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

FULL PUBLIC REPORT

Polyhexamethyleneguanidine phosphate

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Polyhexamethyleneguanidine phosphate****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

SK Global Australia Pty Ltd
Level 31, 2 Park St.
Sydney 2000

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Poly(iminocarbonimidoylimino-1,6-hexanediyl), phosphate

OTHER NAME(S)

Polyhexamethyleneguanidine phosphate

MARKETING NAME(S)

SKYBIO 1100

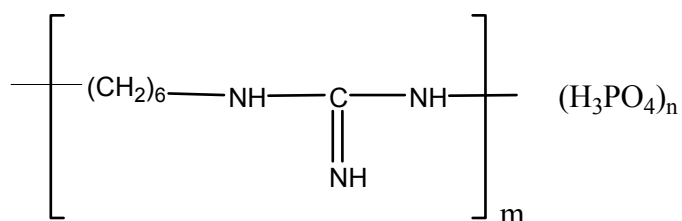
CAS NUMBER

89697-78-9

MOLECULAR FORMULA

$(C_7H_{15}N_3)_m(H_3PO_4)_n$ ratio $m/n = 1-2$

STRUCTURAL FORMULA



$m/n = 1-2$

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	18,500
Weight Average Molecular Weight (Mw)	137,000
Polydispersity Index (Mw/Mn)	7.37
% of Low MW Species < 1000	0.01
% of Low MW Species < 500	<0.01

SPECTRAL DATA

ANALYTICAL METHOD	Infra-red spectroscopy
Remarks	
TEST FACILITY	3311.59, 2125.81, 1635.56, 1473.43, 1356.41, 1075.34, and 986.97 cm ⁻¹

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV Visible Spectrophotometry
Remarks	Skybio 1125 (analogue) forms a coloured complex with Eosin. The complex has a maximum value at 549 nm.
TEST FACILITY	Specialty Chemicals Division, SK Chemicals

3. COMPOSITION

DEGREE OF PURITY

95.5%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

No measurable concentration of residual monomer or reactants

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

<i>Chemical Name</i>	Sodium chloride		
<i>CAS No.</i>		<i>Weight %</i>	3
<i>Chemical Name</i>	Water		
<i>CAS No.</i>		<i>Weight %</i>	1.5

ADDITIVES/ADJUVANTS

None

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>
Polyhexamethylene guanidine phosphate	89697-78-9	~100%

THERMAL DECOMPOSITION

The notified polymer was analysed by pyrolysis/GC/MS analysis using electron ionisation mass spectrometry and chemical ionisation detection. The sample was analysed at 360 °C and 500°C in helium. The proportions of each pyrolysis product was inconsistent. The compounds identified were consistent with the know structure of the notified polymer: derivatives of piperidine and hexahydro azepine. of the sample produced some inconsistent results in the proportions of each pyrolysis

TEST FACILITY Macquarie University Centre for Analytical Biotechnology (2002)

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported either as powder or an aqueous solution containing 25% notified polymer.

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>	10	24	50	75	100

USE

The notified polymer will be used as a microbial additive in plastics, fabric softeners, paints, swimming pools and papers (especially wall paper) and for sanitation in food processing plants and cooling towers.

Plastics

Masterbatches of notified polymer are prepared for incorporation into plastics, eg PVC, polypropylene, polyethylene, polyester and polyurethane. In the manufacturing process, the Masterbatch and other additives are then added in suitable ratios. The concentration of notified polymer in plastics is 0.2-0.7% w/w.

Food processing plants, paper, fabric softeners, paints and cooling towers

Notified polymer added as an aqueous solution at 25% is used in these applications. The applications are automated and involve the use of metering pump additions. The concentration of notified polymer in these applications are as follows:

Water treatment applications* :	100-125 ppm.
Paper:	0.3-1.0% w/w
Fabric softeners:	not specified
Paints	0.15-0.5% w/w

* including pool applications

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not known

IDENTITY OF MANUFACTURER/RECIPIENTS

Not known

TRANSPORTATION AND PACKAGING

The notified polymer is packaged in stainless steel reinforced paper containers (bags) of 25 kg

5.2. Operation Description

The notified polymer is imported as a solution at about 25% or as powder at approximately 100%.

