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July 2003

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)****FULL PUBLIC REPORT****Allianz LT-120**

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**Director  
Chemicals Notification and Assessment**

**FULL PUBLIC REPORT****Allianz LT-120****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188) of 4<sup>th</sup> Floor, 969 Burke Road, Camberwell VIC 3124 and ISP Australasia Pty Ltd (ABN 27 000 011 923) of 73-75 Derby Street, Silverwater NSW 2128.

## NOTIFICATION CATEGORY

The notified polymer meets the PLC criteria.

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Part B: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Hazardous and Non-hazardous Impurities/Residual Monomers, Additives/Adjuvants, Manufacture/Import Volume, and Site of Manufacture or Reformulation.

Part D: Identity and Composition of Polymer, Degradation Products and Loss of Monomers, Other Reactants, Additives, and Impurities.

## 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)

Early Introduction Permit (No. 183, 16 October 2001)

## NOTIFICATION IN OTHER COUNTRIES

USA and Europe (EINECS - exempt)

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Allianz<sup>TM</sup> LT-120 (47% solids)

**3. COMPOSITION**

## DEGREE OF PURITY

≥99%

## PRODUCT COMPOSITION

The notified polymer is not isolated, but produced as 47% aqueous dispersion under the trade name of Allianz LT-120.

**4. INTRODUCTION AND USE INFORMATION**

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

Import.

## 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>	1-3	3-10	3-10	3-10	3-10

## USE

A fixative resin in hair styling products.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

#### IDENTITY OF MANUFACTURER/RECIPIENTS

ISP Australasia Pty Ltd

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported as an aqueous dispersion in plastic drums of 215.5 kg net weight. It will be transported by road directly to a cosmetic manufacturing site for formulating into hair styling spray/gel concentrate, filled in 250 kg drums. They will be sent to an aerosol filter company for packaging into tin plate aerosol cans. Initially, the hair spray will be marketed. Later, the notified polymer may be used in hair gels (typically 200-400 mL plastic tubs or jars) and hair lotions (typically 200-500 mL plastic squeeze bottles).

### 5.2. Operation Description

At a cosmetic manufacturing site Allianz LT-120 (47% solids) will be blended with other components to produce a 10% concentrated hair styling solution. From the imported plastic drums, Allianz LT-120 will be dispensed via a polypropylene tap to a 1000 L stainless steel mixing vessel with mechanical stirring. Once the mixing operation is complete, samples will be taken and tested for pH, colour, viscosity, etc by a quality assurance staff. The hair spray/gel concentrate will then be auto pumped into 250 kg drums and sealed for road transportation to a contract packaging company.

At an aerosol filter company, the 250 kg drums will be auto pumped into a 1500 L stainless steel mixing vessel. Following mechanical stirring, samples will also be taken and tested for quality control. The formulation will then be transferred to the filling heads where it is automatically dispensed into aerosol tin plate cans. The cans will be filled with the dimethyl ether propellant gas, packaged into cardboard shippers for transportation back to the warehouse of the cosmetic company prior to distribution to end users (hair styling professionals and the general public) via sale outlets. A finished aerosol styling product contains  $\leq 5\%$  notified polymer.

In the manufacture of hair gels and lotions, the formulated product would be filled into containers on automatic or semi-automatic filling lines, with the bulk product metered and pumped from a hopper into individual containers on a conveyer belt.

### 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>
Waterside and transport workers	10	4-6 hrs/day	100 days/year
Laboratory/Quality Assurance staff	2		
Testing quality of Allianz LT-120		4 hrs/day	10 days/year
Testing quality of hair spray/gel batches		4 hrs/day	60 days/year
Plant operators			
Dispensing and compounding	2	5-6 hrs/day	4-5 days/year
Filling and packaging	4	5 hrs/day	4 days/year
Hairdressers	>1,000	1-2 hrs/day	100 days/year

#### *Exposure Details*

Waterside and transport workers will handle the drums or packs of aerosol tin cans filled with the notified polymer dispersion for short periods and thus exposure is unlikely unless the packaging is breached.

Formulation of Allianz LT-120 with other ingredients to form the end use product is a batch process. The filling process is automated or semi-automated, with blending and compounding carried out in an enclosed system. Plant operators will be involved in connecting/disconnecting transfer or filling line and cleaning the equipment. If overfilling or spillage occurs, dermal and ocular exposure to the notified polymer is possible. The workers will wear gloves, safety glasses, coveralls and safety boots. Ventilation will be adequate throughout the plant.

