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

**FULL PUBLIC REPORT**

**SilSense PE-100**

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## **FULL PUBLIC REPORT**

<b>SilSense PE-100</b>
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### **1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lubrizol International, Inc (ABN 52 073 495 603)  
28 River Street  
Silverwater NSW 2128

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:

Chemical Name

CAS Number

Structural Formula

Molecular Formula

Molecular Weight

Means of Identification/Spectral Data

Purity

Non-hazardous Impurities

Import Volume

Weight Percentage and Ingredient

Number Average Molecular Weight

Residual Monomer/Other Reactants

Low Molecular Weight Polymer

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Dissociation constant

Particle size

Flammability limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

None.

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

MARKETING NAME(S)

Z-68, SilSense PE-100, Dimethicone PEG-7 Phosphate

SPECTRAL DATA

METHOD            NMR

REMARKS            Spectral data was supplied.

TEST FACILITY        Noveon Technology (2005)

METHODS OF DETECTION AND DETERMINATION

REMARKS            The molecular weight distribution of the polymer was determined by gel permeation chromatography (GPC)  
TEST FACILITY    Noveon Technology (2005a)

### 3. COMPOSITION

DEGREE OF PURITY  
> 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS  
None.

ADDITIVES/ADJUVANTS  
None.

DEGRADATION PRODUCTS  
The notified polymer is not expected to depolymerise under normal conditions.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES  
In normal use there is no natural loss of monomers or reactants from the notified polymer.

### 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS  
The notified polymer will be imported using the trade name SilSense PE-100.

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	1-3	1-3	3-10	3-10

USE  
Anionic silicone for use at up to 2.5% in personal care products for hair and skin such as hair and skin conditioners, creams and lotions, bath gels and liquid soaps.

### 5. PROCESS AND RELEASE INFORMATION

#### 5.1. Distribution, transport and storage

PORT OF ENTRY  
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS  
Probable sites of reformulation include Victoria, New South Wales and Queensland.

TRANSPORTATION AND PACKAGING  
The notified polymer is manufactured outside Australia. It is shipped to Australia as the neat material in 208 L drums or 18.9 L pails depending on the size of the customer. The product is transported from the dock to the customer via truck.  
After formulation into personal care product, the finished end use product containing the notified polymer. The notified polymer is packaged into plastic bottles or containers, ranging in size from 200 to 500 mL. This process is usually highly automated. The filled bottles are then generally packaged into cardboard boxes for shipment to warehouses for storage or to retail outlets.  
If at some point in the future, Z-67 will be imported as part of a finished personal care product such as a shampoo, conditioner or personal cleaner, it will be transported in 100-500 mL plastic bottle or jars. The bottles or jars would be shipped cardboard boxes containing the plastic containers.

#### 5.2. Operation description *Repackaging and Reformulating*

A typical operation by the customer who plans to repackage or reformulate with the neat polymer involves pumping the notified polymer directly from the 208 L drums or 18.9 L pails to a blend tank where it is blended with water, dyes and fragrances as well as other cosmetic additives. All these operations are expected to be carried out manually or semi-automatically in a closed system. Mixing usually requires minimal heating. The finished product being formulated will contain about 1.0 to 2.5% by weight of the substance being notified. This operation is carried out by 3-5 workers at each customer's site. Normal process is completed in less than 8 hours and only 10-20 times per year. Water could be used to flush the isotainer or drum. Residual product remaining in the container is expected to be minimal (approximately 1%) and will be removed by washing with water and properly disposed of at the reconditioning facility.

The finished end use product containing the notified polymer is packaged into plastic bottles or containers, ranging in size from 200 to 500 mL. This process is usually highly automated. The filled bottles are then generally packaged into cardboard boxes for shipment to warehouses for storage or to the stores for sale. It is estimated that 2-3 workers are involved in the packaging and shipping process.

#### *Supermarket*

Supermarket personnel unload the bottles or containers of final consumer product containing the notified substance from a truck and stack them on shelves for sale.

### **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 Storage	2-8	2-4 hours/day	1-5 days/year
Reformulating	3-5	< 8 hours/day	10-20 time/year
Repacking	2-3	< 8 hours/day	10-20 time/year
Supermarket	1-3	< 8 hours/day	50-100 time/year

#### *Exposure Details*

##### *Transport and storage*

Workers are not expected to be exposed to notified polymer as they will be handling closed containers transported in secure pallets. Exposure is possible in the event of an accident where the packaging is breached.