Use as a solution:

Automated process: the notified polymer solution is either directly added from the containers (drums) or pumped to a storage tank for delivery to an automated dosing system.

Manual process: the required volume of notified polymer is measured by dipping or decanting and adding to a vortex in a stirred open tank.

Use as powder:

For the use of notified polymer imported as powder for example in Masterbatch manufacture, the bags will be cut open and the contents tipped into a blender with the other ingredients used in the manufacturing process. The blended masterbatch is then transferred to a hopper, fed into an extruder, then diced and packaged. Plastic articles are then produced by blending masterbatch with resin, followed by processing such as injection moulding.

5.3. Occupational exposure

It is estimated that there will be about 4 companies likely to use the product, and a total of 20 workers (five/company) will handle the product.

Waterside, transport and warehouse workers will only handle closed containers of the product containing the notified polymer.

Exposure of workers to the 25% aqueous solution may occur when dispensing, weighing, mixing and blending, in particular, when the containers are open for insertion of the pump or metering system and when the pump or metering system is withdrawn from the empty container.

During manual processes, workers may contact the product when measuring the required amount, e.g. by dipping or decanting and adding to a vortex in a stirred open tank.

When handling the solid form of the notified polymer, workers may become exposed to dust when cutting the bags, weighing the powder and emptying the contents into a blender for masterbatch production.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a powder in stainless steel reinforced 25 kg containers or as a 25% aqueous solution.

RELEASE OF CHEMICAL FROM USE

Up to 80% of the import volume will be used in the treatment of water in food processing plants, swimming pools and cooling towers and in the manufacture fabric softeners. This will result in the eventual release of up to 80 tonnes per annum to the environment. The remaining 20% will be incorporated into paper products, such as wallpaper, and paints. Production losses from these uses are estimated to be less than 1% of import volume due to the highly automated manufacturing and blending processes employed. This will result in a further release to the environment of up to 1000 kg per annum.

5.5. Disposal

The majority of the notified polymer will be released to sewer. Wastes resulting from spills will either be recovered and used or discarded to landfill or sewer. Products into which the notified polymer has been incorporated, such as painted objects and wallpaper, will eventually be disposed of to landfill.

5.6. Public exposure

The public may be exposed to the product through direct contact to waters that have been treated with the product and through exposure to paints, paper, plastics and fabric softeners.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White powdered solid with no odour
Melting Point/Freezing Point	57°C
Boiling Point	Decomposes at about 250°C before boiling at 101.3 kPa
Density	Not provided (Bulk density 740 kg/m ³)

