

File No: LTD/1191

26 August 2005

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Polyquart Ampho 149

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**Director
NICNAS**

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FULL PUBLIC REPORT

Polymer in Polyquart Ampho 149

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Cognis Australia Pty Ltd (ABN 87 006 374 456)

4 Saligna Drive

Tullamarine VIC 3043

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical identity details

Specific use

Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Vapour pressure

Water solubility

Flash point

Flammability limits

Autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2002), Korea (2003).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polyquart Ampho 149

MOLECULAR WEIGHT

> 10,000

SPECTRAL DATA

METHOD	Infrared (IR) spectrum
Remarks	A reference spectrum was provided

METHODS OF DETECTION AND DETERMINATION

METHOD	Gas Permeation Chromatography (GPC)
Remarks	Several analyses were carried out, showing small variations in molecular weight.
TEST FACILITY	PSS (2004)

METHOD	Gas chromatography (GC)
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Remarks Analyses of residual monomers and impurities carried out by GC. Degree of purity of notified polymer calculated by difference.

3. COMPOSITION

DEGREE OF PURITY
> 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Details of hazardous impurities were supplied

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported by sea in 150 L high density polyethylene (HDPE) drums as an ingredient of Polyquart Ampho 149.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	2-5	2-7	4-9	6-10

USE
Hard surface cleaner additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Polyquart Ampho 149, the product containing < 50% of the notified chemical in an aqueous solution, will initially be stored and distributed from the notifier's site in Broadmeadows, Victoria.

TRANSPORTATION AND PACKAGING
Polyquart Ampho 149 will be imported in 150 L HDPE drums that will be transported by road from the wharf to the notifier's site for storage and re-transporting to manufacturers of hard surface cleaners and car wash detergents. The hard surface cleaners and car wash detergents will then be packed into 5 L or 20 L HDPE containers and transported by road to the major car wash facilities. Alternatively the products may be packaged into smaller containers and distributed for sale to the public through retail outlets.

5.2. Operation description

Polyquart Ampho 149 containing < 50% of the notified chemical will be transported to the notifier's warehouse and thence to formulation sites throughout Australia. At the formulation sites the liquid Polyquart Ampho 149 will be decanted or pumped from the 150 L drums into the mixing vessel and blended with other ingredients. It will be incorporated at less than 1% into hard surface cleaner and car

wash formulations. These will be sampled for QC testing and packaged into a range of container sizes for distribution to industrial customers and to the public.

5.3. Occupational Exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Store Operator	2	½ hr/day	12 days/year
Plant Operator	2	2 hr/day	24 days/year
Laboratory Technician	1	½ hr/day	24 days/year
Car Wash Personnel	1	2 hr/day	300 days/year

Exposure Details

Transport and storage

Occupational exposure is not expected to occur in transport or storage prior to use of Polyquart Ampho 149 in formulation processes. The notified chemical will remain in sealed containers until this time and exposure would only occur in the case of accidental spillage. Similarly there is not expected to be contact with the formulated and packaged end-products during their transport and storage.

Formulation

The plant operator weighs an amount of Polyquart Ampho 149 containing < 50% of the notified chemical into a bucket that in turn is added at the final stage of the manufacture process and blended at low speed. Alternatively Polyquart Ampho 149 may be pumped from the drums into the mixing tank. A laboratory technician is responsible for chemical testing of the final product in the laboratory to ensure compliance to specifications. There is possible eye and skin contact of these workers to the notified chemical, however the PPE to be worn – safety glasses, impervious gloves and protective clothing – is expected to protect against exposure. If other ingredients of the formulation are volatile, engineering controls such as local exhaust ventilation (LEV) may also be present.

End-use of car wash products

Car wash personnel would put a small amount of the formulated cleaner containing < 1% of the notified chemical into a bucket of water or (more usually) an automatic washing station and apply to the vehicle to be washed. Automatic application is likely to be by rollers or high pressure spray. Inhalation exposure to aerosols from high pressure spray would be possible, however workers are unlikely to be nearby during automatic application. Approximately 10 g of the product would be used per car. The diluted cleaner would be used to suds up the car, and then rinsed off with water, usually as part of an automatic process. As a range of exposure situations may occur at the different sites, contact with skin and eyes may occur. The car wash personnel would wear PPE such as safety glasses, safety boots, protective clothing and impervious gloves to protect against exposure.

