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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dow Corning® 8500 Conditioning Agent

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Dow Corning® 8500 Conditioning Agent

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty Ltd (ABN 36 008 444 166)
3 Innovation Road
Macquarie University Research Park
North Ryde NSW 2113

NOTIFICATION CATEGORY
Limited-small volume: Polymer with NAMW ≥ 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Identity of Chemical; and
Composition

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point;
Vapour pressure;
Hydrolysis as a function of pH;
Partition coefficient;
Absorption/desorption;
Dissociation constant;
Particle size;
Flammability limits;
Autoignition temperature;
Explosive properties; and
Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US (PMN 000317, 2000)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Aminofunctional siloxane

MARKETING NAME(S)
Dow Corning® 8500 Conditioning Agent

3. COMPOSITION

DEGREE OF PURITY
<90%

DEGRADATION PRODUCTS
Thermal decomposition products of the notified polymer during fire or high temperature conditions may include carbon oxides, traces of incompletely burned carbon compounds, silicon dioxide and formaldehyde.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None known

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 as a polymer concentrate at 87% and will be stored at the notifier's warehouse prior to distribution to local hair care product formulators. Alternatively, the notified polymer will be imported as formulated hair care products containing <4% notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1	1	1	1

USE
Component of hair care products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not known

IDENTITY OF MANUFACTURER/RECIPIENTS
Dow Corning Australia Pty Ltd (ABN 36 008 444 166)
3 Innovation Road
Macquarie University Research Park
North Ryde NSW 2113

TRANSPORTATION AND PACKAGING
The notified polymer will be packed, stored and transported in 18 kg pails or 190 kg drums. Alternatively, the notified polymer will be imported as formulated hair care products packed in 200 to 500 mL plastic bottles.

The notified polymer will be transported by road from the notifier's warehouse to hair care manufacturers for formulation into hair care products. Locally manufactured or imported formulated hair care products are delivered by road to retail distribution centres prior to distribution to retail outlets.

5.2. Operation Description
The notified polymer will be imported into Australia for subsequent formulation into hair care products. The notified polymer will be poured manually into either an open or closed mixer. The blend will be mixed using a paddle mixer and the resulting mixture will be fed through an enclosed system to an automatic packaging machine, where the product is fed into 200 to 500 mL plastic bottles.

The bottled products will be packed in cardboard cartons and will be sent to retail distribution centres for storage until distribution to retail outlets.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Stevedoring workers	1-5	1	5
Transport	1-5	2	5
Warehouse	1-5	5	10
Reformulation	5-15	8	30

Exposure Details

Warehousing and distribution of the notified polymer involves loading, unloading, moving and storing of packaged notified polymer and packaged hair care products. No exposure is expected except in the case of accident.

Workers involved in reformulation may have dermal and limited ocular exposure to the notified polymer when opening and closing pails or drums, manually pouring the notified polymer into the mixer, connecting and disconnecting transfer lines and when overfilling plastic containers during packaging operations. Skin contamination of maintenance workers can also occur when cleaning equipment and during routine maintenance

Local exhaust ventilation is in operation during reformulation. Filling machines are enclosed and automated. Workers will wear chemical goggles, appropriate gloves and aprons.

The bottled products will be sent to retail distribution centres for storage until distribution to retail outlets. Except in the case of accident, workers handling the finished product during distribution and retail would not be exposed to the notified polymer because of the closed containers, and even in the case of spills, the small packaging size and the low concentration of the notified polymer in the finished products would limit exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental exposure associated with the manufacture of the notified polymer will not occur in Australia. The imported form contains 87% notified polymer. Up to 2.5 kg of the notified polymer is expected to be left in the mixing and packaging equipment during reformulation. This waste will be treated as site industrial waste and dealt with by licensed disposal contractors. A small amount (unspecified) may accidentally be released into the sewer. The residue left in import containers is estimated to be 2.5 kg, which will be disposed of in landfill.

