File No: EX/32/NA/588)

January 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Copolymer in Foraperle 321

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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Copolymer in Foraperle 321

1. APPLICANTS

Original Holder of Assessment Certificate (First Applicant)

An Assessment Certificate for the notified chemical known by the name Copolymer in Foraperle 321 was granted to Elf Atochem (Australia) Pty Ltd (now Atofina (Australia) Pty Ltd) of 270-280 Hammond Road DANDENONG SOUTH VIC 3175).

The Assessment Report for Copolymer in Foraperle 321 is identified by the sequence number NA/588.

Second Applicant

Since granting of the abovementioned Assessment Certificate, International Sales and Marketing Pty Ltd of 55 Halstead Street South Hurstville NSW 2221 (ACN No. 36-467-259-314) has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for Copolymer in Foraperle 321. Elf Atochem (Australia) Pty Ltd (now Atofina (Australia) has agreed to this extension.

Information submitted by International Sales and Marketing Pty Ltd pertains to the introduction of the notified chemical for use in hydrophobing concrete, clay and terracotta products. Introduction volume is 25 kg per year.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of Copolymer in Foraperle 321 to be exempt from publication in the Full Public Report. The data items were:

chemical name
CAS number
molecular and structural formulae
molecular weight
number-average molecular weight
weight percentages of ingredient
purity; and
use, volume and formulation.

Copolymer in Foraperle 321 is not considered to be hazardous based on the nature of the chemical and the data provided.

Trade Name:	Foraperle 321 (aqueous solution containing less than 30% of the notified polymer)
Method of Detection and Determination:	an infrared spectrum was provided for the notified polymer
Spectral Data:	gel permeation chromatography information and infrared spectra were provided for the notified polymer

3. PHYSICAL AND CHEMICAL PROPERTIES

Variation of scheduled requirements was sought in relation to the majority of the physico-chemical properties relating to the notified polymer. Relevant data for the product containing the notified polymer was submitted where available. This request for variation is accepted on the basis that the notified polymer will not be imported into Australia in pure form. Unless stated otherwise, the data provided below relates to the product Foraperle 321, which contains the notified polymer at a concentration of less than 30%.

Appearance at 20°C and 101.3 kPa:	amber coloured solution
Boiling Point:	84-86°C
Specific Gravity:	1.1-1.2 (unspecified solution of notified polymer in N-methyl-2-pyrrolidone (NMP))
Vapour Pressure:	0.06 kPa at 25°C (unspecified solution of notified polymer in NMP)
Water Solubility:	the notifier states that the product containing the notified polymer is 'completely soluble' in water
Partition Co-efficient (n-octanol/water):	not determined, see comments below
Hydrolysis as a Function of pH:	not determined, see comments below
Adsorption/Desorption:	not determined, see comments below
Dissociation Constant:	not determined, see comments below
Flash Point:	not determined; the polymer is not expected to be flammable
Flammability Limits:	not determined; the polymer is not expected to be

	flammable
Autoignition Temperature:	not determined; the polymer is not expected to be flammable
Explosive Properties:	not determined; the polymer is expected to be stable
Reactivity/Stability:	the notifier states that the polymer is stable although contact with strong oxidising agents, strong acids and bases should be avoided

3.1 Comments on Physico-Chemical Properties

The notifier states that the molecule consists of a hydrophobic end and a hydrophilic end and is an acetate salt. Therefore, it is claimed to behave like a surfactant and be soluble in water. The former implies a block polymer but there is no other evidence for this; the polymer is described elsewhere as "complex".

The hydrolytic behaviour of the chemical has not been investigated. The notified polymer contains ester groups that are potentially susceptible to hydrolysis within the environmental pH range (4-9), but the extent of this is unclear in this pH range, due to its solubility.

Due to its high solubility the chemical is likely to have a low octanol/water partition coefficient (Log P_{ow}) but this may be offset by its surface activity.