End-use of other hard surface cleaner products

Manual processes would be used by workers cleaning other surfaces with hard surface cleaners containing < 1% of the notified chemical. Such products may be used without a dilution step or diluted with water before application. Application methods may include spraying. Depending on the type of products, the cleaning product may be rinsed off the surfaces or wiped away. It is expected that PPE similar to that described above would be used by workers.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Local operations will include transport, storage and reformulation. Release to the environment may occur in the unlikely event of an accident during transport or if the packaging (150 L HDPE drums) are damaged during handling and storage. Spilt notified chemical should be physically contained and collected, and be subsequently disposed of by thermal decomposition by incineration or sent to secure landfill. It is expected that this will account for less than 1% (100 kg) of the total import volume per annum.

Reformulation is expected to take place at up to 15 separate sites throughout Australia. During

reformulation and filling there is potential for release to the environment through spills. However, these should be contained by standard physical engineering means, and recycled if not contaminated, or disposed of to sewer as trade waste. It is expected that this will account for less than 1.25% (125 kg) of the total import volume per annum.

The 150 L HDPE import containers and any residual notified chemical are expected to be either recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical has two main uses. It is expected that approximately 80% (8000 kg per annum) will be packaged into 5 and 20 L HDPE containers and will be used in car wash detergents for use by commercial car wash sites and by the general public. It is claimed that there will be negligible release to the environment directly from the commercial car wash sites, as all detergent must be recycled and ultimately disposed of via registered disposal firms. However, it is expected that practically all of the notified chemical used by the general public will be released to the environment on use. This may adsorb to soil, where it will slowly degrade, or be released to the sewer and/or stormwater drains. As the proportion of notified chemical that is directed to commercial car wash sites is unclear, subsequent worst-case calculations will be based on the assumption that all notified chemical used in car wash detergents will be released to the sewer.

The second use, accounting for the remaining 20% (2000 kg per annum) will be in commercial hard-surface cleaners. It is expected that apart from any minimal residual notified chemical remaining in containers, that all of this will be released to the sewer.

Therefore, as a worst case, practically 100% (10000 kg) of the import volume of the notified chemical will be released to aquatic environment via the sewer.

5.5. Disposal

It is expected that containers will be rinsed with water, and therefore negligible quantities of notified chemical will be disposed of with the containers. Containers for commercial use products are expected to be recycled, whereas containers for public use are expected to be disposed of as domestic waste to landfill.

5.6. Public exposure

During transport and storage of Polyquart Ampho 149 and products containing the notified chemical, the opportunity for exposure of the general public will be low, occurring only in the case of accidental spillage.

A proportion of the formulated hard surface cleaners and car wash detergents containing up to 1% of the notified polymer will be sold to the public or used by the public at car wash facilities. There may be some dermal or ocular exposure of consumers during routine use of the products. Any such exposure would be reduced by the low concentration of the polymer in the products. Directions for use would recommend precautions to reduce exposure.

Secondary dermal exposure of the public to surfaces cleaned with products containing the notified polymer is also possible.

Accidental oral exposure to products containing the notified chemical eg by children is also possible, however the concentration of the polymer in the products is low

Inhalation exposure to products containing the notified polymer is less likely due to the liquid form of the Hard Surface Cleaners and car wash detergents, which would be aqueous solutions. However if products were applied by spraying there could be inhalation exposure to aerosols.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellowish clear liquid (Polyquart Ampho 149)
Melting Point/Freezing Point	100-120°C

Remarks From DSC scan.

Density 1.1 kg/m³ (Polyquart Ampho 149)

Remarks No data provided on notified polymer

Vapour Pressure

Remarks Not determined. Vapour pressure is likely to be low because of the high molecular weight and salt form of the polymer.

Water Solubility Miscible

Remarks No test report available. The notified polymer is marketed as an aqueous solution and is stated to be soluble in any proportion in water.

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2} <i>d</i>
1.2	25	>365
4	25	>365
7	25	>365
9	25	>365

Remarks As the test item consists of a carbon backbone that will not be hydrolysed under the conditions of the test method, the percentage hydrolysis of polymer constituents was determined by measuring the increase in content of the neutral non-polymeric constituents. A preliminary test conducted at pH 1.2, 4, 7 and 9 revealed that less than 10% of the test item had been hydrolysed after 120 h (5 d) at 50°C..