Vapour Pressure	Negligible at 20°C
Water Solubility	285 g/L at 20°C
METHOD	OECD TG 105 Water solubility
Remarks	The preliminary test found the water solubility of the notified polymer to be approximately 200-1000 g/L. During the definitive test, the test substance (approximately 5 times the test substance required to produce a saturated solution as determined from the preliminary test) was added to water, agitated for 24 h at 30°C followed by equilibration for 24, 48 and 72 h. The contents of the test vessels were centrifuged and the supernatant layer analysed.
TEST FACILITY	SK Chemicals (2002a)
Hydrolysis as a Function of pH	Stable
Remarks	The test report provided did not detail the procedure used to determine the hydrolytic stability of the notified polymer. However, the information supplied suggests that the notified polymer was added to solutions buffered at pH 1.2, 4, 7 and 9 and then, after an unspecified period of time, analysed by FT-IR. No significant change was observed in the spectra obtained indicating the notified polymer is stable to hydrolysis in the pH range of 1.2-9.
TEST FACILITY	SK Chemicals (2002b)
Partition Coefficient (n-octanol/water)	Not determined
Remarks	While no test report was provided, the notifier indicates that the n-octanol solubility of the notified polymer was determined using a standard shake flask method quantified by a spectroscopic method using Eosin indicator. The octanol solubility of the notified polymer was found to be below the limit of quantification of the analytical method (0.1ppb). Therefore, the polymer is expected to have a low partition coefficient value, which is indicative of partitioning into the aqueous phase.
Adsorption/Desorption	Not determined
Remarks	As a consequence of its cationic character, the notified polymer is expected to have a high affinity for organic matter in soil and sediment.
Dissociation Constant	6.6
Remarks	The dissociation constant for the notified polymer was determined by a titration method using 0.05M sulphuric acid.
TEST FACILITY	Not specified
Particle Size	20-40 µm
Flash Point	Not flammable
Flammability Limits	Not applicable
Autoignition Temperature	Decomposes at above 250°C
Explosive Properties	Not explosive
Reactivity	Stable at pH values between 1 and 10
Remarks	Notified polymer forms water insoluble precipitates with anionic surfactants eg soaps, alkyl aryl sulphonates and anionic caramels. Also, it is precipitated by

strong alkalis and complex phosphates

7. TOXICOLOGICAL INVESTIGATIONS

The toxicity studies were conducted using GUS-07 (notified polymer) in flake form at purity of greater than 98%.

<i>Endpoint</i>	<i>Assessment Conclusion</i>
Rat, acute oral	LD ₅₀ 610 mg/kg bw Harmful
Rat, acute dermal	LD ₅₀ >2000 mg/kg bw Low toxicity
Rabbit, skin irritation	Non-irritating to skin
Rabbit, eye irritation	Causes serious damage to eyes
Guinea pig, skin sensitisation - adjuvant test	Limited evidence of skin sensitisation
Genotoxicity - bacterial reverse mutation	Non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	GUS-07
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague Dawley
Vehicle	1% w/v aqueous methylcellulose
Remarks - Method	No control animals were included

RESULTS

<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
Five males and five females	2000	All rats*
Five males and five females	800	2 males* at 800 mg/kg bw
Five males	320	None

* All deaths occurred during the first 3 hrs of dosing

Median LD ₅₀	857 (610 to 1203) mg/kg bw
Signs of Toxicity	Slight body weight loss; piloerection seen in all rats; hunched posture, waddling/unsteady gait, lethargy, respiratory distress, partially closed eyelids, pallid extremities, increased salivation, walking on toes, bluish colour to extremities and prostration.
Effects in Organs	Generalised congestion in the majority of tissues and organs
Remarks - Results	Surviving rats recovered from all signs of toxicity by Day 7. No abnormalities at macroscopic examination on Day 15.

CONCLUSION The notified polymer is harmful via the oral route.

TEST FACILITY Huntingdon Life Sciences Ltd (1997a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	GUS-07
METHOD	OECD TG 402 Acute Dermal Toxicity.

Species/Strain	Rat/Sprague Dawley
Vehicle	Distilled water
Type of dressing	Occlusive
Remarks - Method	24 hrs exposure period No control animals included

RESULTS

<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
Five males and five females	2000	None

LD ₅₀	>2000 mg/kg bw
Signs of Toxicity - Local	Dermal irritation ranging from slight to moderate in degree (erythema/edema grades 1 to 3) was evident in the majority of animals following removal of the dressings on Day 2 and persisted in a number of animals over the following days. The treatment sites of all animals fully recovered by Day 13.
Signs of Toxicity - Systemic Effects in Organs Remarks - Results	Two females had low weight gains on Day 15. No abnormalities were recorded on Day 15 macroscopic examination.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Huntingdon Life Sciences Ltd (1997b)