Based on the anticipated partition coefficient the polymer would not be expected to strongly adsorb to sediments. However, quaternary ammoniums are known to react with dissolved organic carbon in water to form part of the sediments, and become completely inactivated on contact with soils (Nabholz et al., 1993). The US EPA assumes that for cationic polymers, 90% of the influent polymer concentration will be removed by adsorption on passage through a wastewater treatment plant, with the remaining 10% discharged to receiving waters (Boethling R and Nabholz J, 1997). The notifier claims that 90% of the polymer will be adsorbed to paper pulp during processing.

The notified polymer contains quaternary ammonium centres which are expected to display typical acidity, pKa 10.75 (based on triethylammonium cation).

4. PURITY OF THE CHEMICAL

Degree of Purity:	high
Maximum Content of Residual Monomers	low

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported as a component of the product Foraperle 321, at a concentration of less than 30%, for use as an oil and water repellant product. The main use for Foraperle 321 will be for application to paper or paperboard, where the notified polymer will be present at a final concentration of less than 1% of dry weight product. The imported product may also be used in building applications, where the notified polymer will be present at a final concentration of less than 5%.

The notified polymer will also be imported as Tegosivin HE 503, an aqueous emulsion containing the notified polymer at less than 3%. The volume of Tegosivin HE 503 imported per year is approximately one tonne (in 50 kg and 200 kg containers), equating to approximately 30 kg notified polymer per year. Tegosivin HE 503 will be diluted at 5-25% with water for its application as a hydrophobing agent and the concentration of the notified chemical during application would be 0.125% to 0.625%.

6. OCCUPATIONAL EXPOSURE

The product, Foraperle 321, containing the notified polymer will be imported in 50 kg to 1 tonne containers for use in the paper and building industries.

Waterside, warehouse and transport workers (approximately 8 personnel) will not be exposed to the notified polymer under normal circumstances, as they will be handling unopened containers of the product containing the notified polymer. No details were supplied by the notifier on repackaging of the imported product.

Paper production

For use in paper production, the notified polymer may be used as a surface or internal treatment for paper and paper type products. The number and categories of workers with potential to be exposed to the notified polymer during paper production includes as follows: batch mill operators (10 – 30 personnel) applicators (10 – 30 personnel) and packaging personnel (5-10 personnel).

When used as a surface treatment, the product containing the notified polymer is transferred to a mixing tank, which may have a holding capacity of up to 1 000 L. The product will then be highly diluted with water and applied to paper using rollers and spray equipment.

When used as an internal paper treatment, the product containing the notified polymer will be added to the paper pulp following the washing and bleaching process, but before rolling and cutting of the final paper product.

Little information was supplied by the notifier on the above applications, but it could be expected that the methods of addition and plant equipment used have potential to cause splashes and generate aerosols. During these events, dermal and ocular exposure could occur to workers attending to these processes. The notifier indicates that local exhaust ventilation systems are in place in paper production areas.

Workers will be dermally exposed as they handle finished paper products containing less than one per cent of the notified polymer.

Building industry

Workers in the building industry may be dermally exposed to the notified polymer when applying solutions containing up to 10% of the notified polymer. The notifier states that the product containing the notified polymer usually will be applied by brush hence dermal and accidental ocular exposure may occur. The polymer is used at 2.5 g/m^2.

All workers may also be exposed to NMP, which is present in the imported product within the concentration range of 10 to < 30%. NMP has a propensity to be absorbed dermally and is irritating to skin and eyes. Acetic acid is also present in this mixture at less than 10% and will be the main route of exposure. For both paper and building applications, dermal and inhalation exposure will be the main route of exposure.

Use of Tegosivin HE 503

At the customer's site, two workers will be involved in transferring the imported product from the imported original container to a mixing vessel by pump, diluted with water to the desired concentration and repacked into 20 Litre and 5 Litre containers with locking screw caps. Worker exposure to the notified chemical is possible during opening and closing the container and repacking. Possible route of exposure are dermal, inhalation and eye.