RELEASE OF CHEMICAL FROM USE

The total quantity of the notified polymer imported will be incorporated into a hair care product and will almost completely be released to the environment through washing of hair. Residues in the consumer product containers that will be disposed of to landfill via domestic garbage collection are expected to be 2.5 kg.

5.5. Disposal

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

5.6. Public exposure

There will be a widespread and repeated public exposure to the notified polymer since it is going to be a component of hair care products. There is also a slight chance of ingestion of the notified polymer. However, the hair care products contain low levels of the notified polymer.

The potential for exposure of the public to the notified polymer during normal industrial storage, handling and transportation is negligible, except in the case of an accident. The packaging will protect the contents from being released during normal handling

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Translucent white liquid

Boiling Point >35 ºC

Remarks Test report not provided.

Density 960 kg/m^3 at 25 ºC

Vapour Pressure Not determined

Remarks The notified polymer is unlikely to be volatile due to its high molecular weight and likely cationic nature. It is claimed that the vapour pressure will be less than 1.0 X 10^{-4} Pa at 25 ºC. The impurities present will be volatile.

Water Solubility ≥ 4.3 X 10^{-8} g/L

METHOD Not specified (referred to as a non-regulated study)

Remarks The amount of the test substance present in water was quantified under both rapid and slow-stir conditions. During the slow-stir test, the test substance was added in excess (500 mg/L) to the surface of several types of water. Stirring (using magnetic stir plates) was done at the lowest setting and was stopped during collection of samples. An excess of sodium chloride was added to aliquots removed periodically from the bottom of the vessels, extracted with xylene and analysed by inductively coupled plasma (ICP) for silicon content. The clear polymer floating on the surface of the water turned white and expanded (within a few days), white tendrils of polymer became visible under the surface in some vessels (after 1-2 weeks) and the aqueous phase turned from clear to hazy in some vessels.

Excess product was observed to separate from the aqueous phase and float to the surface during a stability test when a rapid stir method (with approximately 1 g/L applied) was used.

The results were reported as concentrations of silicone, however, it was concluded that the method used was not capable of absolute measurement of test substance concentrations. The solubility is below that determined by the US EPA to require aquatic toxicity testing.

TEST FACILITY Dow Corning (2001)

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer is not expected to hydrolyse significantly in the environmental pH range of 4 to 9 as there are no hydrolysable groups present.

Partition Coefficient (n-octanol/water) Not determined

Remarks Given that the notified polymer is a silicone with a high molecular weight, a class characterised by very low water solubilities, its log P_{ow} is expected to be greater than 20. This is consistent with the low water solubility indicating likely partitioning into the octanol phase and a high affinity for the organic phase and component of soils and sediments.

Adsorption/Desorption Not determined

Remarks The low water solubility of the notified polymer indicate strong adsorption to and low mobility in soils.

Dissociation Constant Not determined

Remarks The notified polymer contains an amine group, which could be expected to have a pKa of approximately 9-10. The polymer, however, is not expected to dissociate due to its low water solubility.

Particle Size Not determined.

Remarks The notified polymer will be imported in a liquid form.

Viscosity 4000 cSt

Remarks Test report not provided.

Flash Point >100ºC (Closed cup)

Remarks Test report not provided

Flammability Limits Not determined

Remarks The notified polymer is not expected to be flammable based on its chemical structure.

TEST FACILITY

Autoignition Temperature Not determined

Remarks The notified polymer is not expected to self-ignite based on its chemical structure.

Explosive Properties Not determined

Remarks The notified polymer is not expected to have explosive properties based on its chemical structure.

Reactivity

Remarks The notified polymer is expected to be stable under normal environmental conditions. It can react with strong oxidising agent. If heated to >150ºC, trace quantities of formaldehyde may be emitted.