7.4. Irritation – skin

TEST SUBSTANCE	GUS-07
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Vehicle	Not diluted
Observation Period	Four days
Type of Dressing	Semi-occlusive.
Remarks – Method	

RESULTS

Remarks - Results	No dermal reactions were observed- all Draize scores were zero
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CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Huntingdon Life Sciences Ltd (1997c)

7.5. Irritation – eye

TEST SUBSTANCE	GUS-07
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	One
Observation Period	Seven days
Remarks - Method	

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	3	7 days	3
<i>Conjunctiva: chemosis</i>	4	7 days	3
<i>Cornea: opacity</i>	2	7 days	2
<i>Cornea: area</i>	1	7 days	2
<i>Iridial inflammation</i>	1	4 days	0

* Calculated on the basis of scores at 24, 48 and 72 hrs for one animal

Remarks - Results	No signs of toxicity or ill health was observed in the rabbit during the observation period. Corneal opacification, iridial inflammation and severe conjunctival irritation was seen in the treated eye, persisting till the end of the observation period.
CONCLUSION	The notified chemical causes severe damage to the eye.
TEST FACILITY	Huntingdon Life Sciences Ltd (1997d)
7.6. Skin sensitisation	
TEST SUBSTANCE	GUS-07
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman
Species/Strain	Guinea pig/ Dunkin/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical application at 1% w/v in distilled water intradermal: 0.1, 0.25, 0.5, 1.0, 2.5, 5.0, 7.5 and 10.0 % w/v topical: 10, 30, 50 and 70 % w/v. 1, 2.5, 5 and 7.5% w/v.
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal injection 0.05% w/v in water for irrigation topical application 7.5% in distilled water
CHALLENGE PHASE	2 weeks after the topical application
1 st challenge	topical application: 1 and 0.5% w/v in distilled water
2 nd challenge	topical application: 1 and 0.5% w/v in distilled water
Remarks - Method	

RESULTS

Remarks - Results	Induction: Intradermal injections: slight irritation was seen in test animals at sites receiving 0.05% notified chemical in water for irrigation. Topical application: slight erythema was observed in animals following topical application with notified chemical at 7.5% w/v in distilled water. Slight erythema was seen in control animals. Challenge: First challenge: Dermal reactions were noted in 5 of the test animals. Second challenge: No dermal reactions were noted in 9 of the test animals. One animal showed a positive response.
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CONCLUSION There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Huntingdon Life Sciences Ltd (1997e)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE GUS-07

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
 Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2 uvrA
 Metabolic Activation System S9 mix derived from rat liver
 Concentration Range in Main Test a) With metabolic activation: 3.13, 6.25, 12.5, 25 and 50 µg/plate.
 b) Without metabolic activation: 3.13, 6.25, 12.5, 25 and 50 µg/plate.
 Vehicle Dimethylsulphoxide
 Remarks - Method Preliminary tests:
 0.05, 0.5, 5, 50, 500 and 5000 µg/plate with and without S9

RESULTS Due to cytotoxicity at high concentrations, the maximum exposure concentration was chosen to be 50 µg/plate, where a substantial reduction in colony counts was obtained in both strains.

Remarks - Results No increases in mutant frequency over controls in the presence or absence of S9 mix at concentrations from 3.13 to 50 µg/plate. Inhibition of bacterial growth occurred in all strains at 50 µg/plate; some inhibition was also observed at 256 µg/plate in the absence of S9.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Huntingdon Life Sciences Ltd (1997f)

8.2. Ecotoxicological investigations

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
 Inoculum Activated sludge – mixed liquor suspended solid.
 Exposure Period 28 days
 Auxiliary Solvent None
 Analytical Monitoring HPLC
 Remarks - Method The biodegradation of the test substance was determined by comparing the extent of oxygen depletion with the theoretical oxygen demand over a period of 28 days after the medium was inoculated with activated sludge and stored in the dark at 20°C. Sodium benzoate was used as the standard material.