TEST FACILITY Infracor Chemistry Services (2003a)

Partition Coefficient (n-octanol/water) log Pow = <-1.74 at 20°C (Pow = <0.018)

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).

Remarks HPLC Method/Flask Method. No significant deviations from the test procedure were reported. The concentration of the test item in both phases of the samples were analysed by nitrogen analysis. The measured nitrogen concentration in water and octanol was ~5.54 mg/L and <0.1 mg/L respectively, at pH 5.6-6.0.

TEST FACILITY Infracor Chemistry Services (2003b)

6.8b **Adsorption/Desorption** log K_{oc} = -1.2 to 1.8 at 40°C

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (*K_{oc}*) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)

Remarks The test substance is a polymeric amino acid with amphoteric properties. As the test substance contains basic and acidic groups, no undissociated form of the test substance exists. For this reason, the test was performed with demineralised water and acetonitrile as eluent. The test substance showed a not completely resolved elution band, and therefore, for the determination of the loc K_{OC} values, the first and last signal of the test substance were used for the evaluation. Six reference samples were used, with log K_{OC} values ranging from 1.45 – 3.16. The first peak of the test item was significantly before 2-Nitrobenzamide (log K_{OC} = 1.45) and the final peak was equivalent to that of methylbenzoate (log K_{OC} = 1.80).

TEST FACILITY Bayer (2005a)

Dissociation Constant pK_{a1} = 7.7

$$\text{pK}_{\text{a}2} = 10.4$$

METHOD	OECD TG 112 Dissociation Constants in Water.
Remarks	Titration method.
TEST FACILITY	Bayer (2005c)

Flash Point

Remarks	Not determined
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Autoignition Temperature

Remarks	Not determined. Notifier has stated that the polymer is not expected to self-ignite.
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Explosive Properties

Remarks	Notifier has stated that the polymer is not expected to have explosive properties, based on its structure.
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Reactivity

Remarks	Not expected to be reactive, based on structure and high molecular weight. It is not an oxidiser and is thermally stable up to the decomposition temperature of 460°C.
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7. TOXICOLOGICAL INVESTIGATIONS

Toxicological test reports were supplied only for a bacterial mutation study and an in vitro red blood cell (RBC) irritancy study. These studies are listed below. In addition the notifier provided the following statements on the likely toxicity of the notified polymer:

Acute oral toxicity

The notifier stated that the LD50 of the notified polymer is likely to be > 2000 mg/kg/bw based on the low acute toxicity of the monomers and the high molecular weight.

Skin sensitisation

The notifier stated that skin sensitisation is not likely, due to the high molecular weight of the notified polymer.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Genotoxicity – bacterial reverse mutation	non mutagenic
Irritancy – in vitro RBC	not haemolytic

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical, 22% in solution. Sample dated 24/7/01.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure (Test 1) and Pre incubation procedure (Test 2).
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, TA102,
Metabolic Activation System	S9 fraction from Phenobarbital/β-Naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33 to 5000 µg/plate b) Without metabolic activation: 33 to 5000 µg/plate
Vehicle	Deionised water
Remarks - Method	The study authors noted that the positive control used without metabolic activation was methyl methane sulfonate (MMS) for TA 102 and 4-nitro-o-phenylene-diamine (4-NOPD) for TA 1537 and TA 98. The positive control with metabolic activation was 2-aminoanthracene (2-AA) for all strains.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	> 5000 in TA 98 and TA 100	> 5000 in all strains	None	Negative
Test 2	-	≥ 2500 in TA 100 and > 5000 in other strains	None	
<i>Present</i>				
Test 1	> 5000 in TA 98 and TA 100	> 5000 in all strains	None	Negative
Test 2		≥ 5000 in TA 100 and > 5000 in other strains	None	Negative

Remarks - Results	No significantly significant increases in revertants were observed in any test. However small increases in revertants at the highest dose (5000 µg/plate) were noted in some tests with strains TA 1535, TA 1537 and TA 98.
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CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
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TEST FACILITY	RCC (2002)
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7.20T. In vitro irritancy by red blood cell test system (RBC-test)