Since the product containing the notified polymer will be available directly to the public for use by home handymen as a sealer on stone, pavers, brick and cement based products by pressure or pump, worker exposure to the notified polymer is possible during opening and closing the containers, filling the pump or the sprayer and during spraying. Possible route of exposure are: dermal, inhalation and eye.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer, other than that of the home handyman will be minimal, despite potential widespread contact with material containing it, such as paper and paperboard. Where exposure does occur, dermal absorption is unlikely due to the high molecular weight of the polymer and its cross-linking within the matrix of the paper.

The product containing the notified polymer may be made available directly to the public for use by the home handyman in the sealing of concrete floors. Dermal exposure is likely during application of a solution containing 5 to 10% of Foraperle when applied to a concrete surface. During this procedure substantial exposure of the applicator, and family of household members, to the notified polymer is possible.

Contact with stone, pavers, brick and cement based products treated with the polymer may be widespread, however the polymer will be present at low concentrations and will be cross linked and bound into the matrix of the material it is used to water proof. Hence, exposure will be negligible.

During use in the production of paper and paperboard the product containing the notified polymer is diluted in water and mechanically applied to the paper using spray and rollers. As the notified polymer has a negligible vapour pressure, its dispersal in air beyond the confines

of the manufacturing site is unlikely. Dispersal of small quantities as aerosols or dust is possible but unlikely to be the source of significant public exposure.

The polymer, which is not classified as dangerous cargo will be imported and transported in 50 kg to 1 tonne containers. In the event of a transport accident the polymer may be recovered using adsorbents such as sand, with subsequent disposal to land fill or incineration in accordance with local government regulations. Given the negligible vapour pressure of the material and its affinity for organic material, residual material from a transport accident is unlikely to be a source of significant public exposure.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Paper

The notifier has indicated that release to the environment may potentially occur from: leaking storage containers (less than 2%); accidental spills (less than 1%); during application (less than 10%) and disposal of residual material in containers (less than 5%). The worst case total of 20% released during the application to paper, corresponds to a maximum of 500 kg per annum at the maximum rate of import.

The use of the coated paper has the greatest potential for environmental release of the polymer, including through disposal of treated paper products. Addition to the pulp suspension as noted above is expected to lead to some release in aqueous effluents. The notifier assumes that 90% of the polymer will be adsorbed to the paper pulp during treatment. This high level of adsorption is supported by the US EPA who in assessing cationic polymers assume that 90% of the influent polymer concentration will be removed by adsorption on passage through a waste water treatment plant, with the remaining 10% discharged to receiving waters (Boethling R and Nabholz J, 1997).

Construction Industry

Release to the environment resulting from the use of the polymer as a concrete coating may occur to the sewer (washing of tools used to apply formulations containing the notified chemical), or to landfill (disposal of residual quantities of the formulations within used containers).

It is expected that losses from application of the coating solution may result from overspray or splatter from rollers or brushes. There may also be some run off. These releases are likely to remain where they fall, mainly on the ground.

8.2 Fate

The majority of the notified polymer will share the fate of the paper onto which it has been coated. At the end of its useful life the paper will be either disposed of to landfill, incinerated or enter the paper-recycling stream.

In a landfill situation the notified material is unlikely to be mobile and would remain associated with paper refuse, and be slowly degraded to water, ammonia, nitrogen, methane, carbon oxides and low molecular weight fluorocarbons through the biological and abiotic processes operative in active landfills. The positive charge carried by the polymer molecules also means that they may undergo ion exchange processes with sodium and other positive ions and bind electrostatically to the surface of clay minerals in soil.

High temperature incineration would destroy the compound with evolution of oxides of carbon and nitrogen, together with release of low molecular weight fluorocarbon compounds, and possibly hydrogen fluoride.