RESULTS

<i>Test substance</i>		<i>Aniline</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
14	0	14	76
28	0	28	76

Remarks - Results After 28 days, the results indicated that 0% of the test substance had degraded, while 76% of the standard degraded in 28 days. As the test substance did not satisfy the criterion that degradation reach 60% within 10 days of reaching 10%, the notified polymer cannot be considered to be readily biodegradable.

CONCLUSION The notified polymer is not readily biodegradable.

TEST FACILITY Huntingdon life Sciences (1997g).

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 203 Fish, Acute Toxicity Test – 96 h - static

Species Red Killifish (*Oryzias latipes*)

Exposure Period 96 h

Auxiliary Solvent None

Analytical Monitoring None

RESULTS

Concentration mg/L Nominal	Number of Fish	Mortality			
		24h	48h	72h	96h
0	7	0	0	0	0
0.15	7	0	0	0	0
0.24	7	0	4	5	5
0.39	7	4	7	7	7
0.63	7	7	7	7	7
1.00	7	7	7	7	7

LC50 0.23 mg/L at 96 hours (CI 0.19-0.27 mg/L).

NOEC 0.15 mg/L at 96 hours.

Remarks – Results The definitive studies were conducted at nominal test substance concentrations of 0.15, 0.24, 0.39, 0.63, and 1 mg/L. After 96 h, 57% mortality was observed at a test substance concentration of 0.24 mg/L and 100% mortality above a concentration of 0.39 mg/L. A 96-hour EC50 and NOEC for the notified polymer to *Oryzias latipes* are 0.23 and 0.15 mg/L, respectively.

CONCLUSION The notified polymer is very toxic to fish.

TEST FACILITY Korea Institute of Toxicology (2002a).

8.2.2 Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test

Species *Daphnia magna*

Exposure Period 48 hours

Analytical Monitoring None

RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	20	0	0
0.01	20	0	0
0.022	20	0	1

0.046	20	0	3
0.1	20	0	9
0.22	20	0	14
0.46	20	1	20
1.0	20	6	20

EC50 0.1 mg/L at 48 hours (CI 0.38-0.47 mg/L).
 NOEC 0.2 mg/L at 48 hours.
 Remarks - Results The immobilisation tests with *Daphnia* were performed in triplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed at a test substance concentration of 0.2 mg/L and 33% at a concentration of 0.4 mg/L. At test substance concentration above 0.8 mg/L, 100% mortality was observed. The 48-hour EC50 for the test substance to *Daphnia magna* is 0.42 mg/L.

CONCLUSION The notified polymer is very toxic to daphnia.

TEST FACILITY Huntingdon life Sciences (1997h).

8.2.2.1 Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test

Species *Daphnia magna*

Exposure Period 48 hours

Analytical Monitoring None

RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	30	0	0
0.1	30	0	0
0.2	30	0	0
0.4	30	4	10
0.8	30	13	30
1.6	30	28	30
3.2	30	30	30

EC50 0.42 mg/L at 48 hours (CI 0.38-0.47 mg/L).
 NOEC 0.2 mg/L at 48 hours.
 Remarks - Results The immobilisation tests with *Daphnia* were performed in triplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed at a test substance concentration of 0.2 mg/L and 33% at a concentration of 0.4 mg/L. At test substance concentration above 0.8 mg/L, 100% mortality was observed. The 48-hour EC50 for the test substance to *Daphnia magna* is 0.42 mg/L.

CONCLUSION The notified polymer is very toxic to daphnia.