Laboratory technicians are expected to be involved in QA activities for up to 4 hours/day, 60 days/year. Spillage can result in dermal exposure but quantities handled are small and staff wear gloves, safety glasses, and laboratory coats.

Hairdressers and salon workers may be potentially in contact with the hair spray (through inhalation) and gel (through dermal contact) containing the notified polymer, but exposure is expected to be minimal given the low concentration of the notified polymer in the end use product ( $\leq 5\%$ ) and the short duration of exposure.

#### 5.4. Release

##### RELEASE OF CHEMICAL AT SITE

The notifier indicates that by year 5 up to 300 kg of the import volume of the notified polymer will be disposed of during formulation and packaging. This will be derived from:

Spills and equipment cleaning:	$\leq 250$ kg/annum
Residues in import containers:	$\leq 50$ kg/annum

Machinery and pumping equipment will be initially cleaned with solvent (alcohol) and water. Wastes containing alcohol will be collected by licensed waste disposal contractors and be treated via a solvent reclamation process. Empty import drums containing residual polymer solution will be washed with water and the drums either recycled or disposed of in landfill. Aqueous wastes will be disposed of to sewer.

##### RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will be incorporated into hair styling products and as such will almost completely be released to the environment through eventual washing of hair. Residues in consumer containers are estimated to be  $\leq 50$  kg per annum. The consumer containers in which the formulated product will be sold to consumers and the residues they contain will be disposed of in domestic landfill.

#### 5.5. Disposal

The notified polymer will ultimately be disposed of in either the sewer (major) or landfill.

#### 5.6. Public exposure

Members of the public may be potentially exposed to the notified polymer following transport accidents involving breakage of the drums carrying the 47% imported product or formulated hair gel batches. However, such accidents are unlikely. It is also unlikely that public exposure to notified polymer waste and residues will occur.

Consumers who purchase and use the aerosol hair styling products containing the notified polymer will be exposed to it. The degree and type of exposure may vary depending on the frequency of application, the care taken with applications, the amount of product applied on different occasions and the frequency of hair washing. However the low concentration of the notified polymer in the final products indicates that public exposure is likely to be minimal.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

The physicochemical properties of Allianz LT-120 (47% notified polymer in water) are provided.

<b>Appearance at 20°C and 101.3 kPa</b>	Milky white liquid with an acrylic odour
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<b>Melting Point/Freezing Point</b>	0°C for water
Remarks	No data available for the polymer solids.
<b>Density</b>	1100 kg/m <sup>3</sup>
Remarks	Test report not provided.
<b>Water Solubility</b>	Not determined.
Remarks	It is indicated that Allianz LT-120 is a low viscosity, aqueous emulsion polymer which is dilutable and will be completely soluble in water once treated with organic or inorganic bases such as aminomethyl propanol, triisopropanolamine, triethanolamine, and potassium hydroxide. It is noted that the polymer contains carboxylic acid functional groups which under the basic conditions (pH 8) of the sewer are likely to deprotonate and thus increasing water solubility of the polymer.
<b>Hydrolysis as function of pH</b>	Not determined.
Remarks	The notified polymer contains chemical linkages expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.
<b>Partition coefficient</b>	Not determined.
Remarks	The likely hydrophilic nature of the polymer is indicative of partitioning into the aqueous phase.
<b>Adsorption/desorption</b>	Not determined.
Remarks	The notified polymer could be relatively mobile in soil due to its expected high water solubility. However, as a consequence of exposure to basic conditions in the sewer, the notified polymer's polyanionic character resulting from deprotonation of carboxylic acid functional groups will lead to association with cations on the surface of sediment and soil. This in turn will retard the mobility of the notified polymer in both terrestrial and aquatic compartments. The results of the inherent biodegradability study (see below) showed that the notified polymer is removed readily due to adsorption to sludge.
<b>Dissociation constant</b>	Not determined.
Remarks	The notified polymer contains carboxylic acid functional groups which are expected to have typical acidity.
<b>Particle Size</b>	Not applicable
Remarks	The notified polymer will be imported as an aqueous dispersion.
<b>Explosive Properties</b>	Not determined.
Remarks	Not expected to be explosive on structural grounds.
<b>Reactivity</b>	Stable under normal conditions.
Remarks	No incompatibility with other substances known. Decomposition is expected at temperature >177°C and may yield hazardous decomposition products.