7. TOXICOLOGICAL INVESTIGATIONS

A 28-day subchronic oral toxicity test report and a bacterial mutation assay for the polymer concentrate containing 87% notified polymer have been provided. In addition, a summary of animal studies conducted on a similar substance, Dow Corning X2-8357, was also provided as "read across" data for the notified polymer. It is proposed that the notified polymer will have similar toxicological profile to that of Dow Corning X2-8357 based on the similarities in chemical structure.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >1500 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Rat, <oral gavage> repeat dose toxicity - 28 days.	1000 mg/kg bw (NOAEL)
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Dow Corning X2-8357 (Analogue polymer)

LD50	>15000 mg/kg bw
Remarks - Results	The test report was not provided. A brief summary report was provided, which states that the study is an internal technical research report. Signs of toxicity or effects in the organ were not reported.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Stanton (1988)

7.4. Irritation – skin

TEST SUBSTANCE	Dow Corning X2-8357 (Analogue polymer)
RESULTS	
Remarks - Results	The test report was not provided. A summary of an internal technical research report states that a single semi-occluded skin contact for 24 hours resulted in slight redness. Repeated prolonged contact to the skin also caused slight redness.
CONCLUSION	The test substance is slightly irritating to skin.
TEST FACILITY	Stanton (1988)

7.5. Irritation - eye

TEST SUBSTANCE	Dow Corning X2-8357 (Analogue polymer)
Remarks - Results	The test report was not provided. A summary of an internal technical research report states that direct eye contact resulted in slight conjunctival redness and very slight injury to the corneal tissue, which disappeared within 24 hours.
CONCLUSION	The test substance is slightly irritating to the eye.
TEST FACILITY	Stanton (1988)

7.6. Skin sensitisation

TEST SUBSTANCE	Dow Corning X2-8357 (Analogue polymer)
Species/Strain	Guinea pig
Number of Animals	Test Group: 20 males Control Group: 10 males
Remarks - Results	The test report was not provided. A summary of an internal technical research report states that there was no evidence of skin irritation or sensitisation observed in any of the test or negative control groups using a Maximisation Test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Hoffman et al (1988)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified polymer (Product containing 87% notified polymer)

METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. US-EPA TG 870.3050 Chronic Toxicity
Species/Strain	Rat/CD® IGS
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 (males) and 29 (females) days Dose regimen: 7 days per week
Vehicle	Tween®80K, Span®80K and Milli-Q water
Remarks - Method	Microscopic examination was confined to control and high dose groups, except for the kidneys of the females where additional examinations were required to resolve the initial observations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10/sex	0	1
II (low dose)	10/sex	125	0
III (mid dose)	10/sex	500	0
IV (high dose)	10/sex	1000	0

Mortality and Time to Death

There were no unscheduled deaths during the study, except for one male in the control group, which was sacrificed on Day 11 because of pain and distress. The effects were reported to be associated with an inadvertent perforation of the oesophagus during dosing.

Clinical Observations

Clinical observations noted in a number of animals in all groups include alopecia (in forelegs, neck, ventral chest and ventral abdominal region), probable porphyrin staining, wet muzzle or laboured respiration. Other observations noted occasionally include bloody toe(s) or toenail (s), blood on chin, soft squeaky vocalisations, red material around the eye, and wet forelegs.

No significant treatment related effects were seen on body weights, food consumption, motor activity and functional observational battery assessments between control and treated groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No significant treatment related effects on haematological indices or clinical chemistry parameters at the end of treatment. Urinalysis was not performed.

Effects in Organs

A significantly greater mean liver to body weight ratio was confined to females in mid-dose group and therefore, was not considered to be treatment related. Only scattered incidence of macroscopic abnormalities was observed, with no apparent relation to treatment.

Non-dose related microscopic findings include slight bronchial hyperplasia, hypertrophy in the lung, minimal to slight lung inflammation, moderate pleuritis, perforation with mucosal herniation through damaged muscle cells, which are attributed to gavage dosing. These findings did not interfere with the evaluation of any effects related to the notified polymer.

Minimal tubular basophilia in the kidneys and minimal inflammation in the kidneys was observed at higher incidence in high dose females than control females, but examination of other female groups showed that this finding was not dose dependent; also similar incidence was seen in both control and high dose males. Other findings which occurred spontaneously and not considered as treatment related include minimal inflammation of the kidney characterised by one or two small aggregates of lymphocytes in the cortical interstitium, moderate bilateral chronic inflammation, slight dilatation of the renal pelvis with slight diffuse hyperplasia, and minimal chronic inflammation of the urinary bladder.

