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

**FULL PUBLIC REPORT**

**Elastomer OS**

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
Chemicals Notification and Assessment**

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## **FULL PUBLIC REPORT**

<b>Elastomer OS</b>
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### **1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Kao Professional Salon Services  
1A The Crescent  
Kingsgrove NSW 2208

NOTIFICATION CATEGORY

Limited: Polymer with NAMW  $\geq 1000$  (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Identity of chemical;  
Composition; and  
Exact import volume.

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)

LVC Permit No 119 issued on 28 July 1996.

NOTIFICATION IN OTHER COUNTRIES

Europe

### **2. IDENTITY OF CHEMICAL**

MARKETING NAME(S)

Elastomer OS (Grades OS-51SJ and OX-40S) 30% polymer in ethanol

### **3. COMPOSITION**

DEGREE OF PURITY

<100%

DEGRADATION PRODUCTS

None known

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Not stated

### **4. INTRODUCTION AND USE INFORMATION**

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

The notified polymer will not be manufactured in Australia. It will be imported neat as a solid polymer or as a 30% solution in ethanol.

## 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>	<30	<30	<30	<30	<30

### USE

The polymer will be used as a component of hair fixative resin used in the manufacture of hair shaping products, such as styling gel, aerosol hairspray, aerosol mousse and non-aerosol pump spray products.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

#### PORT OF ENTRY

Sydney, NSW

#### IDENTITY OF MANUFACTURER/RECIPIENTS

Not stated

#### TRANSPORTATION AND PACKAGING

The solid polymer or the polymer solution will be imported in 20 kg or 20L steel drums, respectively. The notified polymer will be transported by road and stored at the notifier's warehouse prior to distribution by road to hair care formulators. Formulated hair shaping products will be packed in 125, 175 or 250 mL plastic containers, and will be transported by road to distribution warehouses for subsequent distribution to retail outlets.

### 5.2. Operation description

During manufacture of hair shaping products, a compounder will open the drums, weigh and add the required amount of the notified polymer into a mixing vessel. When weighing the polymer in ethanol solution, weighing will take place in a ventilated, flameproof area. Other ingredients will also be added and the mixture is blended in either an open or closed mixing vessel. Mixing operation is automated. Prior to packaging, sampling and quality testing of the hair shaping products are carried out in the laboratory. The formulated product is automatically pumped into an enclosed and automated multi-head filling machine. The concentration of the notified polymer in the hair spray products will be maximum of 0.1%.

Depending on the type of hair shaping products, the mixture is packed in 125, 175 or 250 mL plastic containers. The bottled products will be packed in cardboard cartons and will be transported to distribution warehouses for retail outlets, who will subsequently supply the products to retail outlets for consumer use.

### 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>
Transport and warehousing	5-10	2-3 hours/day	Up to 50 days/year
Compounders	20-50	Up to 8 hours/day	Up to 230 days/year

#### *Exposure Details*

Waterside, transport and warehouse workers will only handle sealed steel drums containing the notified polymer. Exposure is not likely to occur, except in the event of a spill from damaged containers.

There is potential for exposure when opening and closing drums, weighing and adding the notified polymer manually into a mixing vessel. Exposure due to drips and spills and if containers are overfilled at the filling station can also occur. General and local exhaust ventilation is in place at the weighing station, and at transfer and filling points to capture chemical particulates. Some exposure may also be possible during cleaning and routine maintenance of equipment.

Intermittent dermal exposure to small quantities of the notified polymer is possible during quality

testing prior to packaging.

Retail workers will handle the products in their retail packaging. Worker exposure is not expected, except if the packaging is breached.

#### 5.4. Release

##### RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured in Australia. However, in the manufacture of each batch of product, approximately 5 kg of notified polymer is released from cleaning out the tank and filling lines. At a maximum import volume of 30 tonnes, this will equate to 150 kg of the notified polymer per annum. All waste materials are treated to remove solids and oil, and the pH is adjusted prior to release to the sewer.