TEST SUBSTANCE	Notified polymer (identified in report as test substance 40)
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METHOD	INVITTOX protocol number 37 "Red Blood Cell Test System" ZEBET protocol number 30.
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Remarks - Method	Porcine blood was used instead of calf blood. Test samples were diluted to a range of concentrations and incubated with the erythrocytes. The detailed protocol was not included in the translated extract provided of the study report. Test results were compared against those of a standard substance. This substance was not fully identified in the translated extract of the test report.
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RESULTS	The erythrocytes did not lyse when in contact with solutions of the notified polymer up to 8000 µg/mL
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Remarks - Results	Interpretation of the results is based on L ₅₀ (concentration of the test substance at which 50% of the erythrocytes are lysed) and on the substance's denaturing effects on haemoglobin. These could not be determined as the cells did not lyse at the highest concentration tested. However the results were interpreted qualitatively to indicate low irritancy.
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CONCLUSION	The test substance is not considered irritating under the conditions of the test.
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TEST FACILITY	Mediport Biotechnik (2002)
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8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted, however a Zahn-Wellens (Inherent Biodegradability) test was submitted, as detailed below.

8.1.1. Inherent biodegradability

TEST SUBSTANCE	Analogue: Amphopolymer SCI 6060-3
METHOD	Zahn-Wellens Test (OECD TG: 302 B)
Inoculum	Activated sludge from a local sewage treatment plant.
Exposure Period	28 days
Auxiliary Solvent	
Analytical Monitoring	
Remarks – Method	The test sample, Amphopolymer SCI 6060-3 was evaluated at a test concentration of 100 mg/L referred to DOC. Test sample application was by direct addition to the test system.

RESULTS

<i>Test substance</i>		<i>Diethylene glycol</i>	
<i>Day</i>	<i>% DOC Reduction</i>	<i>Day</i>	<i>% DOC Reduction</i>
7	56	7	100
14	10	14	100
21	9	21	99
28	8	28	100

Remarks – Results

The test sample was used at a test concentration of 100 mg/L and initially showed a clear reduction in the DOC content measured as the evaluation parameter. When referred back to the starting value of approximately 30 mg DOC/L measured after 3 h, a DOC reduction of 56% was observed on day 7 of the test. This test sample elimination, which could apparently be traced back to adsorption on the activated sludge, was to a large extent abolished during the further course of the test; the DOC reduction stabilised at 8-10%.

However, this degradation/elimination rate for the routine evaluation did not include the spontaneous elimination of the test sample. Adsorption of the test sample on the activated sludge at the beginning of the test resulted in clearly reduced starting concentrations. Comparison of the determinations carried out immediately on the 0-day with the calculated theoretical concentration produced recovery rates <80%. As such types of mechanisms also occur in STPs, this spontaneous elimination of 69% should be taken into consideration in the final evaluation of the degradation/elimination behaviour of the test substance. For the “aerobic biodegradability (elimination) after 7 days” described in the General Wastewater Administrative Regulations (Rahmen-AbwasserVwV), which is the difference between the theoretical concentration and the DOC concentration after 7 days, a DOC elimination of 88% can be calculated.

Diethylene glycol was tested in parallel as a reference substance. As the reference substance achieved >70% DOC reduction after 14 days, the test is validated.

CONCLUSION

The analogue, Amphopolymer SCI 6060-3 is classified as “not readily biodegradable under the test conditions.”

TEST FACILITY

Henkel KgaA (1997)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue: Amphopolymer SCI 6060-3
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static.
Species	Zebra barbels (<i>Brachydanio rerio</i>)
Exposure Period	96 h
Analytical Monitoring	
Remarks – Method	Due to the good analytical recovery rate (87.1%, measured as DOC) within the 24 h incubation intervals the nominal concentrations were used to determine the effect concentrations. Throughout the test, the water temperature, pH and oxygen saturation remained within the limits of the test criteria. The LC50 was determined by interpolation according to the probit method.

RESULTS

Concentration mg/L <i>Nominal</i>	Number of Fish	Mortality				
		2-4 h	24 h	48 h	72 h	96 h
0	10	0	0	0	0	0
5	10	0	0	0	0	0
10	10	0	0	0	10	10
20	10	0	0	10	10	10
40	10	0	0	30	70	90

LC50	28 mg/L at 96 hours.
NOEC	5 mg/L at 96 hours.
Remarks – Results	The test report states “during the whole duration of the test the [surviving] fish showed no abnormal behaviour”.