Remarks – Results

The occurrence of minimal tubular basophilia in all groups showed a lack of dose response in incidence or severity in females, or treatment-related increase in males. Basophilia is an indication of recent cell division and a common spontaneous finding in these strains of experimental animals.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the absence of treatment related organ or systemic toxicity at any dose.

TEST FACILITY Dow Corning Corporation (2003)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notified polymer (Product containing 87% notified polymer)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9
Concentration Range in Main Test	Experiment 1 a) With metabolic activation: 33 to 5000 µg/plate. b) Without metabolic activation: 33 to 5000 µg/plate. Experiment 2 a) With metabolic activation: 10 to 5000 µg/plate. b) Without metabolic activation: 10 to 5000 µg/plate
Vehicle	Acetone
Remarks – Method	Two independent experiments were performed in triplicate. The first experiment was conducted using a plate incorporation procedure and the second experiment by pre-incubation procedure.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Experiment 1	1000 to 5000 (TA1535); 5000 (TA100)	None	None
Experiment 2	1000 to 5000 (TA98); 5000 (TA100)	1000 to 5000 (TA98 and WP2 urvA); 5000 (TA100)	None
Present			
Experiment 1	5000 (TA100)	None	None
Experiment 2	None	2500 and 5000 (TA98); 5000 (WP2 urvA)	None

Remarks - Results	In the preliminary test, irregular background growth in strains TA1535 without S9 and TA100 without S9 was noted at 5000 µg/plate. In experiment 1, toxicity as evidenced by a slight decrease in the number of revertant colonies was observed in TA1535 without metabolic activation at doses 1000 to 5000 µg/plate and TA100 with or without metabolic activation at 5000 µg/plate. In experiment 2, toxicity as evidenced by a slight decrease in the number of revertant colonies was observed in TA98 without S9 and TA100 without S9 at doses 1000 to 5000 µg/plate and 5000 µg/plate, respectively. Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC-Cytotest Cell Research GmbH (2003)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Dow Corning ® Q2-8413 Polymer (Analogue polymer)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Official Journal of the European Communities:Method C.4-C
Inoculum	Activated sludge from a wastewater treatment plant which receives predominantly domestic sewage.
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Total Organic Carbon and Dissolved Organic Carbon
Remarks - Method	In addition to the test substance (20 mg C/L), blank samples and samples containing a reference substance (sodium benzoate at 20 mg C/L) were measured.

RESULTS

Time (Day)	*% $ThCO_2$ produced*	
	Test substance	*Reference Substance*
2	0.20	42.30
5	3.73	72.06
16	6.00	88.00
28	8.80	88.92
29	13.10	91.79

Remarks - Results	After 29 days, the % $ThCO_2$ observed for the test substance was 13.1 thus the test substance cannot be classified as readily biodegradable. The % $ThCO_2$ for the reference substance was 72.06% by day 5 thus validating the study.
CONCLUSION	Based on the results of this study the test substance is not readily biodegradable.
TEST FACILITY	ABC Laboratories (2000)

8.1.2. Ready biodegradability

TEST SUBSTANCE	Dow Corning ® Q2-8220 Conditioning Additive or Dow Corning ® Q2-8075 Amino Functional Fluid (Analogue polymer)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Official Journal of the European Communities:Method C.4-C
Inoculum	Activated sludge from a wastewater treatment plant which receives predominantly domestic sewage.
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	Total Organic Carbon and Dissolved Organic Carbon
Remarks - Method	In addition to the test substance (20 mg C/L), blank samples and samples containing a reference substance (sodium benzoate at 20 mg C/L) were measured.