TEST FACILITY Korea Institute of Toxicology (2002b).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE The notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	<i>Selenastrum capricornutum</i>
Exposure Period	72 hours
Concentration Range	0.01, 0.23, 0.053, 0.12, 0.28, 0.64 and 1.48 mg/L
Nominal	

RESULTS

<i>Biomass</i>	<i>Growth</i>	<i>NOEC</i>	
<i>E_bC50</i> mg/L at 72 h	<i>E_rC50</i> mg/L at 72 h	<i>Biomass</i> (mg/L)	<i>Growth</i> (mg/L)
0.04 (CI 0.006-0.02)	0.01 (CI 0.03-0.06)	0.02	< 0.01

Remarks - Results Algae were exposed to the test substance at the measured concentrations of 0, 0.01, 0.23, 0.053, 0.12, 0.28, 0.64 and 1.48 mg/L for 72 h at 24°C under constant illumination and shaking. No abnormalities were detected in any of the replicate test samples. Both biomass and growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance.

CONCLUSION The notified polymer is very toxic to algae.

TEST FACILITY Korea Institute of Toxicology (2002c).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Exposure

The notified polymer will be used in the treatment of water in food processing plants, swimming pools and cooling towers and in the manufacture fabric softeners. This will result in the eventual release of up to 80 tonnes per annum to the environment. The remaining 20% will be incorporated into paper products, such as wallpaper, and paints. A further release to the environment of up to 1000 kg per annum will occur from production losses. Products into which the notified polymer has been incorporated, such as painted objects and wallpaper, will eventually be disposed of to landfill.

Fate

The notified polymer is soluble in water and is likely to be mobile in both aquatic and terrestrial compartments. However when released to sewer and in landfill, as a consequence of its cationic character, the notified polymer is expected to associate to negatively charged organic matter in soil and sediment and slowly degrade through the abiotic and biotic processes. Incineration of the notified polymer will produce water vapour and oxides of carbon and nitrogen. The notified polymer incorporated into paints and paper is expected to remain bound to these substrates and pose little risk to the environment, over time slowly degrading through biotic and abiotic processes to water and oxides of carbon and nitrogen.

Based on annual releases of 80000 kg per annum to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 219.2 kg/day. Assuming a national population of 19,500,000 and each person contributing an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.056 mg/L.

Amount entering sewer annually	80000 kg
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC	0.056 mg/L (0.056 ppm)

When released to receiving waters, the concentration is generally understood to be reduced by a

further factor of at least 10, so the Predicted Environmental Concentration (PEC) is around 0.0056 mg/L. Removal processes such as adsorption to sludge would reduce this value further. The PEC calculated above could be reduced further if there were more specific information regarding the proportions of the notified polymer used for each purpose.

Due to its high molecular weight ($\gg 1000$ MW), the notified polymer is not expected to bioaccumulate.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified polymer is very toxic to aquatic life. The most sensitive species are algae, where the 72 hour EC₅₀ is 0.01 mg/L and the NOEC is less than 0.01 mg/L.

A predicted no effects concentration (PNEC) can be determined when at least one acute EC₅₀ for each of the three trophic levels is available (ie. fish, *Daphnia*, algae). The PNEC is calculated by taking the EC₅₀ value of the most sensitive species, and dividing this value by an assessment safety factor of either 100 (OECD) or 1000 (EU). Using a worst case scenario safety factor of 100, the PNEC is 1.0 µg/L.

9.1.3. Environment – risk characterisation

The majority of the notified polymer will be used in the treatment of water in food processing plants, swimming pools and cooling towers and in the manufacture fabric softeners. Most will eventually be released into domestic sewage systems as a consequence of product use. The notified polymer is not readily biodegradable (0% over 28 days), and is expected to have a low partition coefficient and high water solubility (285 g/L), all indicating that the material would be mobile in both aquatic and terrestrial compartments. However as a consequence of its cationic character, the notified polymer is expected to associate to negatively charged organic matter in soil and sediment. Once associated, the notified polymer is expected to slowly degrade to water and oxides of carbon through the processes described above.

Due to its high molecular weight ($\gg 1000$ MW), the notified polymer is not expected to bioaccumulate.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 56. This value is significantly greater than 1, indicating an immediate concern to the aquatic compartment.