## 7. TOXICOLOGICAL INVESTIGATIONS

Toxicological studies were submitted for preparations containing the notified polymer at 5%

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>	<i>References (Rohm &amp; Haas Company, 1998)</i>
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity	Report no. 98R-020
Rat, acute dermal LD50 >5000 mg/kg bw	low toxicity	Report no. 98R-021
Rat, acute inhalation LC50 >5 mg/L/4 hour	low toxicity	Report no. 98R-019
Rabbit, skin irritation	non-irritating	Report no. 98R-022
Rabbit, eye irritation	non-irritating	Report no. 98R-023
Human, skin sensitisation - Repeated insult patch test	no evidence of sensitisation	ETC Panel no. 98143
Rat, repeated dose inhalation toxicity – 13 weeks	*NOEL = 1.3 mg/m <sup>3</sup>	Report no. 98R-082
Genotoxicity - bacterial reverse mutation	non mutagenic	Study no. G98AsQ30.502
Genotoxicity – <i>Salmonella</i> plate incorporation mutagenicity assay	non genotoxic	Study no. G98AV98.501010 through G98AV00.501010
Genotoxicity – in vitro mammalian cell gene mutation test	non genotoxic	Study no. G98AV99.782
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	non genotoxic	Study no. G98AV99.123

\*The no observed effect level (NOEL) of 1.3 mg/m<sup>3</sup> was established in the 13-week, nose-only exposure study in rat, which was based on the observations of lung effects (increased lung weight, pale foci on the lung, increased alveolar macrophage accumulation, and multifocal interstitial inflammation) and lymphoid hyperplasia of the mediastinal lymph nodes following exposure to aerosolised solids of Hair product for 13 weeks and/or after 13 weeks of recovery.

## 8. ENVIRONMENT

No ecotoxicological data were available for the notified polymer. Rohm & Haas Australia Pty Ltd has submitted the ecotoxicity reports for an analogue polymer (50% solids), say “Analogue Polymer A”, for evaluation. Analogue Polymer A is a simpler polymer lacking the two complex monomers in the notified polymer.

### 8.1. Environmental fate

Results for a ready biodegradability study were not provided, but those for inherent biodegradability are summarised below.

#### 8.1.1 Inherent biodegradability

TEST SUBSTANCE	A structural analogue polymer (Analogue Polymer A)
METHOD	OECD TG 302 B Inherent Biodegradability: Modified Zahn-Wellens Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	HPLC
Remarks - Method	The biodegradation of the test substance was determined at 400 mg solid component/L by the measurement of the amount of dissolved organic carbon for a period of 28 days after the medium was inoculated with activated sludge and stored in the dark at 22°C. Sodium benzoate was used as the standard material.
	The methodology used in sampling accounted for both the dissolved portion and the suspended particulate portion.

### RESULTS

<i>Time (Hour/Day)</i>	<i>% degradation*</i>	<i>% elimination*</i>	
	<i>Sodium Benzoate</i>	<i>Test substance</i>	<i>Inhibition Control</i>
0 h	0	0	0
4 h	0	20	0
1 d	22	55	50
2 d	32	53	66
3 d	42	24	95
4 d	38	147	99
7 d	36	95	92
9 d	37	95	89
11 d	57	99	88
13 d	55	112	91
15 d	60	91	93
17 d	76	98	95
20 d	78	101	98
22 d	73	98	97
25 d	78	99	96
28 d	81	106	105

\* % degradation or % elimination =  $1 - (\text{Net DOC at } T_x / \text{Net DOC at } T_0) \times 100$  where  $T_x$  = Time point X and  $T_0$  = Time point 0.

#### Remarks - Results

At all sampling time points the presence of the test material was visible through a cloudy appearance in the filtrate. Based on the percentage dissolved organic carbon removed, the results indicated that 99% of the test substance was eliminated after 25 days, while 81% of the standard Sodium Benzoate degraded in 28 days. The report indicates that the elimination of the test polymer was possibly due to the removal by adsorption to the microbial source or through aggregation of the polymer suspension to form larger particles.

#### CONCLUSION

The report indicated that the test polymer is considered 'readily eliminable'. This terminology was decided upon as a neutral description of the removal process and is equal to the sum of all possible elimination mechanisms in a biological treatment plant including biodegradability, adsorption onto the activated sludge and loss to the atmosphere/system. Adsorption would appear to be the most likely source of elimination of this polymer.

The report concluded that the test substance is ultimately eliminable when compared with a known biodegradable compound Sodium Benzoate and non-inhibitory to sewage organisms.