RESULTS

Time (Day)	*% $ThCO_2$ produced*	
	Test substance	*Reference Substance*
2	0.00	38.53
8	0.00	81.11
15	0.14	91.22
28	0.21	95.15
29	0.43	96.53

Remarks - Results: After 29 days, the % $ThCO_2$ observed for the test substance was 0.43 thus the test substance cannot be classified as readily biodegradable. The % $ThCO_2$ for the reference substance was 65.95% by day 5 thus validating the study.

CONCLUSION: Based on the results of this study the test substance is not readily biodegradable.

TEST FACILITY: ABC Laboratories (1999a)

8.1.3. Bioaccumulation

No bioaccumulation data were provided. The very low water solubility of the notified polymer may indicate a potential for bioaccumulation. However, the high molecular weight will limit bioaccumulation. In literature published by Dow Corning, it states that polydimethylsiloxanes do not bioaccumulate (Dow Corning 1999a).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Dow Corning ® 8500 Conditioning Agent (Product containing 87% notified polymer)

METHOD: OPPTS Test Guideline 850.1075 Fish Acute Toxicity Test, Freshwater and Marine -Static

Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	Acetone (at 0.1 mL/L in all treatments and solvent control)
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	None

Remarks – Method: The temperature and dissolved oxygen content were maintained satisfactorily. The measurements of pH ranged from 7.9 to 8.4 with some pH measurements in test and control solutions exceeding 8.0 (up to 48 hours only).

The test solutions were prepared by mixing the test substance with acetone (solvent stocks), which were then mixed with pH adjusted dilution water at pH 7.0 (aqueous stocks). The aqueous stocks were mixed with dilution water to obtain the required test concentrations and stirred for approximately 1 minute.

Two exceptions to the guidelines were reported. The test concentrations significantly exceeded the water solubility and the nominal test concentrations exceeded 120% of one concentration level to the next higher level of concentration.

All test solutions up to the 32 mg/L solution were cloudy with the cloudiness increased with increasing concentration. The 100 mg/L solution appeared less cloudy than the 32 mg/L test solution.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*% Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
Control	20	0	0	0	0
Solvent control	20	0			
1.0	20	0	0	0	0
3.2	20	0	0	0	0
10	20	0	0	0	0
32	20	0	0	0	0
100	20	0*	0	0*	5.9*

* One fish found cannibalised at 24, 72 and 96 hours (excluded from the cumulative number of dead fish).

LC50	> 100 mg/L at 96 hours.
NOEC (or LOEC)	32 mg/L at 96 hours.
Remarks – Results	One fish was found dead in one of the two replicates of the highest test concentration, while all fish in the other replicate appeared normal and healthy throughout the test. This death was considered in determining the mortality but the three fish cannibalised were excluded from the survival percentage for this group (1 dead out of 17 fish exposed).

CONCLUSION — The test substance is not toxic to fish up to its limit of water solubility.

TEST FACILITY — Dow Corning (2002)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — Dow Corning ® Q2-8413 Polymer (Analogue polymer)

METHOD — Not specified.
Static test

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	210 mg/L (Total hardness)
Analytical Monitoring	Inductively coupled plasma (ICP) Emission Spectroscopy
Remarks - Method	Test solutions were generated by preparing water accommodated fraction (WAF) and water soluble fraction (WSF) of the test substance (10 g/L loading). Test substance was placed on top of culture water contained in a vessel fitted with a stopcock drain near the bottom (for convenient sampling of aqueous phase). Water was stirred using a magnetic stir bar generating a vortex for 24 hours and the contents were allowed to stand for approximately for 24 hours. The aqueous phase was withdrawn via the stopcock drain (WAF). A gas tight syringe with Teflon-tipped plunger fitted with a 0.45 micron filter disk was filled with the WAF solution. The first 5 mL of the filtrate was discarded and the rest collected (WSF). The actual compositions of the WAF and WSF were not determined, however, their silicone levels were determined by ICP. Test substance concentrations were expressed based on the conversion of silicone levels. The method deviations reported were some daphnids being slightly older than specified in protocol and no individual temperature observations made at termination. The temperature of the environmental chamber where test vessels were placed was monitored continuously (designed to maintain 22 ± 2 °C These were mentioned not to have impacted on the validity of the study. The pH and dissolved oxygen levels were maintained satisfactorily.