In an effort to minimise the hazard to the environment when the notified polymer is used as a component of domestic products, the notifier will need to implement the recommendation listed in Section 12.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The highest occupational exposure is expected during masterbatch manufacture using imported powder containing 100% notified polymer and during manual processes using imported aqueous solution containing 25% notified polymer.

During masterbatch manufacture, there is potential of dermal and inhalation exposure to dust when opening the bags containing notified polymer powder (100% notified polymer), weighing and tipping the contents into a blender. It is assumed that blending is enclosed or under local exhaust ventilation. Transferring the mixed material into an extruder and packaging the masterbatch is expected to be automated.

Worker exposure to masterbatch (10 % notified polymer) may occur when producing the plastic articles by blending masterbatch with resin, followed by processing. However, exposure is not expected to be significant as masterbatch pellets are usually above the respirable range and the maximum concentration of notified polymer in plastics is 0.7%.

For the remaining uses, the notified polymer solution is used. Manual processes may result in worker exposure when weighing the required volume and stirring in an open tank due to accidental splashes and spills. Automated processes using imported solution will result in less

exposure than during manual processes. The notified polymer solution is directly added from drums or pumped to a storage tank via an automated dosing system. The maximum concentration of notified polymer in these applications is 1%.

During transport and storage, exposure to notified polymer will be limited because of the packaging.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer will be widespread, for example, when used in swimming pools. However, given the low concentration of notified polymer in pool applications, significant public exposure is not expected. Due to the low concentration of the notified polymer in formulated products such as fabric softeners and in finished wall paper and paints, significant public exposure is not expected.

9.2.3. Human health - effects assessment

The notified polymer is harmful by the oral route and of low dermal toxicity, although dermal irritation was seen in a number of animals which recovered by the end of the study. The notified polymer has a NAMW above 10000, indicating that the extent of dermal absorption is low. Inhalation toxicity was not studied. The vapour pressure of the notified polymer is negligible, therefore, the inhalation hazard of the aqueous solution of the polymer would be low, provided aerosols were not generated. The inhalation hazard of the notified polymer in dust form is significant as the particles are in the inspirable range (20-40µm) and the polymer is severely irritating to the eyes.

The notified polymer was not a skin irritant when tested as powder in a skin irritation study. However, when tested as a formulation dissolved in water in an acute dermal toxicity study, the notified polymer caused dermal irritation in the majority of animals.

The notified polymer was not a skin sensitiser, but may cause severe damage to the eyes. Also, it was not genotoxic using Ames test. No repeat dose toxicity studies were provided.

9.2.4. Occupational health and safety – risk characterisation

The main hazard of the notified polymer is severe eye damage. This hazard is recognised for all products containing greater than or equal to 10% notified polymer. Skin irritation hazard is considered a conservative assumption, since the chemical may cause severe eye damage and there were signs of skin irritation in the acute dermal study.

There is a health risk for workers if exposure to the notified polymer as powder or in solution at 25% occurs on the skin or eyes when opening the bags/container, weighing the required amount/volume and transferring for mixing in an open tank or dosing manually. Workers will need to have safety goggles to avoid exposure on the eyes and gloves to avoid skin irritation. Dust exposure may occur when handling the powder, so workers will need to wear a dust mask.

Handling masterbatch (10%) may require eye protection, when processing into plastics by blending with resin. Risk of exposure to masterbatch is low, since it is likely that all masterbatch pellets are above the inspirable range (>180 µm). However, in case dust particles are present in the inspirable range, a dust mask should be worn.

Certain procedures are automated, such as when applying the solution (25% notified polymer) via an automated dosing system and packaging the masterbatch. It is assumed that local exhaust ventilation is employed. The health risk to workers during these processes is low.

The risk to cleaners/maintenance workers in treated swimming pools and cooling towers is low as the concentration of notified polymer is in parts per million. Workers involved in food processing plants, paper, fabric softeners and paints will be exposed to a maximum of 1% notified polymer and thus the risk is considered low.