#### TEST FACILITY

IRI (1994a)

#### 8.1.2. Bioaccumulation

No bioaccumulation data were provided. Due to the high water solubility the notified polymer is expected to have a poor affinity to lipids and together with its high MW, the notified polymer is not like to diffuse across biological membranes and bioaccumulate (Connell 1989).

#### 8.2. Ecotoxicological investigations

The following data were provided for a structural analogue of the polymer.

##### 8.2.1. Acute toxicity to fish

#### TEST SUBSTANCE

A structural analogue polymer (Analogue Polymer A)

METHOD	OECD TG 203 Fish, Acute Toxicity - Static Limit Test
Species	Rainbow trout ( <i>Oncorhynchus mykiss</i> )
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Test solutions at 100 ppm nominal were opaque throughout the study period. At 24 h a ‘scummy’ foam caused by the test substance was observed at the water surface.

## RESULTS

Concentration mg/L Nominal	Number of Fish	Mortality						
		1 h	3 h	6 h	24 h	48 h	72 h	96 h
0	10	0	0	0	0	0	0	0
100	10	0	0	0	0	0	0	0
100	10	0	0	0	0	0	0	0
100	10	0	0	0	0	0	0	0
100	10	0	0	0	0	0	0	0
100	10	0	0	0	0	0	0	0

LC50	>100 mg/L at 96 hours
NOEC	100 mg/L at 96 hours
Remarks – Results	The results of the limit study showed no mortality in any of the test vessels with a NOEC of 100 mg/L (nominal). No unusual behaviour was exhibited by the fish throughout the study period.

CONCLUSION	The ecotoxicity data indicates the test substance is ‘practically non toxic’ to fish.
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TEST FACILITY	IRI (1994b).
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**8.2.2. Acute toxicity to aquatic invertebrates**

TEST SUBSTANCE	A structural analogue polymer (Analogue Polymer A)
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METHOD	EC Directive 92/69/EEC C2 Daphnia, Acute Toxicity - Static Limit Test
Species	Water Flea ( <i>Daphnia magna</i> )
Exposure Period	48 hours
Auxiliary Solvent	Daphnia synthetic medium
Water Hardness	184 mg CaCO <sub>3</sub> /L
Analytical Monitoring	None
Remarks - Method	The nominal test concentration of 100 mg/L was selected for the limit test based on the lack of an acute effect during a 24 h range finding test using concentrations up to 1000 mg/L. The immobilisation tests with Daphnia were performed in 20 replicates using 5 daphnids per flask with observations performed at 24 and 48 hours. The test solution at 100 mg/L appeared cloudy throughout the test.

## RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	20	0	0
100	100	0	2

EC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	After 48 h, no immobilised daphnids were observed in the control, while 2% immobilisation was observed at 100 mg/L.

CONCLUSION	The test substance is ‘practically non toxic’ to aquatic invertebrates.
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TEST FACILITY IRI (1994c).

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE A structural analogue polymer (Analogue Polymer A)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Unicellular green alga (*Selenastrum capricornutum*)

Exposure Period 72 hours

Concentration Range Five test concentrations between 62.5 to 1000 mg/L

Nominal

Auxiliary Solvent None

Water Hardness Not reported

Remarks - Method Algae were exposed to the test substance at the nominal concentrations of 62.5, 125, 250, 500 and 1000 mg/L for 72 h at 22°C under constant illumination and shaking. Five control replicate flasks, instead of 6 (required by the protocol) were used. This deviation was not considered to have affected the study outcome.

RESULTS No abnormalities were detected in any of the replicate test samples.

<i>Effect</i>	<i>Growth</i>
	<i>Average Specific Growth Rate*</i>
	<i>mg/L</i>
	<i>Biomass*</i>
	<i>mg/L</i>
EC50 at 72 h	>1000
NOEC at 72 h	500
	777.4
	250

\* 95% confidence intervals were not calculated since the distribution of data did not fit a probit model.

Remarks - Results The pH of all flasks except at 1000 mg/L had increased at the end of the test by more than one pH unit. This deviation was attributed to algal growth and not considered to have affected the outcome of the study.

CONCLUSION The test substance inhibited the growth of *Selenastrum capricornutum* at test concentrations tested in excess of 250 mg/L. The test substance is 'practically non toxic' to algae.