RESULTS

LC50	> 5 mg/L at 48 hours (based on the ICP analysis of silicone levels as explained below)
NOEC	Not determined
Remarks - Results	There were no mortalities in the WAF or WSF. Five entrapments were observed in the WAF test solutions. Entrapment was observed in the WAF (less than 10% at 48 hours) but not in WSF replicates. The results of the ICP analysis showed that the silicone (and the corresponding test substance) levels were less than 65% of initial levels (3000 ppb) after 48 hours indicating that the WAF and WSF test solutions were not stable for the duration of the test. Based on these results the EC50 value has been expressed as the average of the 0 and 48 hour concentrations.
CONCLUSION	The test substance is not toxic to daphnia up to its limit of water solubility since deaths observed in the WAF are clearly physical.
TEST FACILITY	Dow Corning (1999b)

8.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Dow Corning ® Q2-8413 Polymer (Analogue polymer)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge collected from a wastewater treatment plant
Exposure Period	3 hours
Concentration Range Nominal	Five test concentrations between 20 and 100 mg/L, two controls and an abiotic control. The test substance was added directly to the appropriate contact flasks on a gravimetric basis. A known inhibitor of respiration as a control for positive inhibition (3,5-dichlorophenol at 3.2, 10 and 32 mg/L) was tested in parallel with two controls.
Remarks – Method	The test was performed as a preliminary test, however, it was not followed up with a definitive test.
RESULTS	
IC50	Could not be determined
NOEC	Not reported
Remarks – Results	All test concentrations showed ≤ 10% inhibition. The respiration rates of control samples were within 15% acceptance criteria. The EC50 of the reference substance was 27 mg/L (within the 5 to 30 mg/L range as required by the guidelines), thus validating the test.
CONCLUSION	The test substance does not show any significant inhibition up to a concentration of 100 mg/L.
TEST FACILITY	ABC Laboratories (1999b)

8.2.4. Microtox assay

TEST SUBSTANCE	Dow Corning ® Q2-8413 Polymer (Analogue polymer)
METHOD	Standard Microtox Test System
Species	Microtox® bioluminescent bacterium (*Vibrio fischeri*) – Microtox Reagent
Exposure Period	15 minutes
Concentration Range	Eight test concentrations between 0.7 and 90 mg/L

Nominal	
Remarks - Method	A phenol (reference article) standard test was conducted to demonstrate the viability of the test system. The test substance was dissolved in ethanol to prepare a stock solution of (10,000 mg/L), which appeared to be homogeneous cloudy white dispersion indicating that the substance was not completely soluble in ethanol. Due to an inadvertent timing error timing of light output readings may have been early up to a minute, however, due to the lack of inhibition it was considered not to have had an effect on the results.
RESULTS	
EC50	≥ 90 mg/L
NOEC	90 mg/L (highest test concentration)
Remarks - Results	The EC50 for the phenol standard was 16.2 mg/L (within the acceptable range of 13 to 26 mg/L) indicating that the Microtox Reagent has retained appropriate sensitivity and validating the test system viability. No inhibition was observed at any of the test concentrations and the 5 minute and 15 minute and the EC50 was considered to be greater than 90 mg/L.
CONCLUSION	The test substance did not inhibit the multiplication of the aquatic bacterium, *Vibrio fischeri*.
TEST FACILITY	Dow Corning (1999c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the imported notified polymer would eventually be discharged into sewerage systems through washing of hair. Release of only up to 8 kg per annum is expected during the reformulation process and as residues in import and consumer containers. Most of this will be disposed of in landfill with a very small amount which may be accidentally released to the sewer at the reformulation sites.

