Salons
Products containing the notified polymer will not be used in hair salons at this stage. However, there is a possibility in the future. This would result in mainly dermal exposure of hairdressers to the notified polymer in concentrations up to 3%. Gloves may sometimes be worn.

6.1.2. Public exposure

There will be widespread and repeated dermal exposure of the public to the notified polymer at up to 3% through use of hair products. The notified polymer will be used in hair products that are both wash-off (shampoos and conditioners) and leave-on (conditioners and styling products). In the case of wash-off products members of the public will dispense approximately 8 g of the product (up to 0.24 g of the notified polymer) from bottles or tubes into the hand/fingers, massage through hair, and then rinse off. For leave-on products approximately 5 g of the product (up to 0.15 g of the notified polymer) will be dispensed into the hands/fingers and worked through the hair. For both wash-off and leave-on products a large proportion of the notified polymer is expected to remain on hair follicles. It is not known how much of the notified polymer will remain on the skin.

Accidental ocular exposure to the notified polymer may also occur. However, the notified polymer is present at a relatively low concentration (up to 3%).

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

6.2. Human health effects assessment

The results from toxicological investigations conducted on batches of the product Solamer GR8 (50% or 60-70% notified polymer) are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Low toxicity, oral LD50 > 2000 mg/kg bw
Rat, acute dermal toxicity	Low toxicity, dermal LD50 > 2000 mg/kg bw
Rat, acute inhalation toxicity	LC50 > 2.03 mg/L/4 hour
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Mouse, skin sensitisation local lymph node assay	Inadequate evidence of sensitisation
Human, Repeat Insult Patch Test	Non-irritating and non-sensitising at 5% and 10%
Genotoxicity – bacterial reverse mutation	Non-mutagenic
Genotoxicity – in vivo mouse micronucleus test	Non-genotoxic

Toxicokinetics
The notified polymer is of high molecular weight (NAMW > 1,000 Da), with < 20% low molecular weight species (MW < 1000 Da, with <6% of this with MW < 500 Da). Absorption across biological membranes is therefore expected to be limited. In addition the notified polymer is hydrophilic (water solubility > 700 g/L; log Pow = -3.2) and therefore dermal uptake is expected to be low, as it is not expected to easily cross the lipid rich environment of the stratum corneum. The notified polymer is likely to be ionised in the gastrointestinal tract, which would also result in poor absorption after oral exposure. Overall, the notified polymer is not expected to be absorbed to a significant degree, and so has the potential to induce mainly local effects at the site of exposure.

Acute toxicity
Based on the test using a 50% solution in rats, the notified polymer is expected to have low toxicity via oral or dermal exposure (LD50 > 1,000 mg/kg bw for the polymer itself). In the inhalation study in rats the maximum dose tested was less than the cut-off for classification (i.e. 5 mg/L/4 hr). However there were no mortalities observed and so the notified polymer solution is expected to be of low toxicity via inhalation.

Irritation and Sensitisation
When the notified polymer solution was tested on rabbits there were no dermal responses at any observation point after 4 hours exposure (dermal irritation study) and only slight irritation observed after 24 hours exposure (acute dermal toxicity study). In the sensitisation study in mice, which was conducted in dimethylsulfoxide,

irritation at concentrations above 15% notified polymer was observed (as a >25% increase in ear swelling). Therefore in some matrices, especially those that include penetration enhancers, the notified polymer may be irritating to the skin.

The notified polymer was slightly irritating to eyes when tested in rabbits. One hour after dose administration to the eyes, the following findings were observed: slight conjunctival redness in all of the test animals; slight to obvious swelling in two out of three test animals; and conjunctival discharge in two out of three test animals. All reactions had cleared by 24 hours.

In a murine local lymph node assay there was evidence of a slight induction of lymphocyte proliferation at the highest concentration tested (30-35% notified polymer, stimulation index of 2.9), however this was accompanied by dermal irritation (as evidenced by the concurrent ear swelling assay) and so may have been due to an irritation response rather than skin sensitisation. Therefore while a weak sensitisation effect cannot be ruled out there is inadequate evidence to classify the notified polymer as a skin sensitiser. In a human repeat insult patch test on 104 subjects no skin responses were observed after induction and challenge with 5 or 10% Solamer GR8 solutions (3-3.5 and 6-7% notified polymer respectively).

Genotoxicity
The notified polymer was not mutagenic to *S. typhimurium* or *E. coli* and did not cause chromosomal aberrations in mouse erythrocytes *in vivo*, and so is not considered to be an *in vivo* genotoxin.

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Although the notified polymer was shown to have slight irritancy to the skin and eye, the level of response was not sufficient for classification and the risk of irritancy effects in reformulation workers would be reduced due to the limited exposure through use of engineering controls and personal protective equipment.

While workers in the beauty industry may be dermally exposed to the notified polymer, the risk of irritancy effects is expected to be low due to the low concentration of notified polymer in the hair care products (< 3%). In addition, the results from the human repeated insult patch test indicate that the notified polymer is unlikely to be a significant skin irritant or sensitiser at the concentrations used in the hair products. However, the risk of skin sensitisation in sensitive individuals cannot be completely ruled out.