CONCLUSION	The analogue is moderately toxic to Zebra barbels.
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TEST FACILITY	Henkel KgaA (1997a)
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9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be used in car wash detergents and hard surface cleaners. As such, it is assumed, in a worst-case scenario, that practically 100% of the total volume of imported notified chemical will eventually be released to the aquatic environment via the sewer or stormwater drain after reformulation and use. Negligible (< 2% or 200 kg) quantities of residual notified chemical in containers may be disposed of to landfill, where it is expected that the notified chemical will adsorb onto soil and not be mobile. Over time, the notified chemical is then expected to slowly degrade by abiotic and biotic processes to form simple carbon and nitrogen-based compounds.

Based on the worst-case scenario of 100% notified chemical being released to the aquatic environment via the sewer, with nil removal, a predicted environmental concentrations (PECs) of the notified chemical have been calculated:

Amount entering sewer per year	10000 kg
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Number of days per year	365
National population	20.1 million
Litres per person	200 L
PEC _{River}	6.8 µg/L.
PEC _{Ocean}	0.7 µg/L.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/yr). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m³). Using these assumptions, irrigation with a concentration of 6.8 µg/L may potentially result in a soil concentration of approximately 68 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.34 and 0.68 mg/kg respectively.

However, based on the result of the Zahn-Wellens test, an elimination of 88%, the PECs have been recalculated to take this into account:

Amount entering sewer per year	10000 kg
Elimination percentage	88%
Effective amount leaving sewer per year	1200 kg
Number of days per year	365
National population	20.1 million
Litres per person	200 L
PEC _{River}	0.82 µg/L.
PEC _{Ocean}	0.08 µg/L.

Using the above assumptions, irrigation with a concentration of 0.82 µg/L may potentially result in a soil concentration of approximately 8.16 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.04 and 0.08 mg/kg respectively.

The potential for the notified chemical to bioaccumulate is low due to its relatively high water solubility and will be limited due to the diffused release to sewer Australia wide.

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate that the notified chemical is moderately toxic to fish (96 h LC₅₀ = 28 mg/L). While ecotoxicological studies were not undertaken with algae, cationic polymers are known to be around 6 times more toxic to algae than fish (Nabholz *et al.* 1993). This is equivalent to a EC₅₀ of 4.67 mg/L.

A PNEC_{Algae} has therefore, been calculated based on the single reported end point (28 mg/L) divided by 6, and using a safety factor of 1000, resulting in PNEC_{Algae} = 4.67 µg/L.

9.1.3. Environment – risk characterisation

The Risk quotient (RQ) values, where $RQ = PEC/PNEC$, for freshwater and marine receiving environments have been calculated for the “worst case” scenario, as shown in the table below.

Worst Case: PNEC _{Algae} & 0% Removal	PEC	PNEC	RQ
River	6.8	4.67 µg/L	1.46
Marine	0.7	4.67 µg/L	0.15

Clearly, this suggests an unacceptable risk to the aquatic environment as the $RQ_{River} > 1.0$. However, when taking into consideration the 88% elimination, the recalculated RQ values are:

Worst Case: PNEC _{Algae} & 88% Removal	PEC	PNEC	RQ
River	0.82	4.67 µg/L	0.18
Marine	0.08	4.67 µg/L	0.02

As the RQ for both river and marine receiving waters is below 1.0, the proposed diffuse use of the notified chemical, at current expected import volumes, is unlikely to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The major route of potential worker exposure to the notified polymer during formulation is dermal. Workers may be exposed to solutions containing < 50% of the notified polymer during formulation, however the potential for exposure will be limited by the uncomplicated nature of the process and the controls commonly applied, in particular standard PPE.

During end-use of the polymer as an ingredient of hard surface cleaners and car wash products at <1%, the major route of exposure is also likely to be dermal. Inhalation exposure could also occur if cleaning solutions were sprayed, or applied in such a way that aerosols are formed. The conditions of use are likely to be variable. At car wash sites both manual and automatic cleaning may occur. For the former, the main controls would be PPE worn by workers to minimise dermal exposure. For the latter, isolation of the automatic processes from workers would reduce exposure. Potential exposure during all types of end-use would be reduced by the low concentration of the notified polymer in marketed products.

Exposure during transport and storage is not expected to occur, except in the case of accidental breaching of the packaging.

9.2.2. Public health – exposure assessment

The notified polymer will be incorporated in domestic hard surface cleaners at concentrations substantially less than 1%. The low concentration and expected intermittent use pattern would reduce the potential for exposure, which would be primarily dermal. Inhalation exposure may occur if products are applied by spraying, but would otherwise be unlikely because of the notified polymer would have a low vapour pressure. A major determinant of exposure would be whether consumers wear gloves while using products containing the notified polymer, however this may not be recommended for all products.