The notified polymer is poorly soluble in water thus is expected to be relatively immobile in both the aquatic and terrestrial compartments. Although not readily biodegradable, if any notified polymer adsorbed onto sludge is applied to soil, it is likely to be gradually degraded to natural components. In dry soils, silicone polymers such as the notified polymer are expected to be rapidly hydrolysed due to abiotic processes (Dow Corning 1998). Residual polymer disposed of to landfill with empty containers can also be expected to be adsorbed to soil particles and will eventually be degraded through biological and abiotic processes. The very low water solubility of the notified polymer may indicate a potential for bioaccumulation. However, the high molecular weight will limit bioaccumulation.

As the majority of the notified polymer in the hair care products will eventually be released into the aquatic environment via the sewerage systems the predicted environmental concentration (PEC) in the aquatic environment is estimated using the following worst-case scenario.

Assuming that the majority of the imported polymer 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 2.74 kg/day, based on a maximum import of 1 tonne per annum. Based on a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the PEC in sewage effluent on a nationwide basis is estimated as 0.6849 µg/L. Based on dilution factors of 1 and 10 for inland and ocean discharges of STP treated effluents, the PECs of the notified polymer in freshwater and marine water may approximate

0.6849 µg/L or 0.0685 µg/L, respectively.

9.1.2. Environment – effects assessment

The ready biodegradability test, acute toxicity to daphnia, inhibition of microbial activity and microtox studies were conducted using an analogue polymer, which has different disposition of amino functionalities compared with the notified polymer. Therefore, the environmental behaviour and toxicity of the notified polymer may be different from those exhibited by the analogue polymer.

The results of the aquatic toxicity tests are listed below. No data for algal toxicity have been provided although algae are likely to be the most sensitive species (Nabholz 1993).

Organism	*Duration*	*End Point*	*mg/L*
Fish	96-h	LC50	>100
Daphnia (based on a analogue polymer)	48-h	EC50	>5 (based on WAF/WSF – loading rate of 10 g/L)

Using the lowest EC50 datum (ie. >5 mg/L), a predicted no effect concentration (PNEC for aquatic ecosystems) >5 µg/L was derived by dividing the LC50 value by an uncertainty (safety) factor of 1000 (since only results for two trophic levels, including one for an analogue were provided and algae is most likely to be the more sensitive species).

9.1.3. Environment – risk characterisation

The risk quotient (PEC/PNEC) value estimated based on the scenario of discharging the entire imported notified polymer into sewage systems in Australia is <0.14.

The actual PECs can be also expected to be lower, given that the concentration of the notified polymer in aquatic environment will further reduce due to:

- removal via treatment (as the notified polymer is expected to be adsorbed to sludge) and/or degradation in the liquid waste and sewerage treatment facilities; and
- adsorption to sediment and further degradation in the aquatic environment.

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very diffused and it is unlikely that it would exist at levels that could pose a threat to aquatic organisms. Although it has low water solubility, the high molecular weight of the polymer indicates a low potential to bioaccumulate. Although the notified polymer is not considered to be readily biodegradable, it is expected to eventually degrade due to abiotic or slow biotic processes.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to the notified polymer is expected to primarily occur during reformulation of personal care products, especially when manually pouring the notified polymer into the mixer where the final products are produce. Subsequent operations such as mixing and packaging are enclosed and automated and involve the notified polymer at much lower concentrations, and therefore, exposure to the notified polymer is expected to be reduced. During reformulation and packaging, workers are clad with chemical goggles, appropriate gloves and aprons to prevent dermal and ocular exposure to the notified polymer and the products containing it. Local exhaust ventilation is in place to capture any volatiles during the formulation process.

Dermal contact with the formulated product is also possible during equipment cleaning and routine maintenance. However, such exposures are expected to be low since the final products will contain low levels of the notified polymer (<4%).

Exposure to waterside, warehouse and transport workers is low considering the handling of sealed packages of the notified polymer and products containing it. Distribution, warehouse and retail workers will have negligible exposure as these workers will only handle sealed containers of finished products.

9.2.2. Public health – exposure assessment

There will be significant public exposure to the notified polymer as it will be used in personal care products. There is a possibility of eye exposure to the notified polymer when used in a personal care product. There is also a slight chance of ingestion of the notified polymer although the quantities consumed would be minimal. The concentration of the notified polymer in finished products would be less than <4%.

