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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dow Corning 7-9030 Quaternary Ammonium Functional Silicone

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Dow Corning 7-6030 Quaternary Ammonium Functional Silicone

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: Polymer with NAMW ≥ 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; 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

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Aminofunctional siloxane
Material No: 04017046

MARKETING NAME(S)
Dow Corning 7-6030 Quaternary Ammonium Functional Silicone

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

DEGRADATION PRODUCTS
Thermal decomposition products during fire or very high temperature conditions may include carbon dioxides, 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 at >90% 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. The formulated hair care products will contain <1% notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	1-10	1-10

USE
Component of hair care products such as shampoo and conditioner.

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 195 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 either as a component of formulated hair care product or for subsequent formulation into hair care products. During reformulation 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 release associated with the manufacture of the notified polymer will not occur in Australia as the polymer is being imported. Environmental release of the notified polymer is unlikely during importation, storage and transportation to the notifier's facility, and accidental spills, leaks and catastrophic mechanical failure during a transport accident is the most likely reason for environmental release. Engineering controls (eg. shipping containers, steel drum specifications) and emergency clean-up procedures (ie. spill response instructions on Material Safety Data Sheet and label) will limit the impact on the environment of such incidents.

Imported drums will contain 195 kg of formulation (>95% notified polymer) and imported ready-to-use plastic bottles (200-500 mL) will contain <1% of the notified polymer. Drums will be transported by road to several formulation facilities for storage prior to blending into finished products (<1% notified polymer) for distribution to retail outlets. Ready-to-use containers will be distributed directly to retail outlets.

At formulation facilities, wastewaters containing a relatively small quantity of the notified polymer (up to 25 kg/yr) will be generated during cleaning of formulation equipment. This waste stream is normally collected by licensed waste contractor for treatment. A fraction may either be treated on-site in industrial wastewater treatment plants before sewer disposal of effluent, or discharged to the sewer directly.

Emptied drums, estimated to contain ~25 kg/yr of the notified polymer in unextractable residues, will probably follows drum lifecycle processes (eg. disposed of to metal recycling facilities, reconditioning and reuse).

Drum reconditioning wastewaters are likely to be released to on-site wastewater treatment plants and/or the sewer.

RELEASE OF CHEMICAL FROM USE

Most of the imported notified polymer will be incorporated into a hair care product and, after use, will mostly be released to the sewer through washing of hair. Some residues of the notified polymer may adhere to hair. Residues in the consumer product containers that will be disposed of to landfill via domestic garbage collection are expected to be less than 25 kg/yr.

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 will 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 20°C and 101.3 kPa Translucent white liquid

Boiling Point >100°C

Remarks Test report not provided.

Density 1000 kg/m^3

Remarks Test report not provided.

Vapour Pressure Not determined.

Remarks The vapour pressure of the polymer is low. The vapour pressure for an analogue chemical (notified as LTD/1123) was estimated as $<1.0 \times 10^{-4}$ Pa at 20°C based on its high molecular weight.

Water Solubility Insoluble

Remarks Silicones are typically classed as having very low water solubility (Hamelink, 1992). A review by the notifier of the solubility of high molecular weight polymethylsiloxanes (PDMS) has shown the following results:

PDMS (Molecular Weight)	Solubility (ppm)
1200	1.6
25000	0.17
56000	0.076

Dow Corning (2001) reported a water solubility of an analogue chemical (notified as LTD/1123) of $\geq 4.3 \times 10^{-8}$ g/L using a non-specified (non-regulatory) method. The results were reported as concentrations of silicone but it was concluded that the method used was not capable of absolute measurement of test substance concentrations. However, the presence of an additional potentially cationic group compared with the analogue could increase the water solubility of the notified polymer.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer does not contain hydrolysable groups.

Partition Coefficient (n-octanol/water) Not determined

Remarks High molecular weight silicones are classed as having very low water solubilities with typical Log Pow of 4-5. However, the notified polymer contains hydrophilic groups and the partition coefficient may be expected to be at the low end of the range.

Adsorption/Desorption Not determined

Remarks The notified polymer is expected to be immobile in soil due to its high molecular weight, low water solubility and adsorption to charged surfaces.

Dissociation Constant Not determined

Remarks The notified polymer contains amine groups that could be expected to have a pKa of approximately 9-10. However, the polymer 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 10533 cP at 25°C

METHOD The method was not stated but the test was carried out in accordance with EPA Good Laboratory Practices.
TEST FACILITY Dow Corning Corporation (2004)

7. TOXICOLOGICAL INVESTIGATIONS

A limited toxicity data was submitted in support of the notification for the notified polymer. These data are summarised below.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	severely irritating
Guinea pig, skin sensitisation – non-adjuvant test.	evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley (Crl:CD)
Vehicle None
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 females	2000	0/6

LD50	>2000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	All animals appeared normal and gained weight throughout the study. No significant macroscopic findings were noted.