9.2.3. Human health – effects assessment

Few data were provided on the toxicology of the notified polymer.

Acute toxicity is expected to be low, based on a statement by the notifier that the monomers are of low acute toxicity.

While an in vitro red blood cell (RBC) test result gave an indication of low irritancy, the structure of the notified polymer suggests that it could cause skin and eye irritation, and skin sensitisation. The possibility of these effects cannot be ruled out, despite a high molecular weight. It is also noted that the polymer contains an impurity that is likely to be irritating at acidic pH.

A well conducted in vitro bacterial mutagenicity test gave negative results. No other genotoxicity data was submitted. Information was not provided on toxicokinetics, repeated dose toxicity, reproductive effects or carcinogenicity.

Based on the limited data available, the notified chemical is cannot be classified in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer cannot be classified under NOHSC criteria based as only limited toxicological data was submitted. It is expected to be of low acute toxicity, and testing for bacterial mutagenicity was negative. Based on the structure of the polymer, irritation and sensitising properties cannot be ruled out. However irritating properties were not revealed in an in vitro red blood cell (RBC) study.

During formulation processes, workers may experience dermal exposure to solutions containing < 50% of the notified polymer. However routine controls for these procedures (particularly use of PPE) is expected to minimise the exposure.

Workers using car wash products or hard surface cleaners are potentially exposed to much lower concentrations of the notified polymer (<1%, or even less if the products are diluted before use), however the range of exposure scenarios and controls is more varied than in the formulation process. Both dermal and inhalation exposure may occur. The potential for eye or skin irritation or sensitisation is likely to be mitigated by the relatively low concentration, and increased if products containing the notified polymer are used repeatedly without PPE.

An impurity in the polymer is also an irritant at low pH.

Overall the risk to workers is considered low if controls appropriate to the exposure scenarios are in place.

9.2.5. Public health – risk characterisation

Few toxicological data on the notified polymer are available. From the available data and characteristics of similar chemicals, the polymer may have eye and skin irritation and skin sensitisation potential, although this has not been demonstrated through testing. The polymer is expected to have low acute toxicity, based on the characteristics of its monomers, and thus would be of low risk if accidentally ingested.

The public is potentially exposed to the notified polymer through consumer use of car-wash or hard surface cleaners containing it at <1%. The major route of exposure would be dermal, with the possibility of inhalation exposure if the products are sprayed. Exposure would be reduced by the low concentration at which the notified polymer will be used in consumer products and the expected low frequency of use. Exposure during use would be further reduced if gloves are worn or if there is no direct contact with the cleaning solution.

As products may not be washed off the hard surfaces after cleaning, there is also a potential for secondary exposure from treated surfaces. The concentration of the notified polymer on such surfaces would be very low.

Based on limited data on the health effects of the polymer, the endpoints of concern are irritation and sensitisation. The risk that the public may experience these effects is considered low, because there will be low levels of the polymer in consumer products and an expected intermittent pattern of use. Products may contain other ingredients that would determine the controls necessary for safe use.

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

10.1. Hazard classification

As only limited data is available on the notified polymer, it cannot be classified for health effects under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

It is noted that the MSDS for the notified polymer states that it is classified as:
R52/53 – Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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. Based on environmental data submitted to NICNAS, the notified chemical can be classified as Chronic Category 3.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern and volume.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as introduced, and in end-use products:
 - Measures to minimise direct handling;
 - Isolation of workers from spray in car-wash applications.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and in end-use products:
 - Good housekeeping to minimise spills and contamination that may lead to worker exposure
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and in end-use products:
 - Dermal protection, including gloves and eye protection;
 - Respiratory protection if exposure to aerosols may occur.

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken marketers of consumer products containing the notified polymer to minimise public exposure to the notified chemical:
 - Directions for appropriate use;
 - Appropriate labelling to encourage minimal consumer contact, eg warning re eye contact.

Environment

- Do not allow concentrated notified chemical to enter the aquatic environment.

Disposal

- The notified chemical should be disposed of by thermal decomposition by incineration or to secure landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment and subsequent disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds ten tonne per annum notified chemical; or
 - the notified polymer is used in consumer products at > 1%.

or

- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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