9.2.5. Public health – risk characterisation

The notified polymer is harmful by the oral route at greater than or equal to 25% and may cause serious damage to eyes at concentration equal to or above 10%. However, the public will only be exposed to low concentrations. In plastics, paper and food processing items, the notified polymer (max 1.0%) is cross linked after application and is not bio-available upon contact. In swimming pools and cooling towers, the concentration will be very low (parts per million) and the risk to public health is hence low.

Overall the risk to public is assessed as low.

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

10.1. Hazard classification

Human health:

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are:

R22 Harmful if swallowed
R41 Risk of serious damage to eyes

Environment

The notified chemical is very toxic to aquatic life and may be considered persistent based on its lack of degradability.

While environmental classification is not a regulatory requirement in Australia, if this chemical were to be classified according to the Globally Harmonised System of Classification and Labelling, it would be classed as Chronic Category 1 and carry the appropriate hazard statement: "Very toxic to aquatic life with long lasting effects".

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the notified polymer may pose a risk to the environment based on the notified use pattern. Further work or actions should be considered (See Section 12).

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is high Concern to occupational health and safety when handling the powder and low Concern when handling the masterbatch pellets and during end use under the conditions of the occupational settings described.

10.3.2. Public health

There is Low Concern to public health when used according to instructions.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
 - R22 Harmful if swallowed
 - R41 Risk of serious damage to eyes
- Use the following risk phrases for products/mixtures containing the notified polymer:
 - $\geq 25\%$: R22 R41
 - 10 - $<25\%$: R41
 - 5-10%: R36 (irritating to eyes)
- The notified polymer is very toxic to aquatic life and may be considered persistent based on its lack of degradability.

While environmental classification is not a regulatory requirement in Australia, if this chemical were to be classified according to the Globally Harmonised System of Classification and Labelling, it would be classed as Chronic Category 1 and carry the appropriate hazard statement: "Very toxic to aquatic life with long lasting effects".

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer [as introduced and in the product at 25%]:
 - *Local exhaust ventilation, automated process*
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer [as introduced and in the product at 25%]:
 - *Avoid contact with eyes*
 - *Avoid contact with skin*
 - *Do not breath dust*
 - *Wear eye/face protection*
 - *Wear suitable gloves*
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer [as introduced and in the product at 25%]:
 - *PVC or rubber gloves, goggles and dust mask*

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to

health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The concentration of the notified polymer in effluent should not exceed 1 ppb at the point of release.
- NICNAS should inform the relevant State and Territory EPAs of the recommendations of this assessment before the notified polymer is used.
- When used in swimming pools, filtrate should be removed, dried and disposed of to landfill, and should not be washed into sewer or stormwater drains.
- While it is expected the notified polymer will be consumed during use, in the event of overdosing or clean systems, release to sewer may be significant. It is further expected that the cationic nature of the polymer will cause it to bind in the sludge phase of the STP and not be bioavailable. However, there is no evidence of this and the available literature is not conclusive in this regard. Due to the high toxicity of this compound, and the certain exposure of aquatic organisms in the event the chemical is not removed in its residence in the STP, data should be generated to show release to receiving waters will be of an acceptable level. Possible testing could include:
 - a) Soil adsorption test; or
 - b) Simulated STP test determining influent and effluent concentrations.

Emergency procedures

- Spills/release of the notified polymer should be contained by sand or inert powder and earth. Collect and seal in properly labelled drums for disposal in landfill.

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 Subsection 64(1) of the Act:

- if the concentration of the notified polymer after application exceeds 1%.
- When the recommended testing has been completed. This should be undertaken within 6 months of receiving the assessment certificate. This should consist of the provision of a result and test report for adsorption/desorption and/or a quantitative study which shows removal of the notified polymer from STP effluent prior to release to receiving waters.

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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