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY Dow Corning Corporation (2003a)

7.2. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None
Observation Period	14 days
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	4	4	4	4	10 days	0
Oedema	3	3	2	3	7 days	0

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

Remarks - Results Desquamation, fissuring, and eschar and blanching in greater than 50% of the test site was observed in all animals. Denuded areas were also seen in all test sites.

CONCLUSION The notified polymer is severely irritating to the skin.

TEST FACILITY Dow Corning Corporation (2003b)

7.3. Skin sensitisation

7.3.1 Skin sensitisation – Guinea pig

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 406 Skin Sensitisation – Non-adjuvant. EC Directive 96/54/EC B.6 Skin Sensitisation – Non-adjuvant.
Species/Strain	Guinea pig/Himalayan spotted

PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 75%	
MAIN STUDY		
Number of Animals	Test Group: 20	Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100%	
Signs of Irritation	No skin irritation was seen on 15%, 50%, 25% and 75% concentration. Therefore, it was decided to start the induction phase at 100% concentration in the main study.	
CHALLENGE PHASE		
1st challenge	topical: 75%	
Remarks - Method	No significant protocol deviations.	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	75%	12/20	16/20
Control Group	75%	0/10	0/10

Remarks - Results	At the 24-hour observation period, discrete/patchy or moderate/confluent erythema, which either persisted or intensified at the 48-hour observation were reported in 12/20 animals. Additional 4 animals showed erythema at the 48-hour observation. No skin reactions were seen in control animals.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	RCC Ltd (2003)

7.3.2. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified polymer (5%)
METHOD	Human Repeated Insult Patch Test (HRIPT)
Study Design	Induction Procedure: 9 days consecutive semi-occlusive application of test material Rest Period: 10 to 15 days Challenge Procedure: 24 hour semi-occlusive application of test material
Study Group	Pilot Study (13 volunteers) and Main Study (116 volunteers)
Vehicle	Dow Corning 200® Fluid
Remarks - Method	Only subjects who had 9 applications and no fewer than 8 subsequent readings during induction, and a single application and 2 readings during challenge were used to assess sensitisation. All subjects in the pilot study completed the study. Thirteen subjects discontinued from the main study; however, the reasons for discontinuation are not related to adverse reactions during the study. A total of 116 subjects completed the study.
RESULTS	
Remarks - Results	There were no skin reactions reported at the induction and challenge observation periods.
CONCLUSION	A human repeated insult path test was conducted using the notified polymer diluted with Dow Corning 200® Fluid to 5% under semi-occlusive dressing. The notified chemical was non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY	TKL Research, Inc (2004)

7.3. Genotoxicity – bacteria

TEST SUBSTANCE	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 (Experiment 1) and Pre incubation procedure (Experiment 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	Phenobarbital/β-Naphthoflavone induced rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 33 to 5000 µg/plate. b) Without metabolic activation: 33 to 5000 µg/plate.
Vehicle	Tetrahydrofuran (THF)
Remarks - Method	The preliminary experiment for toxicity was reported as Experiment 1. In experiment 2, the number of colonies did not reach the lower limit of the historical control data in strain TA100 (negative and solvent control). Also, in strain TA98, the data in the negative control was slightly above the historical control range. These deviations had no detrimental impact on the outcome of the study.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*		
Activation	*Cytotoxicity*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1			
TA1535	2500, 500	5000	none
TA1537	1000, 2500	2500, 5000	none
TA98	1000 to 5000	none	none
TA100	1000	none	none
WP2uvrA	none	none	none
Test 2			
TA1535	none	none	none
TA1537	2500, 5000	none	none
TA98	2500, 5000	none	none
TA100	2500, 5000	none	none
WP2uvrA	none	2500, 5000	none
Present			
Test 1			
TA1535	none	5000	none
TA1537	none	2500, 5000	none
TA98	none	none	none
TA100	none	none	none
WP2uvrA	none	none	none
Test 2			
TA1535	none	5000	none
TA1537	none	5000	none
TA98	none	5000	none
TA100	none	5000	none
WP2uvrA	none	5000	none

Remarks - Results

In Experiment 1, irregular background growth was observed in strains TA1535 (1000, 2500 µg/plate) and TA1537 (1000 µg/plate) without S9. Toxic effects as evident by a reduction in the number of revertants were observed in strains TA1535, TA1537, TA98 and TA100 with or without S9.

In Experiment 2, irregular background growth was observed in strains TA1535 (2500, 5000 µg/plate), TA1537 (1000 to 5000 µg/plate), TA98 (2500, 5000 µg/plate), and TA100 (1000 to 5000 µg/plate) without S9. Toxic effects as evident by a reduction in the number of revertants were observed in strains TA1537, TA98 and TA100 with or without S9.

No substantial increase in revertant colonies of any of the five strains tested was observed at any dose level, with or without S9.

Appropriate positive controls induced marked increases in the number of revertant colonies, indicating 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

Data for several analogues was provided. Of these, the structure of Dow Corning Q2-8220 is closest to the notified polymer.

8.1.1. Ready biodegradability

8.1.1.1. Ready biodegradability – Dow Corning® Q2-8413

TEST SUBSTANCE	Dow Corning® Q2-8413 (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	*% $ThCO_2$ produced*	
(Day)	*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)

8.1.1.2. Ready biodegradability - Dow Corning® Q2-8220

TEST SUBSTANCE Dow Corning® Q2-8220 (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 that 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	*% $ThCO_2$ produced*	
(Day)	*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)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. The very low water solubility 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

Data for two analogue polymers was submitted, Dow Corning® 8500 and Dow Corning® Q2-8413. Dow Corning® Q2-8413 contains a lower proportion of cationic groups than the notified polymer.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Dow Corning® 8500 (Analogue 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. 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	0	0	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 each of 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 toxicity to aquatic invertebrates

TEST SUBSTANCE	Dow Corning ® Q2-8413 (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 silicon levels were determined by ICP. Test substance concentrations were expressed based on the conversion of silicon 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 deviations mentioned did not affect 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 silicon (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 due to physical stressors.
TEST FACILITY	Dow Corning (1999b)

8.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Dow Corning ® Q2-8413 (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	>100 mg/L
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)

8.2.5. Microtox assay

TEST SUBSTANCE	Dow Corning ® Q2-8413 (Analogue polymer)
METHOD	Standard Microtox Test System
Species	Microtox® bioluminescent bacterium (*Vibrio fischeri*) – Microtox Reagent
Exposure Period	15 minutes
Concentration Range Nominal	Eight test concentrations between 0.7 and 90 mg/L
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 (10000 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 between 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 at the 5 minute and 15 minute exposure times. 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 <50 kg per annum is expected during the reformulation process and as residues in import containers (total maximum release <10 tpa). The use pattern will be widespread and release diffuse throughout Australia.

As the majority of the notified polymer in the hair care products will eventually be released into the sewerage system, and treated effluent from many sewerage systems is discharged into the aquatic environment, the predicted environmental concentration (PEC) in the aquatic environment is estimated using an STP Model developed by Environment Australia (2003) using the following worst-case scenario. If the estimated worst-case quantity sent to sewer were not treated (ie. 10000 kg/y), a national average effluent concentration of ~6.8 μg/L may be expected based on a national wastewater flow of 1.46×10^{12} L/annum (based on an Australian population of 20.1 million people generating an average of 200 L wastewater/d). River and ocean PECs following sewer effluent discharge of 6.8 µg/L and 0.68 µg/L may be derived using dilution factors of 1 and 10, respectively. However, the notified polymer is poorly soluble in water and thus may be relatively immobile in both the aquatic and terrestrial compartments. An affinity to particulate matter and aggregation of most in sludge is expected. Adsorption to sewage sludge by a factor of 90% may be expected for cationic polymers (Boethling and Nabholz, 1997), resulting in PEC values for fresh and marine waters using the above assumptions of 0.68 µg/L and 0.068 µg/L, respectively.

Although not readily biodegradable, if any notified polymer adsorbed onto sewage sludge is applied to soil (eg. biosolids) 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).

The low water solubility of the notified polymer may indicate a potential for bioaccumulation. However, the high molecular weight will limit bioaccumulation.

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.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for analogue polymers, Dow Corning® 8500 and Dow Corning® Q2-8413 are listed below. Dow Corning® 8500 was considered to be a more appropriate analogue for the polymer than Dow Corning® Q2-8413 since the later contains a lower proportion of cationic groups compared with the notified polymer. No data for algal toxicity has been provided although algae may be more sensitive than fish or daphnids (Nabholz, 1993).