6.3.2. Public health
The public may come into contact with the notified polymer (< 3%) through the use of hair care products.

Systemic toxicity
Systemic toxicity after repeated exposure to the notified polymer is not expected to be a significant risk as the notified polymer is expected to have limited absorption across biological membranes, based on its high molecular weight and physical-chemical properties.

Local toxicity
The public will be exposed to the chemical at a maximum concentration of 3%. At this concentration the notified polymer is unlikely to cause any irritancy effects to the skin and eye. The repeated insult patch test conducted in human volunteers using concentrations up to 7% notified polymer indicates that the notified polymer is unlikely to be a significant skin irritant or sensitiser at the concentrations used in hair care products available to the public. However, while the notified polymer is unlikely to be a moderate or strong skin sensitiser and could not be classified as a skin sensitiser according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), the risk of skin sensitisation in sensitive individuals cannot be completely ruled out.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Initially no manufacture or reformulation is expected in Australia, as the notified polymer will be imported as a component of an end use consumer product. No releases of marketed product containing notified polymer are anticipated at the various storage locations. Small accidental spills can be easily cleaned up with absorbent towels or similar.

However, the chemical may in the future be imported as the polymer solution (60-70% polymer) and reformulated into cosmetic products. Approximately 0.5 kg Solamer active is expected to remain in the 200 L import drums. This is approximately 0.25 % of the import amount (< 13 kg per annum). Empty drums are expected to be disposed of in licensed waste handling sites. Other residual sources of Solamer active are expected to be minimal (0.1%; < 5 kg per annum), as closed systems to avoid contamination of the final cosmetic products will be used. Any residual amounts will be captured on site and removed as solid waste to landfill.

RELEASE OF CHEMICAL FROM USE

Assuming a worst case of 5% remaining in packaging then <250 kg per annum will be disposed of as household waste as residue in packaging. The remaining amount ~ 4.8 tonnes per annum will be used for its intended use as a hair care product and flushed to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Small quantities of marketed product containing notified polymer may be left in consumer packages, and these will end up in landfill. Assuming as a worst case approximately 5% (< 250 kg per annum) of marketed product containing notified polymer is disposed of in this way.

Degradation products have not been determined for the notified polymer. The notified polymer is expected to be stable at environmental pHs for 2 years.

7.1.2 Environmental fate

No environmental fate data were submitted. The consumer product containing notified polymer is stable in environmental conditions for 2 years. The notified polymer is unlikely to be readily biodegradable.

The notified polymer is highly water soluble and is therefore unlikely to bioaccumulate in aquatic organisms. Also, due to the molecular size the notified polymer is unlikely to cross biological membranes.

The notified polymer is expected to eventually break down to simple molecules including oxides of carbon and methane; oxides of nitrogen and ammonia; and water vapour by biotic and abiotic processes.

7.1.3 Predicted Environmental Concentration (PEC)

The polymer is imported into Australia as the finished consumer hair care product. The majority of this (≥ 95%) will be flushed to sewer during use. A small amount (≤ 5%) will remain in packaging, and will be disposed of as domestic waste to landfill. In a worst case where ~95% of the polymer is flushed to sewer with no adsorption to sludge or biodegradation the PEC may be calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	95%	
Annual quantity of chemical released to sewer	4,750	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.01	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	

PEC - River:	3.07	µg/L
PEC - Ocean:	0. 31	µg/L

However, potentially cationic polymers are likely to mainly (> 90%) partition to the solids in sewage treatment plants (STP), (Boethling and Nabholz 1997).

Mitigated PEC assuming 90% adsorption of the chemical to sludge

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	95 %	
Annual quantity of chemical released to sewer	4,750	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.01	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.31	µg/L
PEC - Ocean:	0.03	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on 60-70% notified polymer are corrected for concentration and summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 0.284 mg/L	Very toxic
Fish Toxicity with humic acid	EC50 12.1mg/L	Harmful
Daphnia Toxicity	EC50 1.67 mg/L	Toxic
Daphnia Toxicity with humic acid	EC50 22.5 mg/L	Harmful
Algal Toxicity	EC50 0.000972 mg/L (0.972 µg/L)	Very toxic
Algal Toxicity with humic acid	EC50 4.82 mg/L	Toxic

7.2.1 Predicted No-Effect Concentration

For a worst case scenario a PNEC is calculated from the lowest EC50 for algae and applying an assessment factor of 100, as three trophic levels were tested.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50	0.000972	mg/L
Assessment Factor	100	
Mitigation Factor	1	
PNEC:	0.00972	µg/L*

*Although this appears to be anomalously low, the notifier has indicated that they are unable to demonstrate that this was due to an error in the test.