##### *Formulation of hair care products*

The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source. However, dermal and limited ocular exposure to notified polymer, due to drips and spill may occur when opening and closing the drums containing notified polymer, manually charging the mixing vessel, and connecting and disconnecting transfer and filling lines.

At filling stations dermal exposure to the notified polymer may also occur due to drips and spills if containers are overfilled with finished hair product.

Dermal exposure may occur when maintenance workers are cleaning equipment and during routine maintenance. Workers involved in the above activities wear personal protective equipment (PPE) such as, overalls, safety glasses, safety shoes, gloves, hair covering and facemasks.

##### *Quality Control*

During quality control there is limited chance for dermal exposure to small quantities during sampling and testing which will be carried out in a fume cupboard. Laboratory technicians will wear laboratory coats, gloves and eye protection during sampling and testing.

##### *End-users*

Retail workers (e.g. supermarkets) workers will unpack the boxes and place the consumer packaging on the supermarket shelves. Exposure is only likely to occur in the event of a spill from damaged containers.

### **5.4. Release**

#### RELEASE OF CHEMICAL AT SITE

The notified polymer is manufactured outside Australia. It is shipped to Australia as the neat material in 208 L drums or 18.9 L pails depending on the size of the customer. The product is transported from the dock to the customer via truck where it is formulated as described above.

The notified polymer is directly pumped from the 208 L drums or 18.9 L pails to a blend tank where it is blended with water and other components. All these operations are expected to be carried out manually or semi-automatically in a closed system. Water could be used to flush the isotainer or drum. Residual product remaining in the container is expected to be minimal (approximately 1%) and will be removed by washing with water and properly disposed of at the reconditioning facility.

#### RELEASE OF CHEMICAL FROM USE

The notified polymer is an anionic polymer used in hair and skin conditioning personal care products. The notified polymer is present in the final formulation up to 2.5%. Since the formulated product will be applied to the skin and hair, the majority of the polymer is expected to be washed off and enter the sewer, with the remainder disposed of in landfill as residue in product containers.

### 5.5. Disposal

It is not expected that there will be a need to dispose of notified polymer other than as additive in cosmetic. However, in the event of disposal, the product should be incinerated. Residual of personal care product remaining in the bottle will likely be rinsed off with water and disposed of to sewer or be left in the bottle and disposed as solid waste.

### 5.6. Public exposure

The notified polymer will be used in the formulation of personal care products, which will be available to the general public. Public exposure will be widespread and will result through the use of personal care products containing < 2.5% notified polymer. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer.

Typical use information is as follows (SSCNFP 2003):

Product	Grams/application	Use frequency (applications per day)	Total dermal exposure (Grams per day)
Hair shampoo	8.0	1	8.0
Hair conditioner	14.0	0.28	3.9
Hair styling gel or mousse	5.0	2	10
Liquid shower soap	5.0	2	10
Face cream	0.8	2	1.6
Body lotion	8.0	1	8.0
Hand cream (general purpose cream)	1.2	2	1.2

Since the personal care product will be stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

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

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa**      Slight hazy liquid, clear to pale yellow in colour

**Pour Point**      -17 ± 3°C

METHOD	OECD TG 102 Melting Point/Melting Range BS 2000: Part 15 (equivalent to ISO 3016)
Remarks	The polymer is a liquid at room temperature.
TEST FACILITY	Safepharm (2005)

**Boiling Point**  $\geq 480^{\circ}\text{C}$  at 101.3 kPa (calculated value)

METHOD OECD TG 103 Boiling Point.  
Remarks Differential scanning calorimetry method. Polymer was found to volatilise with gradual decomposition from approximately  $305^{\circ}\text{C}$  at 101.61 kPa.  
TEST FACILITY Safepharm (2005)

**Density**  $1100 \text{ kg/m}^3$  at  $20.0 \pm 0.5^{\circ}\text{C}$

METHOD OECD TG 109 Density of Liquids and Solids.  
Remarks Pycnometer method  
TEST FACILITY Safepharm (2005)