##### RELEASE OF CHEMICAL FROM USE

Following application of hair shaping products, almost all of the notified polymer will be washed from hair and released to sewer.

#### 5.5. Disposal

The import containers are expected to be disposed of to landfill together with the residues. The majority of the notified polymer will be released to the sewer following washing of hair. Empty hair product containers will be disposed of to landfill.

#### 5.6. Public exposure

The notified polymer will be used in the manufacture of hair shaping products, which will be available to the public through retail outlets. Public exposure will be widespread and will result through the use of hair shaping products containing a maximum of 0.1% notified polymer. Consumers will apply the product on the hair twice daily. The average quantity of the product used per application is 5 grams (0.005 grams notified polymer/application or 0.01 grams notified polymer/day).

Public exposure during transport, storage and retail distribution is unlikely unless the packaging is breached.

### 6. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance at 20°C and 101.3 kPa</b>	Yellowish solid (OX-40S), white to pale yellow solid (OS-51SJ) or colourless to pale yellow solution (polymer in ethanol)
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<b>Melting Point</b>	147 - 153°C (OS-51SJ), >160°C (OX-40S)
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Remarks	Test report not provided.
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<b>Density</b>	1095 kg/m <sup>3</sup> at 20°C
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Remarks	Test report not provided.
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<b>Vapour Pressure</b>	Not determined
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Remarks	The vapour pressure is not expected to be significant given the very high molecular weight of the polymer.
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<b>Water Solubility</b>	Not determined
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Remarks	The notified polymer does not have any significant water solubility. It may be dispersed in water, as demonstrated during the chromosome aberration test, where the notified polymer in ethanol was diluted in water by twice the volume and the ethanol removed by evaporation. Following evaporation, the polymer remained dispersed in water. However, the notified polymer cannot be dispersed in water on
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its own when stirred for 6 h at 80°C. On the basis of these experiments, the notified polymer is considered to be insoluble in water, consistent with the low charged density of the notified polymer and its high molecular weight. Siloxanes are known to be water insoluble (Hamelink, 1992).

<b>Hydrolysis as a Function of pH</b>	Not determined
Remarks	Not relevant for water insoluble polymers. The polymer contains siloxane and amide groups, which can undergo hydrolysis under extreme conditions.
<b>Partition Coefficient (n-octanol/water)</b>	Not determined
Remarks	The notified polymer has a very high molecular weight and low water solubility.
<b>Adsorption/Desorption</b>	Not determined
Remarks	The notified polymer has a very high molecular weight and low water solubility, hence, this parameter cannot be determined. However, waste water treatment plants monitoring and simulation studies have confirmed that siloxanes related to the notified polymer when present in treatment plants are largely removed by adsorption to sludge and will be almost completely absent from treated effluent (Fendinger et al, 1997).
<b>Dissociation Constant</b>	Not determined
Remarks	The notified polymer contains amine groups in salt form and is expected to be slightly acidic.
<b>Particle Size</b>	Not determined
Remarks	The notified polymer is in the form of waxy beads measuring 5 – 8 mm in diameter.
<b>Flash Point</b>	>100°C (OS-51SJ)
Remarks	Test report not provided.
<b>Flammability Limits</b>	Not determined.
Remarks	The polymer alone is not expected to be flammable. The imported polymer in ethanol is flammable.
<b>Autoignition Temperature</b>	Not determined.
Remarks	The polymer is not expected to autoignite.
<b>Explosive Properties</b>	Not determined.
Remarks	The polymer is not expected to have explosive properties.
<b>Reactivity</b>	Not determined.
Remarks	The notified polymer is stable under normal conditions of use.

## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/SD
Vehicle	Not stated
Remarks - Method	The notified polymer was administered once by gavage using metal cannula.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	2000	None

LD50	>2000 mg/kg bw
Remarks – Results	A summary of the study (translated from Japanese) was provided. Signs of toxicity and effects in organs were not reported in the summary provided.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Drug Safety Testing Centre Co. Ltd (1994a)
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### 7.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	
Species/Strain	Rabbit/Japanese albino.
Number of Animals	3
Vehicle	ethanol and water
Observation Period	48 hours.
Type of Dressing	Occlusive
Remarks - Method	Four abraded skin and four intact skin sites were used as application sites. The sites were treated with (1) 30% notified polymer in ethanol, (2) 10% notified polymer (30% notified polymer in ethanol, then diluted with water), (3) 24% ethanol and (4) 70% ethanol. Skin reactions were evaluated at 3, 24 and 48 hours after exposure.



## RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	0	-	0
<i>Oedema</i>	0	0	0	0	-	0

\*Calculated on the basis of the scores at 24 and 48 hours for EACH animal.

Remarks - Results	There were no deaths or test related clinical signs during the study period. There were no dermal reactions observed at any treatment dose and vehicle control used. All individual Draize scores were zero.
CONCLUSION	The notified polymer is non-irritating to skin.
TEST FACILITY	Saitama Institute (1994a).

### 7.3. Irritation – eye

TEST SUBSTANCE	Notified polymer in ethanol.
METHOD	Not provided.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks – Method	A 30% notified polymer solution in ethanol was diluted with water to achieve 10% and 20% notified polymer solution.

## RESULTS

### a) 20% notified polymer in ethanol and water

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	1.67	1.33	1.67	2	4 days	0
<i>Conjunctiva: chemosis</i>	0.33	0	0.33	2	24 hrs	0
<i>Conjunctiva: discharge</i>	0.67	0.67	0.33	2	48 hrs	0
<i>Corneal opacity</i>	1	0	0	1	72 hrs	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

### b) 10% notified polymer in a mixture of ethanol and water

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0	0	0	2	6 hrs	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	6 hrs	0
<i>Conjunctiva: discharge</i>	0	0.33	0	1	24 hrs	0
<i>Corneal opacity</i>	0	0	0	0	3 hrs	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

\*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

## Remarks – Results

Test animals treated with 20% notified polymer solution showed more severe ocular lesions when compared with animals treated with 10% notified polymer solution. However, the ocular lesions observed in animals treated with 20% notified polymer solution was of similar degree to those observed in animals treated with solvent control containing 47% ethanol. Two animals treated with 20% notified polymer solution and another 2 animals treated with solvent control (47% ethanol) had conjunctival redness, which persisted up to 4 days.

Low level ocular lesions were observed in animals treated with 10% notified polymer solution and in animals treated with solvent control containing 24% ethanol.

All ocular irritation effects were resolved within 7 days.

## CONCLUSION

The notified polymer is slightly irritating to the eye.

## TEST FACILITY

Drug Safety Testing Center Co. Ltd (1994b)

## 7.4. Skin sensitisation

### TEST SUBSTANCE

Notified polymer

### METHOD

Similar to OECD TG 406 Skin Sensitisation - Maximisation test

#### Species/Strain

Guinea pig/Dunkin-Hartley.

#### PRELIMINARY STUDY

Maximum Non-irritating Concentration

intradermal: 1%

topical: 30%

#### MAIN STUDY

#### Number of Animals induction phase

Test Group: 10

Control Group: 10

Induction Concentration

intradermal injection: 3%

topical application: 30%

#### Signs of Irritation

No signs of irritation were observed.

#### CHALLENGE PHASE

#### 1<sup>st</sup> challenge

topical application: 3, 10, 30%

## RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1<sup>st</sup> challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	3, 10, 30%	0/10	0/10
<i>Control Group</i>	3, 10, 30%	0/10	0/10

## CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

## TEST FACILITY

Saitama Institute (1994b).