For a more realistic scenario where the water is likely to contain organic matter a PNEC is calculated from the lowest EC50 for algae in a medium containing 8 ppm humic acid. Natural waters will contain other organic species besides humic acid, but a good correlation was shown between the mitigation factors for humic and dissolved organic carbon (DOC), (Boethling and Nabholz 1997). The value of 8 ppm humic is considered reasonably representative of DOC, in natural waters with clean water being considered to contain less than 2

mg/L Total Organic Carbon (TOC) and the geometric mean of measured levels in US rivers being 6.8 mg/L TOC (Boethling and Nabholz 1997). Further monitoring of Australian water (ACT State of the Environment Report 2004) disclosed TOC and DOC values for waterways in the Murray Darling Catchment Area of between 2 and 14 mg/L. A mitigation factor of 4963 may be calculated from the ratio of the algal toxicity in clean water to the algal toxicity in natural water containing organic carbon equivalent to that containing 8 ppm humic acid. An assessment factor of 100 is then applied, as three trophic levels were tested.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50	0.000972	mg/L
Assessment Factor	100	
Mitigation Factor	4963	
PNEC:	48.2	µg/L

7.3. Environmental risk assessment

For a worst case scenario:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	3.07	0.00972	**317**
Q - Ocean:	0.31	0.00972	**31.7**

A worst case scenario shows an unacceptable risk to the environment.

However, this does not account for the 90% adsorption of the notified polymer to sewage sludge (see above). Accordingly the PEC will be less than 0.317 µg/L at sewage outfall.

Scenario: mitigated for sewage sludge adsorption but not for decreased toxicity due to humic acid in natural waters.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.31	0.00972	**31.7**
Q - Ocean:	0.03	0.00972	**3.17**

However, the value of the PNEC is likely to be too high in natural waters as the worst case tests do not contain organic carbon. The polymer is likely to bind to such material through it's potentially ionic sites. Further the correctness of the EC50 value of the worst case algal test has not been verified, although the value is accepted by the notifier (see appendix C).

Using a more realistic PNEC (as calculated above) the risk assessment is as follows:
More realistic scenario using water containing organic carbon (equivalent to 8 ppm humic acid) with a mitigation factor of 4963 and mitigated for adsorption to sewage sludge.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.31	48.2	**0.0064**
Q - Ocean:	0.03	48.2	**0.0006**

The risk is therefore considered acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Aquatic toxicity	1	Very toxic to aquatic life with long lasting effects

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

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.

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 contact with skin
  - Avoid contact with eyes

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

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by authorised landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a cool, dry place, out of direct sunlight.

- Avoid contact with incompatible materials that support combustion, such as strong oxidising agents.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by soaking up with absorbent material. Place in suitable-covered properly labelled containers. Wash affected areas.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000; or

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component (up to 3%) in hair care products, or is likely to change significantly;
- the amount of polymer being introduced has increased from 5 tonnes, or is likely to increase, significantly;
- if the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

AICS Annotation

- When the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS) the entry should be annotated with the following statement(s):
  - For use in cosmetic hair care products only

Material Safety Data Sheet
The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility > 700 g/L at 20°C

Method Not Tested
Remarks Notified polymer is marketed as a 70% aqueous solution. Source MSDS

Partition Coefficient (n-octanol/water) log Pow = -3.2 ± 0.2 at 20°C

Method US EPA method OPPTS 830.7550. A solution (~1%) of polymer in pre-saturated (n-octanol) water was added to an equal amount by weight of pre-saturated (water) n-octanol (1:1). A further test was conducted using the same conditions except the ratio of water to n-octanol was 1:2. The polymer concentration in each phase from each test was determined using Refractive Index (RI) and UV detection.

	Pow and estimate of error	
Test Method	1:1 o/w	1:2 o/w
RI	-3.167 ± 0.208	-2.784 ± 0.069
UV	-3.544 ± 0.078	-3.311 ± 0.067

The average of all values was calculated and the error was estimated by the addition of all absolute errors and dividing by the square root of the number of measurements.

Remarks Shake Flask Method
Test Facility Nalco (2005)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat / Wistar albino
Vehicle	None. Dosed as supplied
Remarks - Method	There were no significant deviations from the protocol. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0
2	5 females	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	The only abnormal physical signs noted during the observation period were instances of chromodacryorrhea, sagging eyelids and tachypnea. Body weight changes were normal in 9/10 animals. One of the animals in Group 2 lost weight during the second week of the observation period.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	All the animals survived the 2000 mg/kg oral dose. Given that the test substance contained 50% of the notified polymer, the LD50 for the polymer itself is > 1,000 mg/kg bw.
CONCLUSION	The product containing 50% of the notified polymer is of low toxicity via the oral route.
TEST FACILITY	MB Research Laboratories (2004a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rabbit / New Zealand White
Vehicle	None. Dosed as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	There were no significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	0
2	5 females	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Group 1: Very slight incidences of erythema and oedema within the first 24 hours of the observation period. There were no dermal reactions thereafter. Group 2: Very slight incidences of erythema within the first 24 hours of the observation period. There were no dermal reactions thereafter.