**Vapour Pressure**  $3.5 \times 10^{-6} \text{ kPa}$  at  $25^{\circ}\text{C}$

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.  
Remarks Vapour pressure balance – extrapolated from readings taken between  $75$  and  $85^{\circ}\text{C}$   
TEST FACILITY Safepharm (2005a)

**Water Solubility** Miscible in all proportions with water at  $20.0 \pm 0.5^{\circ}\text{C}$

METHOD OECD TG 105 Water Solubility.  
Remarks Flask Method. Three samples were tested at different concentrations between 5 and 95% having a natural pH range from 1.4 to 2.0.  
TEST FACILITY Safepharm (2005)

#### Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> ( $^{\circ}\text{C}$ )	<i>t</i> <sub>1/2</sub>
5	25	> 1
7	25	> 1
9	25	> 1

Remarks The concentration of samples was determined by gel permeation chromatography after 96 – 120 hours at  $50^{\circ}\text{C}$ .  
Sample solutions were prepared at nominal concentration of 1.0 g/L. Chromatography conditions were not optimum as a small peak under the peak of the notified polymer did not achieve chromatographic separation. The decrease in concentration and the appearance of a new peak in the chromatogram is an indication of new substance formation from the notified polymer. Furthermore, by comparing peak areas between the same concentration (1 g/L) of standard and samples, it is possible to observe a decrease in the area from 0 hours, which is consistent over the length of the experiment.  
TEST FACILITY Safepharm (2005)

**Partition Coefficient (n-octanol/water)**  $\log K_{ow} = < -0.967$  at  $25^{\circ}\text{C}$

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).  
EC Directive 92/69/EEC A.8 Partition Coefficient.  
Remarks Shake Flask Method. The HPLC method was impracticable due to the polymeric nature of the material and the high solubility in both water and n-octanol. The concentration of samples was determined by gel permeation chromatography.  
TEST FACILITY Safepharm (2005)

**Adsorption/Desorption**  $\log K_{oc} = < 0.517$



Remarks	An estimation of adsorption coefficient was obtained by calculation using The Quantitative Structure Activity Relationship $\log K_{oc} = 0.52 \log P_{ow} + 0.2$ . The HPLC method was not suitable for the notified polymer as it was not possible to elute the test material from the cyanopropyl column, even with 100% organic solvent.
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<b>Dissociation Constant</b>	Testing was not conducted
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Remarks	Testing was not conducted primarily due to the polymeric nature of the test material. Estimation using ACD software: pKa1: $11.42 \pm 0.10$ pKa2: $6.35 \pm 0.30$ pKa3: $1.85 \pm 0.10$ . The polymer is expected to be anionic throughout the environmental pH range of 4 to 9.
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<b>Particle Size</b>	The material is a liquid. The test is not applicable.
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<b>Flash Point</b>	$106 \pm 2^{\circ}\text{C}$ at 101.325 kPa
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METHOD	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Closed cup equilibrium method
TEST FACILITY	Safepharm (2005a)

<b>Flammability Limits</b>	Since the notified polymer is a viscous liquid, the test was not performed.
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<b>Autoignition Temperature</b>	$360 \pm 5^{\circ}\text{C}$
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METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	A flask heater was used.
TEST FACILITY	Safepharm (2005a)

<b>Explosive Properties</b>	Not expected to have explosive properties.
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Remarks	In handling the notified polymer has not demonstrated any explosive properties.
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**Reactivity**

Remarks	The notified polymer is not an oxidiser. This product is stable and hazardous polymerisation or depolymerisation does not occur.
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## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 5000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Mouse, skin sensitisation – Local Lymph Node Assay EC3 21.7%	Sensitising

### 7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer Lot No. Lab-05-147-B
METHOD	FHSLA, 16 DFR 1500.3
Species/Strain	Rat/Wistar derived albino
Vehicle	
Remarks - Method	The rats were fasted for 18 hours and appropriate amounts of the test material were delivered by gavage. Once the material had been ingested completely, feed and water were provided ad-libitum. The rats were individually caged and observed for mortality or other signs of gross toxicity for 14 days.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 males	5000	0
2	5 females	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	The test substance did not produce any notable observation.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	AMA (1991)
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### 7.2. Irritation – skin