TEST FACILITY IRI (1994d)

### 8.2.4. Microtox assay

TEST SUBSTANCE A structural analogue polymer (Analogue Polymer A)

METHOD Microtox Model 500 Toxicity Test System – Microbial Activity Inhibition Test (In-house Protocol no. 93P-030)

Test species *Photobacterium phosphoreum* (Microtox Reagent)

Exposure Period 15 min

Concentration Range 0.0000%, 0.5625%, 1.1250%, 2.2500%, and 4.5000%.

Nominal

Remarks – Method A phenol reference standard Microtox test was performed with each reconstituted vial of Microtox Reagent dosed with the test material or control reagents. EC50 is the effective concentration of the test sample which causes a 50% decrease in the light output of the Microtox Reagent at a specific time and temperature. A primary dilution of 1:10 was recommended for testing after performing a 2% Screen Protocol.

RESULTS	<i>Effect</i>	<i>EC50 (ppm)</i>	<i>95% Confidence Interval (ppm)</i>
Without colour	5 min	30,631	24,156-38,843
correction	15 min	16,039	12,370-20,796

With colour correction	5 min	31,297	24,575-39,858
	15 min	16,207	12,523-20,974

Remarks – Results The EC50 values with colour correction were slightly higher than the sample initially tested without colour correction (ie the sample with colour correction was slightly less toxic). The report indicated that the sample colour was possibly contributing to the toxicity of the sample and may have caused it to appear to be slightly more toxic than its true value. It was also suggested that the sample colour and/or its physical attributes were causing a decrease in the light output measured.

TEST FACILITY Bio-Aquatic Testing, Inc. (1994).

### 8.2.5. Inhibition of microbial activity

TEST SUBSTANCE A structural analogue polymer (Analogue Polymer A)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum Activated sludge from a local municipal sewage works with predominantly domestic sewage

Exposure Period 3 hours

Concentration Range Five test concentrations between 5 and 100 mg/L and two controls. A known inhibitor of respiration as a control for positive inhibition (3,5-dichlorophenol at 5, 15 and 30 mg/L) was tested in parallel with two controls.

Nominal

Remarks – Method The respiration rate of control samples for the test substances were about 9% less than the 15% acceptance criteria under the Guidelines, therefore the test was repeated. Since about 50% of the test substance is water, the concentrations used in the test were based on the solid component and not the whole product basis.

RESULTS The repeat test results (given below) showed a similar trend to the original test.

<i>Nominal concentration mg/L</i>	<i>Respiration rate mg O<sub>2</sub>/L/h</i>	<i>% Inhibition</i>
0 (Control 1)	5.5	n/a
5	3.1	44
25	3.4	38
50	3.4	38
75	6.9	-25
100	2.7	51
0 (Control 2)	5.5	n/a

n/a: Not applicable.

EC50 > 100 mg/L (solid component)

Remarks – Results The respiration rate of control samples for the reference material were about 2% less than the 15% acceptance criteria but the results were accepted as it is within the experimental error for the method and considered not to have affected the integrity of the study. The positive control test using 3,5-dichlorophenol showed adequate inhibition of respiration with an estimated EC50 of 8 mg/L, which validates the test.

CONCLUSION Based on the results of this study supported by those obtained in the Modified Zahn-Wellens Inhibition Test (IRI, 1994a), it was concluded that the test substance does not show any significant inhibition up to a concentration of 100 mg/L.

TEST FACILITY IRI (1994e).

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

The notified polymer will eventually be released into the environment with the majority expected to be discharged into sewerage systems through washing of hair. It is expected that up to 98% of the import volume will be released to sewer. The remaining 2% will remain in the import containers and go into domestic rubbish and ultimately to landfill.

The notified polymer is expected to be highly soluble in water and as such will be mobile in both the aquatic and terrestrial compartment. Under the basic conditions generally found in the sewer (pH 8) deprotonation of the acidic groups present will occur resulting in anionic character. This will lead to eventual association with soil and sediment where the notified polymer will slowly degraded through biological and abiotic processes to water and oxides of carbon. Residual chemical disposed of into landfill with empty containers are also expected to slowly adsorb to soil/sediment particles and be slowly destroyed by similar mechanisms.

Based on annual import of 3-10 tonnes per annum, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 8-27 kg/day. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 2-7 µg/L.

Amount of notified polymer entering sewer annually	3-10 tonnes
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365
PEC	2-7 µg/L

When released to receiving waters (ocean) the concentration is generally reduced by a further factor of at least 10. However, as the hair styling products containing the notified polymer will be used nationwide, no further dilution on released to receiving waters will be assumed as a worst-case estimate.