Signs of Toxicity - Systemic	Body weight changes were normal in 9/10 animals. One of the animals in Group 1 lost weight during the second week of the observation period.
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	All the animals survived the 2000 mg/kg dermal application in good health. Given that the test substance contained 50% of the notified polymer, the LD50 for the polymer itself is > 1,000 mg/kg bw.
CONCLUSION	The product containing 50% of the notified polymer is of low toxicity via the dermal route.
TEST FACILITY	MB Research Laboratories (2004b)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	Rat / Wistar albino
Vehicle	The test substance was diluted with distilled water to a 50% concentration.
Method of Exposure	Whole-body exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol.
Particle Size	1.4 μm (MMAD)
Remarks - Method	The method of randomisation, as required in the protocol, was not recorded in the study file. The animals used in the study were selected without conscious bias and were all within 20% of the mean weight.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <mg/L/4h>*		*Mortality*
		Nominal	*Actual*	
1	5 males	3.73	2.03	0
2	5 females	3.73	2.03	0

LC50	> 2.03 mg/L/4hours
Signs of Toxicity	All animals were observed with coating of the fur with the test substance and wetness in the nose and mouth area. Group 1: There were a few incidences of chromodacryorrhea and chromorhinorrhea on the fourth hour of the observation period. A few feces were observed on the first day. Group 2: There were incidences of chromodacryorrhea started on the second hour and an incidence of chromorhinorrhea was observed on the fourth hour. In the fourth, fifth and sixth day of the observation period, two animals emaciated and a few feces were observed.
Effects in Organs	Necropsy results revealed abnormal kidneys in one animal while the nine animals appeared normal.
Remarks - Results	Six of the ten animals lost weight during the first seven days of the study, but all gained weight normally by day 14. All animals survived the four hour 2.03 mg/L exposure.
CONCLUSION	The product containing 50% of the notified polymer is expected to be of low toxicity via inhalation.
TEST FACILITY	MB Research Laboratories (2005)

B.4. Irritation – skin

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit / New Zealand White
Number of Animals	3 (2 males, 1 female)
Vehicle	As supplied.
Observation Period	1, 24, 48 and 72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	There were no significant deviations from the protocol.
RESULTS	
Remarks - Results	There was no erythema or oedema noted at any observation period. There were also no abnormal physical signs noted and all body weight changes were normal.
CONCLUSION	The product containing 50% of the notified polymer is non-irritating to the skin.
TEST FACILITY	MB Research Laboratories (2004c)

B.5. Irritation – eye

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit / New Zealand White
Number of Animals	3 (2 males, 1 female)
Observation Period	1, 24, 48 and 72 hours
Remarks - Method	There were no significant deviations from the protocol.
RESULTS	
Remarks - Results	There was no corneal opacity or iritis noted at any observation period. Conjunctival irritation, noted in all of the animals' eyes after 1 hour of administration, cleared by 24 hours.
CONCLUSION	The product containing 50% of the notified polymer is slightly irritating to the eye.
TEST FACILITY	MB Research Laboratories (2004d)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Solamer GR8 (60-70% notified polymer in aqueous solution)
METHOD	Adaptation of OECD TG 429 Skin Sensitisation Local Lymph Node Assay
Species/Strain	Mouse / CBA/J
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	The study was GLP-compliant. The lymphocyte proliferation was measured using a non-radioactive method. Five days after the initial dose the mice were given an intraperitoneal injection of the thymidine analogue 5-bromo-2'-deoxy-uridine (BrdU). After sacrifice the lymph node cell (LNC) suspensions

were analysed for BrdU incorporation and total number of LNC by flow cytometry. The amount of proliferating (#BrdU+) LNC was determined as a measure of the proliferative response of the local lymph node. The stimulation index (SI) was calculated as a ratio of the control and test proliferative responses. Test articles that yielded a SI ≥ 3 were characterized as sensitising substances.

A preliminary dermal irritation assay, as well as a concurrent dermal irritation assay, using the ear swelling method was undertaken. An ear swelling greater than 25% was considered indicative of irritation.

Although the non-radioactive method is not detailed in the OECD TG 429 the guideline does state that other endpoints for assessment of proliferation may be employed provided there is justification and appropriate scientific support, including full citations and description of the methodology. The testing laboratory provided a report on the in-house validation of this method conducted using 50 chemicals under a US Federal grant. This validation showed an accuracy similar to the radioactive LLNA method, and showed that the threshold value of SI ≥ 3 was also appropriate for this non-radioactive method. Data from this test laboratory have also shown that using this method an equivocal result was obtained for the acidic impurity (present at <5% in the notified polymer), which is considered to be a non-sensitiser and possible irritant.