It is expected that during the extensive re-pulping and bleaching procedures implied by paper recycling, the material would be either destroyed chemically or be incorporated into waste sludge. Given that the compound is claimed to have appreciable water solubility, it is possible that some of the notified chemical could also partition into aqueous waste streams generated during recycling. Waste sludge from the recycling plants would be either incinerated or disposed of to landfill. The aqueous waste would be comprehensively treated prior to discharge, but it is unlikely this would degrade the fluorocarbon portion (Remde A and Debus R, 1996), and this portion would be discharged with the plant effluent.

Although not required under the Act, the notifier has supplied a study of the biodegradability of the polymer (in French with some English translation). The biodegradability of the notified polymer was investigated in accordance with OECD test guideline 301A (Modified AFNOR test). During the test, 100% disappearance of the dissolved organic carbon (DOC) was observed within five days of the commencement of the test. This result was taken to indicate the substance is readily biodegradable under the conditions of the test, suggesting that the perfluorinated part of the molecule also degrades rapidly. However, Remde and Debus (Remde A and Debus R, 1996) were not able to establish the fate of fluorinated moieties in the biodegradation of three different fluorinated surfactants investigated. They concluded that in all cases, the formation of a highly fluorinated water insoluble fragment with unknown toxicity could not be ruled out (even when one was readily degraded), and it is likely that the fluorocarbon portion will be persistent.

Additionally, the observed disappearance of the DOC may also be accounted for by the adsorption of the polymer to the sludge during the test (see above). This would also be consistent with the fact that a polymer of this type with its relatively high molecular weight would be unlikely to degrade completely within 5 days (Cook B et al, 1997). The vast majority of synthetic polymers are essentially nonbiodegradeable, and the assessment of the removal of polymers in wastewater treatment essentially reduces to an assessment of removal by sorption and/or precipitation (Boethling R and Nabholz J, 1997). As noted above, the USEPA assumes that for cationic polymers 90% of the influent concentration of a cationic polymer will be removed by passage through a waste water treatment plant, and the remaining 10% is assumed to be discharged to receiving (Boethling R and Nabholz J, 1997).

The high molecular weight, water solubility (and consequential likely low partition coefficient) and ionic nature of the chemical would indicate that the chemical is unlikely to bioaccumulate (Connell DW, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The notified polymer has been notified under the limited notification category. Although not specifically required under the Act for this notification category the notifier has submitted reports of a number of toxicological tests, which are summarised below. Toxicity tests were carried out on the product Foraperle 321, which contains the notified polymer at a concentration of less than 30%.

Summary of the acute toxicity of Foraperle 321 containing the notified polymer

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(Baudet L, 1993)
skin irritation	rabbit	non-irritant	(Besson C, 1993b)
eye irritation	rabbit	slight irritant	(Besson C, 1993a)
skin sensitisation	guinea pig	non-sensitiser	(Besson C, 1993c)

9.1.1 Oral Toxicity (Baudet L, 1993)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single limit dose of 2 000 mg/kg of the test material by gavage; vehicle was distilled water
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

LD_{50}:	> 2 000 mg/kg
Result:	Foraperle 321 was of low acute toxicity when orally administered to rats in a limit test

9.1.2 Skin Irritation (Besson C, 1993b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/female
Observation period:	72 hours
Method of administration:	single topical doses of 0.5 mL test substance to the shorn flank; test site was covered by semi-occlusive wrap for 4 hours
Draize scores (Draize, 1959):	all Draize scores at all time points were zero
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	Foraperle 321 was not irritating to rabbit skin

9.1.3 Eye Irritation (Besson C, 1993a)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/female (the first of the three was used in a pre-study)
Observation period:	8 days
Method of administration:	0.1 mL of the test substance instilled into the conjunctival sac of the left eye; the right eye served as a control

Draize scores (Draize, 1959) of unirrigated eyes:

Time after instillation

Animal	*1 day*	*2 days*	*3 days*	*8 days*
Cornea	no lesion of the cornea was found at any time point by direct examination, however following instillation of fluorescein at all time points up to and including 72 hours, a fluorescent zone covering up to half of the corneal surface was evident in the treated eye of two animals; in the control eye of the same animals, a fluorescent zone covering less than one quarter of the corneal surface was observed at 24 and 48 hours; this fluorescence indicated the existence of erosion of the corneal epithelium. The test authors suggest it may be the result of rubbing by fur or other mechanical trauma; no further irritation reactions were seen at day 8.			
Iris				
1	0	0	0	0
2	0	1	0	0
3	0	1	0	0

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	1	-	1	1	-	1	0	-	0	0	-
2	1	2	-	1	1	-	0	0	-	0	0	-
3	1	2	-	1	0	-	1	0	-	0	0	-

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Test method: according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Comment: slight to moderate conjunctival redness was reported in all animals within the first 24 hours of the test; at 48 and 72 hours, the degree of these lesions tended to decrease in all animals;

approximately 1 hour after instillation of test material, the iris of the test eye of one animal was markedly folded. At 48 hours this effect was also reported in the other two animals. No further iris lesions were visible at 72 hours;

Result: Foraperle 321 was a slightly irritating to rabbit eye

9.1.4 Skin Sensitisation (Besson C, 1993c)

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20/sex (20 test; 10 positive control; 10 negative

control)

Induction procedure: Day 1: 3 pairs of intradermal injections:

- 0.1 mL Freund's complete adjuvant (FCA):isotonic NaCl solution (1:1(v/v))

- 0.1 mL of 75% concentration of test material in water

- 0.1 mL of 75% concentration of test material in FCA: isotonic NaCl solution (1:1 (v/v))

for positive control: 0.1mL of 1% DNCB was substituted for the test material

negative control: 0.1mL of water was substituted for the test material

Day 8: test area treated with 0.5 mL per injection site of 10% (w/w) sodium lauryl sulfate in paraffin oil

Day 9: non-occluded application of 0.5mL of 50% concentration of test material in water for 48 hours (DNCB and water substituted for positive and negative controls, respectively)

Challenge procedure: Day 22: non-occluded application of 50% concentration of test material for 24 hours (DNCB and water substituted for positive and negative controls, respectively)

Challenge outcome:

Challenge concentration	***Test animals***		***Positive Control animals***		***Negative Control animals[#]***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***	***24 hours***	***48 hours***
50%	0/20**	0/20	9/10	4/10	0/9	0/9

*time after patch removal

**number of animals exhibiting positive response

[#]one negative control animal was found dead on day 18

Test method: according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Result: Foraperle 321 was not sensitising to guinea pig skin

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Moliner B, 1995)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA98, TA100 and TA102
Concentration range:	312.5 – 5 000 μg per plate; assays were carried out in the presence or absence of S9 mix
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	Foraperle 321 was not mutagenic to S.typhimurium strains tested under the conditions of this assay

9.4 Overall Assessment of Toxicological Data

This polymer has been notified under the limited notification category. Although not specifically required, reports of a number of toxicological tests carried out on the product Foraperle 321 containing less than 30% of the notified polymer were provided by the notifier.

Foraperle 321 was of low acute oral toxicity when tested in rats (LD_{50} > 2 000 mg/kg). It was not irritating to rabbit skin and was not sensitising to guinea pig skin. Foraperle 321 did cause slight eye irritation (iris and conjunctiva lesions), mainly during the first 48 hours of the test. No irritant effects were reported on the last day of the test, Day 8. The mean scores for each type of ocular lesion were below the thresholds for classification as an eye irritant according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a).

Foraperle 321 was not mutagenic when tested in bacteria, either in the presence and absence of metabolic activation provided by rat liver S9 mix.

Based on the data provided by the notifier, Foraperle 321 containing the notified polymer would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not specifically required under the Act, the following English summaries of ecotoxicity studies have been supplied by the notifier (originals supplied in French). The tests were carried out according to ISO guidelines.