TEST SUBSTANCE	Notified polymer Lot No. Lab-05-147-B
METHOD	FHSLA, 16 CFR 1500.41.
Species/Strain	Rabbit/New Zealand Albino
Number of Animals	3 Males/3 Females
Vehicle	
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	Six healthy rabbits were each uniquely identified and then prepared by clipping the trunk free of hair. Two 2.5 cm square patches were placed over intact skin and abraded skin on each rabbit. 0.5 mL or 0.5 g of the test material was placed under each patch. The entire trunk of the animal was wrapped with a rubberised elastic cloth to retard evaporation and as an aid in maintaining test patch position. Rabbits were placed in neck collars and returned to their individual cages. Collars were removed after 24 hours. All test sites were wiped with a cloth to prevent further exposure. Skin lesions were evaluated at 24 and 72 hours and scored in accordance with FHSLA 16 CFR 1500.41.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar</i>	0	0	0	0
<i>Oedema</i>	0	0	0	0

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

Remarks - Results	The test substance did not produce any notable observation on either intact or abraded skin.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	AMA (1990)

### 7.3. Irritation – eye

TEST SUBSTANCE	Notified polymer Lot No. Lab-05-147-B
METHOD	FHSLA 16 CFR 1500.42
Species/Strain	Rabbit/New Zealand Albino
Number of Animals	3 Males/3 Females
Observation Period	72 hours
Remarks - Method	Six healthy young adult albino rabbits exhibiting no ocular defects or corneal defects were selected for testing. The test animals were each uniquely identified. 0.1 mL of the test material was placed on the everted lower lid of one eye of each rabbit. The upper and lower lids were gently held for one second before releasing, to prevent loss of the test material. The contra lateral eye of each rabbit remained untreated and served as a control. Ocular lesions were evaluated by the method of Draize. The Draize scores were then classified according to Kay and Calandra. Lesions were evaluated at 24, 48 and 72 hours.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Cornea opacity</i>	0	0	0	0
<i>Cornea area</i>	0	0	0	0
<i>Iris values</i>	0	0	0	0
<i>Conjunctivae hyperaemia</i>	0	0	0	0
<i>Conjunctivae chemosis</i>	0	0	0	0
<i>Conjunctivae discharge</i>	0	0	0	0

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

Remarks - Results	No effects were observed.
CONCLUSION	The notified polymer is non-irritating to the eye.
TEST FACILITY	AMA (1990a)

### 7.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified polymer Batch #142954507
METHOD	OECD, Section 4, Health Effect, No. 429, Paris Cedex EC, Council Directive 67/548/EEC, Annex IV C, B.42 (Draft)
Species/Strain	Mouse/CBA strain, inbred, SPF-Quality
Vehicle	Propylene glycol
Remarks - Method	Test substance concentrations selected for the main study were based on

the results of a preliminary irritation study. In the main study, groups of four female mice were treated with the test material at concentration of 5%, 50% and 100% w/w in propylene glycol (25 µL/ear) by daily application to the dorsal surface of each ear for three consecutive days. Based on the results, one additional group was treated with an intermediate (10%) concentration of test substance. Three days following the first topical application, all mice were injected with <sup>3</sup>H-methyl thymidine and after five hours the draining (auricular) lymph nodes were excised. After precipitating the DNA of the lymph node cells, radioactivity measurements were done.

## RESULTS

<i>Concentration (% w/w)</i>	<i>Proliferative response (DPM/lymph node)</i>	<i>Stimulation Index (Test/Control Ratio)</i>
<i>Test Substance</i>		
0 (vehicle control 1)	34 ± 29	1.0
0 (vehicle control 2)	61 ± 67	1.0
5	73 ± 50	2.1 ± 1.1*
10	66 ± 24	1.1 ± 0.9**
50	262 ± 230	7.6 ± 1.2*
100	776 ± 270	19.3 ± 0.7***
<i>Positive Control</i>		
0	40 ± 23	

\* SI calculated using vehicle group 1

\*\* SI calculated using vehicle group 2

\*\*\* SI calculated using positive group

### Remarks - Results

In the preliminary study, irritation was only found at the highest concentration (100%). In the main test, the largest nodes were found in the higher dose groups. No other macroscopic abnormalities of the nodes were noted. Proliferation of lymphocytes as measured by disintegrations per minute (DPM), increased in the test groups in a dose-related manner. Slight erythema was seen on the treated ears of the animals of the main study. It is not expected that this kind of irritation would lead to stimulation of the nodes. The stimulation index data for the test substance showed a dose-response and an EC3 value of 21.7% was calculated.

## CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.

## TEST FACILITY

NOTOX (2003)

## **8. ENVIRONMENT**

### **8.1. Environmental fate and toxicity**

No environmental data were submitted.

## **9. RISK ASSESSMENT**

### **9.1. Environment**

#### **9.1.1. Environment – exposure assessment**

Up to 50 kg of the notified polymer is expected to be released to the environment during the formulation process (to wastewater and as residue in empty import containers). Nearly all of the imported notified polymer will eventually be released into the aquatic environment via the sewerage systems through formulation and use (washing off the care products). A small amount of the notified polymer is also expected to be disposed of to landfill as residue in empty consumer containers via domestic garbage.

The notified polymer is not volatile, therefore, is not expected to dissipate into air from the surfaces to which the products containing it is applied. The notified polymer is readily soluble in water, contains functional groups which have the potential to hydrolyse only under extreme pH conditions. However, in the environmental pH range 4-9 it is expected that it will be hydrolytically stable.

The estimated log Pow and calculated log Koc indicate a low affinity for the organic component of the soils and sediments. However, these results should be treated with some caution as the notified polymer seems to have similar solubility in organic solvents and water preliminary partitioning results.

When disposed in landfill the notified polymer can be expected to eventually become associated with soil and sediment and will slowly degrade through biological and abiotic processes.

Based on maximum annual imports of 10000 kg per annum, and assuming a worst-case scenario that all 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 27.40 kg/day. The estimated Predicted Environmental Concentration (PEC) has been estimated as follows:

Amount entering sewer annually (Worst Case): 10000 kg/y

Number of days used per year: 365 d/y

Amount entering sewer per day (Worst Case): 27.40 kg/d

Population of Australia: 20,100,000 persons

Daily water use per person: 200 L/person/d

Daily water entering sewer: 4000 ML/d

Predicted Environmental Concentration: 6.85 µg/L

Assuming no removal on passage through the sewage treatment works, the worst-case PEC for the aquatic environment resulting from the nationwide release of the notified polymer into the sewage systems is therefore assumed to be 6.85 µg/L prior to any dilution and the respective concentrations in freshwater and marine water will be approximately 6.85 µg/L and 0.685 µg/L.

It is unknown if the notified polymer is readily biodegradable. Based on the notified polymer partition coefficient ( $< 1$ ) and water solubility, the main environmental distribution will be the water columns. As the notified polymer contain acidic groups, could be expected to be ionic under normal environmental condition (pH 4 to 9).

The potential for the notified polymer to bioaccumulate is low due to its level of water solubility, low log partitioning coefficients, high molecular weight and charge stage.

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

No ecotoxicity data were submitted.

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. Whether this applies to the notified polymer is unclear. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups (Nabholz et al. 1997).

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

The notified polymer is considered to have moderate toxicity to the aquatic environment due to its water solubility and charge stage. However, on the basis of the widespread uses and release pattern, the safety margin between the expected toxicity and the estimated PEC is satisfactory and the notified polymer is unlikely to pose an unacceptable risk to the aquatic environment.

### **9.2. Human health**

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

Dermal and possibly ocular exposure to the notified polymer could occur during its transfer from drums to the blending vessel. The level of exposure would vary from site to site depending on the level of automation of the formulation process. The estimated dermal exposure is 420 mg/day, based on the EASE model using reasonable worst case defaults for the exposure scenario ‘manual addition of liquids’ (European Commission, 2003) and assuming the notified polymer is present at concentration of 100%. Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 6 mg/kg bw/day. However the high molecular weight of the notified polymer would limit dermal absorption.

Exposure would be further limited by the use of PPE.

Following formulation of the end use products, exposure to the notified polymer is expected to be reduced further due to the low concentration of the notified polymer (< 2.5%) and the expected use of PPE.