RESULTS

Concentration (% w/w)	*% Increase in ear swelling Day 3/Day 6 (irritation assay)*	*Lymphocyte Proliferation*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	5.0% / 10.0%	24956	1.0 ± 0.4
10%	10.5% / 15.8%	20001	0.8 ± 0.5
25%	16.7% / 27.8%	32377	1.3 ± 0.6
50%	26.3% / 31.6%	73604	2.9 ± 0.8
Positive Control			
25% HCA	31.6% / 73.7%	115555	4.6 ± 1.7

HCA = Hexyl cinnamic aldehyde

Remarks - Results

In the preliminary irritation (ear swelling) assay mild irritation (ear swelling change of 27.8%) was observed at the 50% concentration, but not the 100% concentration. Therefore 50% (i.e. 30-35% notified polymer) was used as the highest dose point in the main sensitisation study.

There was evidence of a slight induction of lymphocyte proliferation by the test substance, although the highest dose tested still had a stimulation index of just less than 3. This was accompanied by irritation, as evidenced by the concurrent ear swelling assay, and therefore the lymphocyte proliferation observed may be due to an irritation response. Although no irritation after acute exposure (4 hour) was observed in the rabbit (see B.4 above), slight irritation was observed after 24 hour exposure in the dermal toxicity study (see B.2 above). In the sensitisation study repeated exposure for long periods (over 3 days), as well as the use of DMSO as the vehicle (a known penetration enhancer), may have resulted in an increased irritation response compared to the tests in rabbits.

The SI for the positive control was dose related, with a positive response observed at 25% w/w, therefore confirming the validity of the assay.

	Alopecia was detected at the dose site in the 50% dose group starting at day 2. There were no deaths or substance-related bodyweight changes during the study.
CONCLUSION	While a weak sensitisation effect cannot be ruled out there is inadequate evidence to classify the notified polymer as a skin sensitiser.
TEST FACILITY	MB Research Laboratories (2007)

B.7. Skin sensitisation – human volunteers

TEST SUBSTANCE	Solamer GR8 (60-70% notified polymer in aqueous solution)
METHOD	Human Repeated Insult Patch Test (In-house method)
Study Design	Induction Procedure: 9 sequential 24-hour induction applications over 2.5 weeks. Skin responses were graded 24 hours or 48 hours after patch removal. Rest Period: 12 days Challenge Procedure: 2 concurrent 24-hour challenge applications, one on initial induction site and one on a naïve site. Skin responses were graded immediately after patch removal as well as 24 and 48 hours after. Follow-up phase: In the two weeks following the test subjects were given the opportunity to report any delayed effects.
Type of Dressing	Semi-occlusive.
Test concentration(s)	Two separate concurrently run studies: 5% and 10% Solamer GR8 (3-3.5% and 6-7% notified polymer)
Vehicle	Water
Study Group	The panel consisted of 110 subjects: 77 females aged 19-81 years and 33 males aged 18-61 years. 104 subjects completed the study.
Remarks - Method	The Thursday and Friday of the third week were public holidays and so the laboratory was closed. The applications scheduled for Wednesday and Friday of Week 3 were performed on Thursday of Week 2 and Tuesday of Week 3. Six of the 110 subjects dropped out of the study. None of these had any skin responses prior to this.
RESULTS	
Remarks - Results	No responses were noted on any of the 104 subjects at either concentration during the induction or challenge phases.
CONCLUSION	A Human Repeat Insult Patch Test was conducted using the notified polymer diluted with water to both 3-3.5% and 6-7% under semi-occlusive dressing. The product containing 60-70% of the notified polymer was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Product Investigations, Inc. (2008a and 2008b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 471 Genetic Toxicology: Bacterial Reverse Mutation Test.

	Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Sterile distilled water
Remarks - Method	There were no significant deviations from the protocol. The assay was performed in two phases. The preliminary toxicity assay (Test 1) was used to establish the dose-range for the mutagenicity assay. The second phase, the mutagenicity assay, initial and independent repeat assays (Tests 2-4), was used to evaluate the mutagenic potential of the test substance.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (Preliminary Toxicity)	> 5000 µg/plate		> 5000 µg/plate	Negative
Test 2 (Initial Mutagenicity)		> 5000 µg/plate	> 5000 µg/plate	Negative
Test 3 (Independent Repeat)		> 1000 µg/plate	> 5000 µg/plate	Negative
Test 4 (Retest of Test 3)		> 5000 µg/plate	> 5000 µg/plate	Negative
Present				
Test 1 (Preliminary Toxicity)	> 5000 µg/plate		> 5000 µg/plate	Negative
Test 2 (Initial Mutagenicity)		> 5000 µg/plate	> 5000 µg/plate	Negative
Test 3 (Independent Repeat)		> 1000 µg/plate	> 5000 µg/plate	Negative
Test 4 (Retest of Test 3)		> 5000 µg/plate	> 5000 µg/plate	Negative

Remarks - Results	There were no toxicity or precipitation observed. The test substance did not cause a marked increase in the number of revertants per plate in any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254 induced rat liver (S9). Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The product containing 50% of the notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BioReliance (2003a)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE	50% notified polymer in aqueous solution
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse / ICR
Route of Administration	Oral gavage
Vehicle	Sterile distilled water
Remarks - Method	There were no significant deviations from the protocol. In a pilot toxicity study the test substance was administered to two male mice each at a dose of 1, 10, 100 or 1000 mg/kg bw and to five male and five female mice at a dose of 2000 mg/kg bw. No mortality or clinical signs were observed during the course of the pilot study.