Organism	*Duration*	*End Point*	*mg/L*
Fish	96 h	LC50	>100
Daphnids	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 is derived by dividing the LC50 value by an uncertainty factor of 1000 (since only acute test results for two trophic levels for analogues, some of uncertain validity, were provided and algae is most likely to be more sensitive taxa than fish or invertebrates).

9.1.3. Environment – risk characterisation

Using a risk quotient approach, and assuming a worst-case discharge scenario involving no sewage treatment, risk quotient values for riverine and ocean receiving environments of <1.4 (6.8 ÷ >5) and <0.14 (0.68 ÷ >5) may be derived. However, with the expected sewage system attenuation of the notified polymer to sludge of at least 90%, risk quotients are ≤0.1 indicating a low risk to the aquatic environment from the proposed use and disposal pattern of the notified polymer.

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 (<1%).

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. Dermal and possibly eye exposure to the notified polymer can occur 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 <1%.

9.2.3. Human health - effects assessment

The notified polymer is of very low acute oral toxicity but is a severe skin irritant. Desquamation, fissuring, and eschar and blanching in greater than 50% of the test site was observed in all animals. Denuded areas were also seen in all test sites. Being a severe skin irritant, the polymer is also considered to have an eye irritation potential. The notified polymer showed evidence of sensitisation effects in experimental animals. However, when a mixture containing 5% notified chemical was repeatedly applied (topically) to human volunteers, there was no skin irritation or sensitisation effects observed.

Bacterial mutation assay suggests that the notified polymer is not mutagenic.

Based on the available data, the notified polymer is classified as a hazardous substance (Irritant, Xi) in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002) and warrants the risk phrases: R36/38 – Irritating to eyes and skin; and R43 – May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer will be imported as a polymer concentrate containing >90% notified polymer, and subsequently reformulated into hair care products containing <1% 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. Inhalation exposure during normal handling and use is unlikely due to the high viscosity of the notified polymer.

Although exposures may also occur when overfilling containers, cleaning equipment and during maintenance operations, such exposures are expected to be intermittent. Due to the skin and eye irritation and sensitisation potential of the notified polymer, dermal and ocular exposure should be avoided when handling the notified polymer.

Overall, the risk of adverse effects arising from exposure to the notified polymer is low due to largely enclosed and automated operations in the reformulation of hair care products. 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 1% solution would receive a dose of approximately 5 mg/kg bw which is significantly below the lethal dose (LD_{50} >2000 mg/kg bw) for the notified polymer. The polymer has a low acute oral toxicity and the quantities consumed would be minimal.

The pure notified polymer is a skin and eye irritant, and a skin sensitiser. However, in a human patch test, no signs of irritation or sensitisation were reported at 5% concentration. The notified polymer will be present at <1% in consumer products, which, given the lack of effects in the patch test at 5%, provides an appropriate margin of safety for sensitisation effects. The notified polymer is not expected to cause adverse health effects when used as a component of hair care products at the proposed concentration of <1%.

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 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 a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R36/38 – Irritating to eyes and skin; and
R43 – May cause sensitisation by skin contact.

and

As a comparison only, the classification of 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.

Skin Irritation Category 2:
Symbol: Exclamation mark
Signal word: Warning
Hazard statement: Causes skin irritation

Eye Irritation Category 2b:
Symbol: No symbol
Signal word: Warning
Hazard statement: Causes eye irritation

Skin Sensitiser Category 1:
Symbol: Exclamation mark
Signal word: Warning
Hazard statement: May cause allergic skin reaction

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 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 NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - R36/38 – Irritating to eyes and skin; and
  - R43 – May cause sensitisation by skin contact.

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - ≥20%: R36/38 - Irritating to eyes and skin.
  - ≥1%: R43 - May cause sensitisation by skin contact.

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.

Disposal

- Dispose of wastes containing the notified polymer in accordance with local jurisdiction waste management regulations.
- Do not dispose of the notified polymer to drains or natural waterways.
- Spilled notified polymer (including saturated absorbent or cleaning material) may be hazardous as spontaneous heating may occur. Such wastes should be disposed of to landfill or incinerated.
- Emptied finished product containers with residues of the notified chemical should be cleaned and recycled or sent to landfill for disposal.
- Small quantities of waste/spilled formulation containing the notified chemical should be disposed of to landfill or sewer.

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. Inform local authorities if this cannot be prevented.
- Clean up spilled quantities of notified polymer by pumping into labelled, sealable containers. Clean up remaining materials from spill with suitable absorbent. Final clean using steam, solvents or detergents and collect washwaters for treatment and appropriate disposal.

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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