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

Since the notified polymer will be in products sold to the general public, widespread public exposure to the notified polymer at a concentration up to 2.5% is expected.

##### *Systemic exposure*

Based on an exposure estimate for multiple use of a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal and inhalation) to the notified polymer through use of a wide range of products containing the notified polymer, is estimated to be up to 6.6 mg/kg bw/day, assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 2.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified polymer and uses the maximum ‘product amount used’ from the range in the dataset.

Maximum single product use exposure is expected for the products: fragrance cream, facial moisturiser, body lotions and hand moisturiser. Exposure to the notified polymer in these products assuming a bodyweight of 60kg, a 100% dermal absorption factor, a concentration of 2.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe, is as follows:

Fragrance cream: 0.6 mg/kg bw/day  
Facial moisturiser: 0.7 mg/kg bw/day  
Body lotion: 2.3 mg/kg bw/day  
Hand moisturiser: 2.3 mg/kg bw/day

If the notified polymer is used in baby care products, a child's exposure is estimated to be 8.1 mg/kg bw/day assuming a bodyweight of 15kg, a 100% dermal absorption factor, a concentration of 2.5% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified polymer are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

#### *Estimated dermal exposure*

The estimated dermal exposure is calculated for the personal care product containing the notified polymer based on SSCNFP 2003 as follows:

Product category	Grams/application	Area of dermal exposure (cm <sup>2</sup> )	Calculated dermal exposure per application in µg/cm <sup>2</sup>
Hair shampoo	8.0	1440	140
Hair conditioner	14.0	1440	240
Hair styling gel or mousse	5.0	1010	124
Liquid shower soap	5.0	17500	7.1
Face cream	0.8	565	35
Body lotion	8.0	15670	13
Hand cream (general purpose cream)	1.2	860	35

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

The acute oral toxicity of the notified polymer was evaluated in rats and it was regarded as orally non-toxic with an LD50 > 5 g/kg.

The skin irritation of the notified polymer was evaluated in rabbits and it was regarded as a non-primary irritant. The eye irritation of the notified polymer was evaluated in rabbits and it was regarded to be non-irritating to eyes.

The skin sensitisation potential of the notified polymer was evaluated in the mouse. Slight erythema was noted in the treated ears of the animals of the main study. The largest nodes were found in the higher dose groups. No other macroscopic abnormalities of the nodes were noted. The stimulation index (SI) was determined to be 2.1, 1.1, 7.6 and 19.3 at 5%, 10%, 50% and 100% respectively. Based on these results and according to the recommendations made in the test guidelines, the notified polymer should be regarded as a skin sensitiser.

Based on the available data, the notified polymer is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

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

Due to the high molecular weight of the notified polymer, dermal and oral absorption is unlikely. The low volatility of the notified polymer will restrict the possibility of exposure through inhalation. Although the notified polymer was found to be a skin sensitiser in a mouse local lymph node assay (LLNA), exposure of workers will be minimised by the use of safety glasses, gloves and overalls.

Once the final consumer product is packed, exposure should be low. Hence, exposure for warehousing and distribution workers and retail workers is unlikely unless the packaging is breached.

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

Consumer dermal exposure to personal care products containing up to 2.5% of the notified

polymer will be widespread, through deliberate application of the products to skin or hair. Due to the high molecular weight of the polymer, dermal absorption is unlikely. The low volatility of the notified polymer will preclude the possibility of exposure through inhalation. However, inhalation exposure may occur if a product is in spray form and aerosols are generated. The estimated exposure for members of the public using the products containing notified polymer will be varied depending on the type of product and the concentration of notified polymer.

Based on available data, the notified polymer is of low acute toxicity and is non-irritant to eyes and skin. It was sensitising in a mouse local lymph node assay (LLNA), with an EC3 of 21.7%, and may be described as a moderate sensitiser.

As dermal absorption of the polymer is not likely to occur and acute toxicity is low, the risk to the public through systemic effects is estimated to be low.

There is a risk of sensitisation to consumers using personal care products. Calculations of exposure per unit area of skin have been made for the proposed product categories using the maximum proposed concentration of 2.5%.