9.2.3. Human health - effects assessment

A 28-day oral repeat dose and bacterial mutation studies were provided for the notified polymer. Studies conducted on an analogue polymer were also provided as read across data for the acute toxicological properties of the notified polymer.

The notified polymer is expected to have low acute oral toxicity. Although animal studies conducted on a polymer similar to the notified polymer demonstrated a slight skin and eye irritation effects, the notifier classified the notified polymer as a skin and eye irritant based on the amino functional group present at a higher level in the notified polymer than in the analogue polymer. Therefore, skin and eye contact during reformulation and packaging operations should be avoided. An analogue polymer did not show any sensitising potential.

Upon repeated exposure, the notified polymer did not cause any adverse effects. The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day (the highest dose tested) in this study. The notified polymer was not mutagenic in bacteria.

On the basis of the data supplied, there is insufficient information to classify the notified polymer as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, the notifier classified the notified polymer as a hazardous substance based on the amino functional group present in the polymer. The notifier classified the notified polymer as an Irritant (Xi) and has given the risk phrases R36/R38 – Irritating to eyes and skin.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer will be imported as a polymer concentrate containing 87% notified polymer, and subsequently reformulated into personal care products containing <4% notified polymer. Alternatively, the notified polymer will be imported as a component of finished hair care products. The majority of reformulation process is enclosed and automated. However, addition of the notified polymer to the mixer involves manual operations. Exposure is limited to dermal and to a lesser extent ocular when manually pouring the notified polymer into the mixer. Although exposures may also occur when overfilling containers, cleaning equipment and during maintenance operations, such exposures are expected to be intermittent. The notified polymer may have skin and eye irritation potential based on the presence of amino functional group. However, the limited and intermittent exposure during reformulation and packaging is not expected to pose a significant hazard to human health.

Based on the low probability of exposure and the engineering controls available to these workers, the health risk for workers involved in reformulation and packaging of personal care products is assessed as low. The health risk for workers handling the packaged finished products during distribution and retailing will be negligible.

The potential for exposure during storage and transport would also be considered low and would only be envisaged following accidental spillage or damage of the containers. Therefore, the health risk for transport workers would also be assessed as low.

9.2.5. Public health – risk characterisation

Public exposure to the notified polymer will arise from using hair care products containing the notified polymer. The exposure is expected to be widespread and repeated. There is also a slight chance of ingestion of the notified polymer. A 10 kg child ingesting 5 mL of a 4% solution

would receive a dose of approximately 20 mg/kg bw which is significantly below the lethal dose (LD_{50} > 15000 mg/kg bw) for an analogous polymer and the NOAEL for the notified polymer. The polymer has a low acute oral toxicity and the quantities consumed would be minimal. The notified polymer has skin and eye irritation potential. Given the intermittent exposure and low concentration of the notified polymer in the hair care products, the risk to the public health is considered as a low.

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

10.1. Hazard classification

On the basis of the data supplied, there is insufficient information to classify the notified polymer as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, the notifier classified the notified polymer as a hazardous substance based on the amino functional group present in the polymer. The notifier classified the notified polymer as an Irritant (Xi) and has given the risk phrases R36/R38 – Irritating to eyes and skin.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio 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 a component of hair care 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 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 introduced:
  - Local exhaust ventilation during transfer and mixing operations

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - During transfer operations and cleaning equipment, avoid spills and splashing.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Chemical resistant gloves, safety glasses, protective clothing or equivalent when handling the notified polymer

  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.

Environment

Disposal

- The notified polymer or material used in the clean up of spills should be disposed to landfill in accordance with local regulations.
- Dispose empty import containers in accordance with regional and/or national regulations.

Emergency procedures

- Spills/release of the notified polymer should be prevented from spreading or entering into drains, ditches or rivers by using sand, earth or other appropriate barriers.
- If diked material can be pumped, store recovered material in appropriate container. Clean up any remaining material with suitable absorbent.

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:

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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