Dose *mg/kg bw*	*Number and Sex* *of Animals*	*Sacrifice Time* *hours*
0 (vehicle)	5 males, 5 females	24
0 (vehicle)	5 males, 5 females	48
500	5 males, 5 females	24
1000	5 males, 5 females	24
2000	5 males, 5 females	24
2000	5 males, 5 females	48
50 (positive control)	5 males, 5 females	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	There were no mortalities or clinical signs observed at any dose level and all of the animals appeared normal throughout the observation period. Reductions of 1 to 15% in the ratio of polychromatic erythrocytes to total erythrocytes were observed in some of the test substance treated groups relative to the respective vehicle controls. However this effect did not show a dose response. Therefore, while not definitive these reductions suggest possible bioavailability of the test article to the bone marrow target.
Genotoxic Effects	The test substance is considered negative in this micronucleus assay. The test substance did not induce a statistically significant increase in the frequency of micronucleated PCE over the levels observed in the vehicle control. The positive control induced a significant increase in micronucleated polychromatic erythrocytes in both male and female mice.
Remarks - Results	The negative and positive controls were consistent with the historical control data, indicating that the test system was operating as intended.

CONCLUSION	The product containing 50% of the notified polymer was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	BioReliance (2003b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to fish

TEST SUBSTANCE	60-70% notified polymer in aqueous solution
METHOD	US EPA: EPA/600/4-90/027 Acute Toxicity for Fish -static.
Species	Fathead Minnows (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None specified
Water Hardness	42-44 mg $CaCO_3$/L
Analytical Monitoring	Visual
Remarks – Method	Three replicates of ten fish and a control were subjected to various concentrations of test substance (below). These were determined from a range finding test not detailed in the report. A positive control using NaCl as a reference was run in the month in which the test was performed. Temperature: 24.8-25.1°C. Dissolved Oxygen (DO) 7.5-8.3 mg/L pH 7.50-7.98 Specific Conductivity: 129-198 µmhos/cm

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		30	0	0	0	0
0.156	ND	30	0	0	0	0
0.313	ND	30	0	0	0	0
0.625	ND	30	25	29	29	30
1.25	ND	30	25	26	27	28
2.5	ND	30	30	30	30	30
5.0	ND	30	30	30	30	30
10.0	ND	30	30	30	30	30

ND = Not Determined

LC50	0.474 mg/L (CI 0.469-0.486 mg/L) at 96 hours; 0.284-0.332 mg/L corrected for concentration.
NOEC	0.313 mg/L at 96 hours; 0.188-0.219 mg/L corrected for concentration.
Remarks – Results	No abnormal observations were recorded. The LOEC and NOEC values were determined via TOXSTAT's Fisher's Exact Test. The EC50 of the reference substance was 5.66 g/L and compared well with the running mean of 5.58 g/L.
CONCLUSION	The notified polymer is very toxic to fish.
TEST FACILITY	Asci (2004a)

C.1.2. Acute toxicity to fish

TEST SUBSTANCE	60-70% notified polymer in aqueous solution
METHOD	US EPA: EPA/600/4-90/027 Acute Toxicity for Fish -static.
Species	Fathead Minnows (*Pimephales promelas*)
Exposure Period	96 hours
Auxiliary Solvent	None specified
Water Hardness	52-58 mg $CaCO_3$/L
Analytical Monitoring	Visual
Remarks – Method	Three replicates of ten fish and a control were subjected to various

concentrations of test substance (below) in water containing 20 ppm humic acid. These were determined from a range finding test not detailed in the report. A positive control using NaCl as a reference was run in the month in which the test was performed.
Temperature: 25.1-25.5°C.
Dissolved Oxygen (DO) 6.8-8.3 mg/L
pH 7.89-8.31
Specific Conductivity: 139-263 µmhos/cm

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		30	0	0	1	1
6.25	ND	30	0	0	0	0
12.5	ND	30	1	1	1	1
25	ND	30	8	16	21	24
50	ND	30	25	28	30	30
100	ND	30	30	30	30	30

LC50	20.2 mg/L (CI 19.0-23.1 mg/L) at 96 hours; .12.1-14.1 mg/L corrected for concentration.
NOEC	12.5 mg/L at 96 hours; 7.50-8.75 mg/L corrected for concentration.
Remarks – Results	No abnormal observations were recorded. The water was brown in colour. The LOEC and NOEC values were determined via TOXSTAT's Fisher's Exact Test. The EC50 of the reference substance was 5.66 g/L and compared well with the running mean of 5.58 g/L.
CONCLUSION	The notified polymer is harmful to fish in natural water containing humic acid.
TEST FACILITY	Asci (2004b)