Calculations below are estimates of maximum dermal exposure in  $\mu\text{g}/\text{cm}^2$ , relevant to the risk of skin sensitisation, and are based on a concentration of 2.5% in products. Using this predicted exposure information and the skin potency value of  $5425 \mu\text{g}/\text{cm}^2$  derived from the LLNA, Indicative estimates of risk and margin of safety have been made. This calculation was done using the fact that the LLNA was performed by applying  $25 \mu\text{L}$  of test solution to  $\sim 1 \text{ cm}^2$  of the mouse's ear. The conversion assumed that  $1 \text{ mL} = 1 \text{ g}$ . Using this data, the amount of test solution applied to the mouse ear was  $25 \mu\text{L}$  assumed to be  $25 \text{ mg}$ . The calculated EC3 concentration was 21.7%, so the quantity of polymer causing sensitisation was  $0.217 \times 25\,000 \mu\text{g} = 5425 \mu\text{g}/\text{cm}^2$ .

Product category	Calculated dermal exposure per application in $\mu\text{g}/\text{cm}^2$ #	Margin of safety
Hair shampoo	140	39*
Hair conditioner	240	23*
Hair styling gel or mousse	124	44*
Liquid shower soap	7.1	760
Face cream	35	160
Body lotion	13	420
Hand cream (general purpose cream)	35	160

#See Estimated dermal exposure in section 9.2.2

\*The margin of safety would be increased above these calculated values, because part of the exposure will be to the hair rather than the skin.

The above calculations give varying margins of safety for use of different personal care product categories. For the risk of sensitisation, most margins of safety were estimated to be  $> 100$ , as recommended by the SCCNFP 2003, however those for some hair treatment products were below 100. The margins of safety for these products would be higher than calculated because no allowance has been made for product which would be in contact with hair rather than skin.

Overall the risk of skin sensitisation in consumers cannot be ruled out for personal care products containing the notified polymer but is considered to be unlikely for most product categories. It is considered that use of "leave-on" skin or hair products would present a higher risk of sensitisation than the equivalent "wash-off" product, if all other factors remain the same. It is possible that children may have a high risk of sensitisation.

Since products formulated with the notified polymer will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified polymer by accidental ingestion. However, as the notified polymer is considered to be of low acute toxicity and given the low concentration of the notified polymer in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be 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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi: irritant

R43 may cause sensitisation by skin contact

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Skin sensitisation	1	May cause allergic skin reaction

### 10.2. Environmental risk assessment

The notified 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 Low Concern to public health when used in the proposed manner, with precautions to avoid and monitor any sensitisation.

## 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

### REGULATORY CONTROLS

#### Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified polymer:
  - Xi: irritant
  - R43 may cause sensitisation by skin contact

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

#### Health Surveillance

- As the notified polymer is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

#### CONTROL MEASURES

##### Occupational Health and Safety

- Appropriate engineering controls, work practices and personal protective equipment should be used to prevent dermal contact of workers to the notified chemical as introduced, and in formulated products.

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.
- The MSDS for products containing the notified polymer at  $\geq 1\%$  should include the relevant risk phrase and include precautions to avoid sensitisation of workers.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

##### Public Health

- Any adverse health effects resulting from use of the notified polymer in consumer products should be reported to NICNAS.
- The following measures should be taken by industry to minimise the risk to the public from skin sensitisation:
  - Importers and marketers of the notified polymer should inform formulators of the potential for sensitisation
  - Formulators, importers and marketers of personal care products containing the notified polymer should take account of the sensitisation potential, the pattern of use and whether the product is retained on the skin and, if warranted, should limit the concentration in the product.

##### Environment

##### Disposal

- The notified polymer should be disposed of by incineration.

##### Storage

The following precautions should be taken: keep container close when not use. Empty containers product residue which may exhibit hazards of product.

##### Emergency procedures

- Spills/release of the notified chemical should be handled by prevent to enter into the sewers and waterways. Pick up free liquids for recycle and/or disposal. Residual liquid can be adsorbed on inert material.

### 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 concentration of the chemical in personal care consumer products exceeds 2.5%.
  - the notified polymer is incorporated in personal care products that will be used in the workplace eg hairdressing or beauty salons.
  - the notified polymer is used in personal care products specifically marketed for babies or children.
  - The notified polymer is in a product of a spray form.
  - further information becomes available on the sensitisation potential of the notified polymer

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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