## 7.5. Genotoxicity – bacteria

### TEST SUBSTANCE

Notified polymer

### METHOD

Plate incorporation procedure

#### Species/Strain

*S. typhimurium*: TA1535, TA1537, TA98, TA100.

Metabolic Activation System	<i>E. coli</i> : WP2 uvrA.
Concentration Range in Main Test	S9 fraction from phenobarbital, 5,6-benzoflavone-induced SD rat liver.
Vehicle	a) With metabolic activation: 0 - 5000 µg/plate. b) Without metabolic activation: 0 - 5000 µg/plate.
Remarks - Method	Distilled water A range finding study was conducted on the above bacterial strains with and without metabolic activation in order to determine the concentration levels in the main test. Toxicity was not observed at concentrations up to 5000 µg/plate.

## RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Present</i>				
Test 1	None	None	None	None
Test 2		None	1000 and 5000	None
<i>Absent</i>				
Test 1	None	None	None	None
Test 2		None	1000 and 5000	None

Remarks - Results	<p>No substantial increases in the number of revertant colonies were seen in any strain either in the presence or absence of metabolic activation. In the main test, precipitation was observed at 1000 µg/plate and above.</p> <p>Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.</p>
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Japan Biological Chemistry Co. (1994a).

## 7.6. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test
Cell Type/Cell Line	Chinese Hamster Lung (CHL) cells
Metabolic Activation System	S9 fraction from Phenobarbital, 5,6-benzoflavone-induced SD rat liver
Vehicle	Distilled water
Remarks-Method	An inhibition test was conducted to determine the dose levels for the test substance. Since cytotoxicity was not observed, 5000µg/ml was taken as the highest concentration for analysis in the main tests

Metabolic Activation	Test Substance Concentration (µg/mL)	Exposure Period	Harvest Time
<i>Present</i>			
Test 1	1250*, 2500*, 5000*		
<i>Absent</i>			
Test 1	1250*, 2500*, 5000*	24 hours	24 hours
Test 2	1250*, 2500*, 5000*	48 hours	48 hours
Test 3	1250*, 2500*, 5000*		

\*Cultures selected for metaphase analysis.

## RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Present</i>				
Test 1		None	None	None
<i>Absent</i>				
Test 1		None	None	None
Test 2		None	None	None
Test 3		None	None	None

### Remarks – Results

A comparative test was conducted with and without metabolic activation in addition to an experiment in which no S9 fraction was present and treatment times were 24 or 48 hours. In the comparative test treatment time was not indicated. The preliminary test demonstrated no effect of the notified polymer on cell division. No precipitation was recorded.

Appropriate positive controls induced marked increases in the number of aberrant cells, indicating that the test system responded appropriately.

### CONCLUSION

The notified polymer was not clastogenic to CHL cells treated in vitro under the conditions of the test.

### TEST FACILITY

Japan Biological Chemistry Co. (1994b).

## 8. ENVIRONMENT

### 8.1. Environmental fate

No environmental fate data were submitted.

#### 8.1.1. Ready biodegradability

No test report or results has been provided. However, the amide can undergo hydrolysis under extreme conditions.

#### 8.1.2. Bioaccumulation

Given the low water solubility and the high molecular weight, the notified polymer is unlikely to bioaccumulate (Connell, 1990).

### 8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. Although the notified polymer is cationic, its low water solubility and the calculated low charge density (FGEW >5000) are unlikely to give rise to toxic effects to aquatic organisms. The MSDS for OS-51SJ indicates an aquatic toxicity > 100 mg/L.

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

Based on the release estimates in Section 5.4, virtually all the notified polymer will be discharged to sewer. Using a worst case scenario it has been assumed that 30 tonnes of the notified polymer is discharged to sewerage systems throughout Australia and none is attenuated within these systems. Assuming a national population of 19,500,000 and that each person contributes an average of 200 L/day to overall sewage flows and all of the polymer is partitioned into water, the predicted concentration in sewage effluent on a nationwide basis is estimated as  $(30,000 \text{ kg} / (200 \text{ L} \times 365 \text{ days} \times 19,500,000 \text{ persons})) = 21 \text{ µg/L}$ .

Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified polymer in freshwater and marine water may approximate 21 or 2.1 µg/L, respectively.

In the absence of vapour pressure and solubility data, calculations for partitioning and losses in sewage treatment plants based on the SIMPLETREAT model cannot be conducted. Waste water treatment plants monitoring and simulation studies have confirmed that siloxanes related to the notified polymer which enter treatment plants are largely removed by adsorption to sludge and will almost be completely absent from treated effluent (Fendinger et al, 1997). Assuming that 90% of the notified polymer will be adsorbed to the sludge and the remaining 10% may potentially stay in solution, passing through the STP, the amount of notified polymer present in the effluent after the waste treatment is considered to be low.

Assuming 30 tonnes of the notified polymer would be discharged to sewer per year, and based on the assumption that 0.1 tonnes of biosolids is generated for each ML of STP effluent, this may result in an average biosolid concentration of  $1.89 \times 10^{-1}$  mg/kg  $[(0.9 \times 30,000 \text{ kg}) / (1.42 \times 10^6 \text{ ML} \times 0.1 \times 1000 \text{ kg})]$  assuming 90% attenuation in sludge during the STP process. Biosolids are applied to agricultural soils, with an average rate of 10 tonnes/ha/year. Assuming a bulk density of 1000 kg/m<sup>3</sup> and a soil mixing zone of 0.1 m, the concentration of the notified polymer may approximate 189 mg/kg in the applied soil, assuming accumulation of the notified polymer in soil for 10 years under repeated biosolids application. Thus an estimated worst case PEC for the notified polymer in soils following application of biosolids would be 18.9 mg/kg.

The effluent re-use (eg irrigation purposes) concentration of the notified polymer may potentially approximate 21 µg/L, assuming no attenuation during the STP process. STP effluent re-use for irrigation in Australia occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 21 µg/L may potentially result in a soil concentration of approximately 2.1 mg/kg assuming accumulation of the notified polymer in soil for 10 years under repeated irrigation. Thus, 2.1 mg/kg is an estimated worst case PEC for the notified polymer in soils following effluent irrigation.

#### **9.1.2. Environment – effects assessment**

No ecotoxicity data were provided.

#### **9.1.3. Environment – risk characterisation**

Based on the nationwide diffuse use of the notified polymer, the low charged density and the expected low water solubility, the notified polymer is unlikely to have toxic effects on aquatic organisms. While no ecotoxicity data have been provided, there is likely to be an acceptable safety margin between the worst case PEC of 21 µg/L and the potential toxicity of the polymer to aquatic organisms since its FGEW is >5000.

The notified polymer is likely to adhere to sludge resulting from wastewater treatment because of its low water solubility. Should such wastes be placed in landfill, the notified polymer is not expected to leach due to its low water solubility and its likely degradation via the slow abiotic and biotic process.

### **9.2. Human health**

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

##### *Transport and, Storage*

Transport, warehouse and retail workers will handle and transport the sealed containers containing the polymer or the products containing it. Therefore, these workers are unlikely to be exposed to the notified polymer except in the event of transport accident, or when the containers are damaged or punctured.

##### *Manufacture of Hair Shaping Products*

Manufacture is carried out predominantly in closed systems, and addition of the notified polymer would generally involve manual operations. Dermal, ocular and inhalation exposure to the polymer is possible when manually weighing and charging the notified polymer into the mixing vessel. Dermal exposure is also possible when opening and closing drums, connecting and disconnecting transfer and filling lines, and during cleaning and maintenance of equipment. All workers involved in handling the notified polymer and formulated products will wear safety glasses, rubber gloves, coveralls and respiratory protection, as required.