#### 9.1.2. Environment – Effects assessment

In summary, the aquatic toxicity data indicate:

Fish 96-h LC50	>100 mg/L
Aquatic invertebrate 48-h EC50	>100 mg/L
Alga 72-h EbC50 (biomass)	777.4 mg/L
Alga 72-h ErC50 (growth)	>1000 mg/L

Using the lowest EC50 datum (ie >100 mg/L), a predicted no effect concentration (PNEC) for aquatic ecosystems of >1 mg/L (1000 µg/L) has been derived by dividing the EC50 value by an uncertainty (safety) factor of 100.

#### 9.1.3. Environment – risk characterisation

The resulting risk quotient (RQ = PEC/PNEC) is <0.007. Therefore, based on the proposed use pattern the notified polymer is not expected to pose an unacceptable risk to the health of aquatic life. It is also likely that removal processes such as adsorption to sludge will reduce the predicted environmental concentration further.

### 9.2. Human health

#### 9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. The MSDS states that spills will be contained and collected in accord with the government regulations.

Dermal and ocular exposure due to spillage could occur during certain formulation and packaging processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

Considering the short duration and small volumes of the polymer dispersion handled, quality assurance workers are not expected to come into substantial contact with the notified polymer under normal circumstances.

Similarly, a low occupational exposure is expected for packaging and retail workers, who are likely to be dermally or inhalationally exposed to low concentrations of the notified polymer in the event of an accident.

Although intermittent, widespread use with direct handling is expected to occur among hairdressers and salon personnel, these end users are only exposed to the notified polymer at a maximum concentration of  $\leq 5\%$ .

#### **9.2.2. Public health – exposure assessment**

As the notified polymer will be used as a fixative resin in hair styling products which are available throughout Australia in aerosol tin cans, public exposure is expected to be widespread. Dermal and inhalation contact is expected to be likely the main route of exposure. However, given the small amounts used per application, the low frequency of use and the low concentration of the polymer in the product, the public exposure is determined to be low.

#### **9.2.3. Human health - effects assessment**

The notified polymer meets the PLC criteria. In addition, all test results of the toxicological studies submitted were negative. It is thus determined that the notified polymer will not pose a significant health hazard when used in the proposed manner.

#### **9.2.4. Occupational health and safety – risk characterisation**

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

#### **9.2.5. Public health – risk characterisation**

The risk to public health will be low because the notified polymer is present at low concentrations. However, inhalation should be avoided during use. High concentration of polymer particles may trigger an increased macrophage and inflammatory cell response that can cause lung damage or impairment of clearance by macrophages in the deep lung.

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

#### **10.1. Hazard classification**

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

#### **10.2. Environmental risk assessment**

Based on the proposed nationwide, diffuse use pattern and the PEC/PNEC ratio, the notified polymer is not considered to pose an unacceptable risk to the environment.

#### **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 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****CONTROL MEASURES****Occupational Health and Safety**

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
  - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Employers should ensure that the following personal protective equipment is used by plant operators and quality assurance staff to minimise occupational exposure to the polymer dispersions (max. 47% solids):
  - Coveralls/laboratory coats;
  - Protective gloves;
  - Safety glasses; and
  - Safety boots.
- Employers should implement the following engineering controls to minimise occupational exposure to the polymer dispersions (max. 47% solids):
  - Adequate ventilation, process automation and use of enclosed systems at the formulation and aerosol packaging sites, including enclosed and automatic transfer lines/pumps for loading and emptying of the mixing vessels;
  - Fume cupboard or local exhaust ventilation for maintenance and quality control personnel.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the 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.

**Disposal**

- The notified polymer should be disposed of in accordance with the methods described in the MSDS (i.e. coagulate the emulsion by the stepwise addition of ferric chloride and lime, remove the clear supernatant and flush to a chemical sewer, land fill or incinerate liquid and contaminated solids). This should be done by a licensed waste contractor and in accordance with local jurisdiction waste management guidance.

#### Emergency procedures

- Spills/release of the notified polymer should be handled in accordance with the MSDS.
- Spills/release of the notified chemical should be immediately contained using inert material (e.g. sand or earth).
- Transfer liquids and solids diking material to separate suitable containers for recovery or disposal.
- Keep spills and cleaning waste runoff out of municipal sewers and open bodies of water.

#### 12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if

- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

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.

### 13. BIBLIOGRAPHY

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