C.1.3. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	60-70% notified polymer in aqueous solution
METHOD	US EPA: EPA/600/4-90/027 Acute Toxicity for Daphnia -static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	42-44 mg $CaCO_3$/L
Analytical Monitoring	Visual
Remarks - Method	Four replicates of five daphnia and a control were subjected to various concentrations of test substance (below). These were determined from a range finding test not detailed in the report. A positive control using NaCl as a reference was run in the month in which the test was performed. Temperature: 20.2-20.9°C. Dissolved Oxygen (DO) 7.5-8.3 mg/L pH 7.62-7.98 Specific Conductivity: 129 -150 µmhos/cm

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal	*Actual*		*24 hour*	*48 hour*
Control		20	0	0
0.156	ND	20	0	0
0.313	ND	20	0	0
0.625	ND	20	0	0
1.25	ND	20	0	0
2.5	ND	20	0	9
5.0	ND	20	0	18
10.0	ND	20	12	20

LC50 2.78 mg/L (CI 2.39-3.41 mg/L) at 48 hours; 1.67-1.95 mg/L corrected for concentration.

NOEC 1.25 mg/L at 48 hours; 0.75-0.88 mg/L corrected for concentration.

Remarks - Results No abnormal observations were recorded. The LOEC and NOEC values were determined via TOXSTAT's Fisher's Exact Test. The EC50 of the reference substance was 5.66 g/L and compared well with the running mean of 5.21 g/L.

CONCLUSION The notified polymer is toxic to daphnia.

TEST FACILITY Asci (2004a)

C.1.4. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE 60-70% notified polymer in aqueous solution

METHOD US EPA: EPA/600/4-90/027 Acute Toxicity for Daphnia -static.

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None specified

Water Hardness 52-58 mg $CaCO_3$/L

Analytical Monitoring Visual

Remarks - Method Four replicates of five daphnia and a control were subjected to various concentrations of test substance (below) in water containing 20 ppm humic acid. These were determined from a range finding test not detailed in the report. A positive control using NaCl as a reference was run in the month in which the test was performed.
Temperature: 20.4-20.5°C.
Dissolved Oxygen (DO) 7.2-9.0 mg/L
pH 7.95-8.24
Specific Conductivity: 150-257 µmhos/cm

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hour*	*48 hour*
Control		20	0	0
6.25	ND	20	0	0
12.5	ND	20	0	0
25	ND	20	0	0
50	ND	20	11	20
100	ND	20	16	20

LC50 37.5 mg/L at 48 hours; average of two points (CI not calculated); 22.5-26.3 mg/L corrected for concentration

NOEC 25 mg/L at 48 hours; 15-17.5 mg/L corrected for concentration.

Remarks - Results No abnormal observations were recorded. The water was brown in

colour. The LOEC and NOEC values were determined via TOXSTAT's Fisher's Exact Test. The EC50 of the reference substance was 5.66 g/L and compared well with the running mean of 5.58 g/L.

CONCLUSION — The notified polymer is harmful to daphnia in natural water containing humic acid.

TEST FACILITY — Asci (2004b)

C.1.5. Algal growth inhibition test

TEST SUBSTANCE — 60-70% notified polymer in aqueous solution

METHOD — OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum Capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: 0.576 – 10 µg/L ≡ (5.76×10^{-4} – 1×10^{-2} mg/L). Although this range appears to be anomalously low, the notifier has indicated that they are unable to demonstrate that this was due to an error in the test.
Auxiliary Solvent	None specified
Water Hardness	9.6 – 10 units not specified but presumed to be mg $CaCO_3$/L
Analytical Monitoring	Cell Density
Remarks - Method	Triplicate tests of algal cells of approximately 10^4 cell/mL were exposed to a range of test concentrations of the notified polymer, as determined by a range finding test (not detailed in the test report). Six replicates were run as a control. A positive control using NaCl as a reference was also run. Specific Conductivity: 47.8-100.6 µmhos/cm

RESULTS

Growth	
ErC50 µg/L at 72 hours	*ErC50 µg/L at 96 hours*
1.62 ≡ 0.00162 mg/L CI 0.86-2.22 µg/L 0.972-1.13 µg/L (corrected for concentration)	2.16 ≡ 0.00216 mg/L CI not calculated 1.297-1.51 µg/L (corrected for concentration)

Remarks - Results — No abnormal observations were recorded. Growth data were normal and homogenous with unequal replication. The LOEC and NOEC values were determined via Toxcalc Version 5.0.23. The EC50 of the reference substance was 1.09 g/L and was within the expected range.

CONCLUSION — The notified polymer is very toxic to algae

TEST FACILITY — Asci (2007a)

C.1.6. Algal growth inhibition test

TEST SUBSTANCE — 60-70% notified polymer in aqueous solution

METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum Capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: 0.8 – 30 mg/L
Auxiliary Solvent	None specified
Water Hardness	15-55 units not specified but presumed to be mg $CaCO_3$/L
Analytical Monitoring	Cell Density
Remarks - Method	Triplicate tests of algal cells of approximately 10^4 cell/mL were exposed to a range of test concentrations of the notified polymer and 8 ppm humic acid, as determined by a range finding test (not detailed in the test report). Six replicates containing algal test medium (ATM) and 8 ppm humic acid were run as a control as well as triplicate tests of ATM only. A positive control using NaCl as a reference was run in the month in which the test was performed. Specific Conductivity: 95.8-352 µmhos/cm

RESULTS

Growth	
ErC50 mg/L at 72 hours	*ErC50 mg/L at 96 hours*
8.04	8.61 mg/L
CI 7.47-8.33	8.33-8.67
4.82-5.63 (corrected for concentration)	5.17-6.03 (corrected for concentration)

Remarks - Results	No abnormal observations were recorded. Growth data were normal and homogenous with unequal replication. The ATM control (without the 8 ppm humic acid) had higher conductivity and hardness readings to the ATM control containing humic acid. This may have been due to nutrient binding. The LOEC and NOEC values were determined via Toxcalc Version 5.0.23. The EC50 of the reference substance was 3.04 g/L and was within the expected range.
CONCLUSION	The notified polymer is toxic to algae in natural waters containing humic acid.
TEST FACILITY	Asci (2007b)

BIBLIOGRAPHY

ACT State of the Environment Report (2004), http://www.environmentcommissioner.act.gov.au

Asci (2004a), Acute Toxicity of Solamer GR8 to Flathead Minnows and *Daphnia Magna,* Study ID# 5010-054, June 2004 Asci Corporation, Environmental Testing Laboratory 4444 Airpark Boulevard Duluth MN 55811.

Asci (2004b), Acute Toxicity of Solamer GR8 to Flathead Minnows and *Daphnia Magna,* Study ID# 5010-054, July 2004 Asci Corporation, Environmental Testing Laboratory 4444 Airpark Boulevard Duluth MN 55811.

Asci (2007a), Algal Growth Inhibition of Solamer GR8 to *Selenastrum Capricornutum* Study ID# 5030-050-006 Asci Corporation, Environmental Testing Laboratory 4444 Airpark Boulevard Duluth MN 55811.

Asci (2007b), Algal Growth Inhibition of Solamer GR8 *Selenastrum Capricornutum* in carbon enriched test media Study ID# 5030-050-006 Asci Corporation, Environmental Testing Laboratory 4444 Airpark Boulevard Duluth MN 55811.

BioReliance (2003a) Bacterial Reverse Mutation Assay with an Independent Repeat Assay (Study Number AA80BG.502001.BTL, 24 November 2003) BioReliance, Rockville MD, USA (unpublished report provided by the notifier).

BioReliance (2003b) Mammalian Erythrocyte Micronucleus Test (Study Number AA80BG.123.BTL, 25 November 2003) BioReliance, Rockville MD, USA (unpublished report provided by the notifier).

Boethling R B and Nabholz J V (1997). Environmental Assessment of Polymers under the US Toxic Substances Control Act, in Hamilton JD and Sutcliffe R (eds): Ecological Assessment of Polymers. ITP, USA. Pp 187-234.

FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service.

MB Research Laboratories (2004a) Single Dose Oral Toxicity / LD50 in Rats (Research Project # MB 03-11768.01, 26 January 2004) MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

MB Research Laboratories (2004b) Acute Dermal Toxicity / LD50 in Rabbits (Research Project # MB 03-11768.02, 26 January 2004) MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

MB Research Laboratories (2004c) Primary Dermal Irritation/Corrosion in Rabbits (Research Project # MB 03-11768.03, 26 January 2004) MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

MB Research Laboratories (2004d) Primary Eye Irritation/Corrosion in Rabbits (Research Project # MB 03-11768.04, 26 January 2004) MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

MB Research Laboratories (2005) Acute Inhalation Toxicity / LC50 in Rats. Research Project # MB 05-13220.05. MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

MB Research Laboratories (2007) Local Lymph Node Assay in Mice (LLNA) (Research Project # MB 07-15245.26, 15 March 2007) MB Research Laboratories, Spinnerstown PA, USA (unpublished report provided by the notifier).

Nalco (2005), n-Octanol/Water Coefficient (log Kow) for Solamer GR, Batch No. 718C040630, Nalco Analytical Resources, 1601 West Diehl Rd, Naperville, Illinois.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Product Investigations Inc. (2008a) Determination of the Irritating and Sensitizing Properties of Solamer GR8, Batch #XS7K0624 (5%) on Human Skin (Study Report No. 23188, 18 January 2008) Product Investigations Inc., Modesto CA, USA (unpublished report provided by the notifier).

Product Investigations Inc. (2008b) Determination of the Irritating and Sensitizing Properties of Solamer GR8, Batch #XS7K0624 (10%) on Human Skin (Study Report No. 23189, 18 January 2008) Product Investigations Inc., Modesto CA, USA (unpublished report provided by the notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.