Exposure to small quantities during sampling and testing is possible. Laboratory workers will wear laboratory coats, safety glasses and impermeable gloves.

Overall, occupational exposure to the notified polymer will be low due to the predominantly closed and automated operations involved in the manufacture of hair shaping products, and the use of engineering controls and personal protective equipment when handling the polymer and the products containing it.

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

The public exposure to the hair shaping products containing the notified polymer will be widespread and repeated. During use, 5 g/day of the product containing the notified polymer is expected to be applied twice daily. Assuming 10% of the product (containing 0.1% notified polymer) is absorbed by the skin, the consumer would be exposed to 1 mg/day notified polymer, which is equivalent to a systemic exposure of 0.017 mg/kg/bw for a 60 kg female.

Overall, the public exposure to the notified polymer is low due to the low frequency of use (maximum twice/day), the low concentration (up to 0.1%) of the notified polymer present in the products and the expected low systemic exposure of the notified polymer when used as a component of hair shaping products.

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

The notified polymer has low toxicity via the oral route. It is non-irritating to skin and at most slightly irritating to eyes, as evidenced by transient ocular effects. The slight irritating effects were assumed to be primarily due to the presence of ethanol as they were seen in both test and control animals. Precautions should be taken to avoid ocular contact with the hair shaping preparations, as slight eye irritation may occur.

There is no evidence of skin sensitisation. The notified polymer is not mutagenic in bacteria and not clastogenic in *in vitro* chromosomal aberration assay using chinese hamster ovary cells.

On the basis of the data supplied, the polymer would not be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria For Classifying Hazardous Substances* (NOHSC, 2002).

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

##### *Transport and, Storage*

Worker exposure to the notified polymer is expected to be low since warehouse, retail and transport workers will handle sealed containers.

##### *Manufacture of Hair Shaping Products*

The manufacture of hair shaping products will be carried out predominantly in closed and automated systems, however addition of the notified polymer may involve manual operations. Limited dermal and ocular exposure to the notified polymer is possible when opening and closing drums, connecting and disconnecting transfer and filling lines, and cleaning and maintenance of equipment. Dermal exposure due to drips and spills at the filling station can also occur. Due to the flammable property of the polymer solution, precautions should be taken to avoid handling of the notified polymer where sources of flame are in close proximity.

Overall, given the non-hazardous nature of the polymer and the low potential for exposure, the risk posed by the notified polymer to occupational health and safety is low.

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

Public exposure to the polymer will arise during use of the hair products containing it. Assuming 10% dermal absorption, systemic exposure would be 0.017 mg/kg/bw for a 60 kg female, which is much lower compared with the acute oral LD50 in rats (>2000 mg/kg bw), and would provide an adequate margin of safety. Although the notified polymer may be a slight eye irritant, it is present at a very low concentration in the shaping products, and it is normal practice to minimise eye contact with hair sprays.

Since the total polymer content in the product is low (maximum of 0.1%) and the non-hazardous nature of the polymer, the risk to public health is considered low.

### **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**

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

#### **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 as an ingredient in hair products.

### **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, 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 polymer 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 engineering controls to minimise occupational exposure to the notified polymer as imported:
  - Exhaust ventilation during addition and mixing of ingredients.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as imported:
  - During weighing and addition to the mixing vessel, avoid spills.

- When handling the ethanol solution, ensure that there are no open flames in close proximity.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as imported:
  - Rubber gloves;
  - Chemical safety glasses;
  - Overalls (or similar protective apparel); and
  - Respiratory protection, as required.

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the 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 by the public to minimise exposure to the notified polymer:
  - Avoid eye contact.

#### Environment

#### Disposal

- The notified polymer should be disposed of by landfill.

#### Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Avoid breakage of containers
  - Store away from flame

#### Emergency procedures

- Protect spreading of large spills by sand, then absorb spill with diatomaceous or other suitable adsorbent.

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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