Test	***Species***	***Results (mg/L)***

Static 48 h acute toxicity	Water Flea *(Daphnia magna)*	EC50 = 3.78 (C.I. 3.00-4.76) NOEC = 0.5
16 h acute toxicity	Bacteria (*Pseudomonas putida)*	EC50 = 18 (C.I. 14-24)

* NOEC - no observable effect concentration

The supplied ecotoxicity data for the notified polymer indicate that it is moderately toxic to daphnia and bacteria. Algal species are known to be sensitive to polycationic quaternary ammonium polymers (Boethling R and Nabholz J, 1997).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified substance is expected to share the fate of the paper to which it is adsorbed. The paper will be used Australia wide and either be disposed of in garbage or recycled. Garbage containing the polymer bound to paper may either be incinerated or disposed of to landfill.

Based on an annual quantity of municipal solid waste of 13 million tonnes, the average concentration of the notified substance entering landfill from the disposal of coated paper would be less than 150 ppt (2 tonne per 13 000 000 tonne). This is assuming the entire product is used to coat paper, which is consigned to landfill at the end of its useful life. This figure would be further reduced by recycling and the incineration of coated paper, and the use of the notified polymer in the construction industry. The polymer bound to paper is not expected to be mobile in landfill.

During the recycling of coated paper, the notified polymer may partition with the waste sludge (and consigned to landfill or incinerated). It is also possible that some of the notified polymer could remain in the aqueous waste streams generated during recycling (given the polymer's appreciable water solubility). The aqueous waste would be comprehensively treated prior to discharge, but it is unlikely that this would degrade the fluorocarbon portion (Remde A and Debus R, 1996), and this portion (and possibly some of the undegraded polymer) would be discharged with the plant effluent.

The release of the notified polymer with the greatest potential for environmental impact is the discharge of the wastewater from the pulp and paper mill. The following Predicted Environmental Concentration (PEC) calculation is based in a worst case that all the chemical is used to coat paper at a single plant operating for 300 days per year.

Usage of the chemical:	2 000 kg per year
Treatment plant flow rate:	55 mL per day
Plant operating days/year:	300 days
Adsorption to paper:	90%
Predicted Environmental Concentration (PEC):	12 µg/L (ppb)

The above PEC represents the concentration leaving the paper mill treatment plant assuming no adsorption or degradation. The PEC is well below the level, which has been shown to be toxic to daphnia. Even allowing for a ten-fold increase in the sensitivity of algae compared to daphnia the levels are unlikely to present a hazard. Additionally, the results of the

biodegradation study would indicate that the level in the waste water leaving the mill treatment plant would be considerably lower and would be further reduced by the use of the polymer at more than one mill and in the construction industry. In the assessment of cationic polymers the USEPA assumes that 90% of the influent polymer concentration will be removed by adsorption on passage through a waste water treatment plant, with the remaining 10% discharged to receiving waters (Boethling R and Nabholz J, 1997).

The moderate toxicity of the polymer to bacteria is noted. If levels of the polymer in influent to a sewage treatment plant approaches these toxic levels it may affect the treatment plant's biological treatment process. However, for this to occur, a large quantity of the notified polymer would need to be used at the plant. Under the proposed rate of import, toxic levels in the influent would not be achievable. The overall environmental hazard of the notified polymer can be rated as low at the proposed level of import.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Health Hazard Assessment
Foraperle 321 containing the notified polymer was of low acute oral toxicity (LD_{50} > 2 000 mg/kg), was not a skin irritant or sensitiser, but was slightly irritating to rabbit eye. On the basis of the toxicology data provided, Foraperle 321 would not be classified as hazardous according to NOHSC criteria (NOHSC, 1994a).

Occupational Health and Safety
The risk of occupational health and safety effects posed to transport workers, who will be handling unopened containers of the product containing the notified polymer, is low.
Workers in the paper industry may be exposed to solutions containing up to 30% of the notified polymer by dermal, ocular and inhalation routes during paper production phases, that is, internal and external treatment of paper and paper products. Little information was provided by the notifier on these processess. Although not classifiable as an eye irritant, ocular exposure to Foraperle 321 may cause immediate irritation should eye contact occur. The notifier indicates that workers at the paper mills will be required to wear eye protection, gloves and overalls. Given that the results of a skin sensitisation and irritation study conducted on Foraperle 321 were negative, and that dermal absorption of the polymer is unlikely because it has a high molecular weight, the risk of workers experiencing acute health effects from handling the notified polymer is low.

No data on inhalation toxicity has been provided. However, the notifier states that local exhaust ventilation systems are in place in paper production areas, which will serve to control inhalation exposure and therefore any potential health effects via this route of exposure.

Dermal exposure is the primary route of exposure to the notified polymer for workers in the building industry. However, the risk of occupational health effects for these workers is low, given the results of toxicological studies submitted by the notifier.

Foraperle 321 also contains NMP and acetic acid. NMP is readily absorbed through the skin and is also a skin and eye irritant (R36/38) (NOHSC, 1994b). These risk phrases are incorporated on the Foraperle 321 label. NOHSC has not established a national exposure standard for NMP. Acetic acid has a NOHSC exposure standard of 10 ppm or 25 mg/m^3

(TWA) and 15 ppm or 37 mg/m^3 (STEL) (NOHSC, 1995). Employers are responsible for ensuring that the exposure standard is not exceeded in the workplace. As inhalation exposure to and dermal absorption of these components may occur in the workplace, workers should wear personal protective equipment as indicated in the Recommendations of this report. These outline the special glove requirements as given in the Foraperle 321 Material Safety Data Sheet (MSDS)

For the use of the notified polymer in Tegosivin HE 503 as a hydrophobing agent for concrete, clay and terracotta, no significant risk to worker health and safety is expected. This is based on the expected low hazard of the polymer and the very low concentration of polymer in the product as applied.

Public Health
Where the product is sold to the public for application in the home, the primary hazards associated with this application will, based on the limited data available, relate to the content of NMP in Foraperle 321, rather than the notified chemical. The skin and eye irritancy of NMP has prompted consideration of this compound for inclusion in the Standards for the Uniform Scheduling of Drugs and Poisons (SUSDP) by the National Drugs and Poison Scheduling Committee (NDPSC) at its February 1998 meeting. The NDPSC has included this compound in the SUSDP in Schedules 6 and 5 and have additionally classified it as a designated solvent. At the concentration of NMP used in Foraperle 321 the preparation will require labelling as a Schedule 5 poison.

Based on the use pattern of the notified polymer and its physico-chemical and toxicological properties, the copolymer in Foraperle 321 is considered not to pose a significant risk to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Copolymer in Foraperle 321 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);
- Impermeable gloves or mittens should conform to AS 2161 (Standards Australia, 1998). The MSDS states that neoprene, polyvinyl chloride, natural rubber or butyl rubber gloves should be worn;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

Due to the presence of NMP and acetic acid in the product Foraperle 321, appropriate general and exhaust ventilation should be employed in areas where the product is being handled in undiluted form. There is a NOHSC exposure standard for acetic acid of 10 ppm or 25 mg/m^3 (TWA) and 15 ppm or 37 mg/m^3 (STEL) (NOHSC, 1995). Employers are responsible for ensuring that this level is not exceeded in the workplace.

The NDPSC has included this compound in the SUSDP in Schedules 6 and 5 and have additionally classified it as a designated solvent. At the concentration of NMP used in Foraperle 321 the preparation will require labelling as a Schedule 5 poison.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product Foraperle 321 containing the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994c).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

A Material Safety Data Sheet for the product Tegosivin HE 503 was provided in a format consistent with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994b). The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Secondary notification under Section 64 of the Act will also be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified polymer, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the polymer. Based on an assumed 10-fold increase in the sensitivity of algae compared to daphnia, secondary notification would be required if the import rate of the notified polymer exceeds 10 tonnes per annum. This notification should include ecotoxicity studies for fish and algae and full English translations of the ecotoxicity and biodegradation reports submitted in French.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe