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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Dow Corning 9506 Powder

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FULL PUBLIC REPORT

Dow Corning 9506 Powder

1. APPLICANT

Dow Corning Australia Pty Ltd of 3 Innovation Rd North Ryde NSW 2113 (ABN 36 008 444 166) has submitted a standard notification statement in support of their application for an assessment certificate for Dow Corning 9506 Powder.

2. IDENTITY OF THE CHEMICAL

Marketing Name: Dow Corning 9506 Powder
Trefil E-506C
Dow Corning 5-8452 Electronic Powder

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and purity, and the chemical identities of analogue polymers used for toxicity testing have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: white powder

Melting Point: not determined

Specific Gravity: 0.98 at 25°C

Vapour Pressure: not volatile

Water Solubility: not determined

Particle Size: average 3 μm, range 1-15 μm; majority of particles in the respirable range

Partition Co-efficient (n-octanol/water): log P_{ow} ~ 4-5

Hydrolysis as a Function of pH: not determined

Adsorption/Desorption: not determined

Dissociation Constant:	no dissociable groups are present
Flammability Limits:	not flammable
Explosive Properties:	not explosive
Reactivity/Stability:	stable under normal environmental conditions

3.1 Comments on Physico-Chemical Properties

The water solubility was not determined, but based on its structure the solubility of the notified polymer is expected to be low. The notified has indicated that silicones are classed as having low water solubilities as indicated by their high partition coefficients, typically log P equals 4-5. The solubility of a polydimethylsiloxane with MW 56000 is said to be < 0.1 ppm.

The notified polymer contains no linkages that could be expected to undergo hydrolysis under the environmental pH range of 4 to 9. However, polydimethylsiloxanes are unstable in landfill situations.

The partition coefficient of the notified polymer has not been determined due to its expected low water solubility, and its likely hydrophobic nature, indicative of partitioning into the octanol phase. Typically, compounds of this class are said to have log P values of 4-5.

No adsorption/desorption tests were conducted for this notification. The notified polymer is expected to be relatively immobile in soil due to its high molecular weight and expected low water solubility.

Although no tests were conducted, the notified polymer will not undergo dissociation as it does not contain any functional groups able to undergo dissociation.

4. PURITY OF THE CHEMICAL

Degree of Purity:	99 %
Hazardous Impurities:	none
Maximum Content of Residual Monomers:	confidential; all residual monomers below the respective cutoffs for classification of the notified polymer as a hazardous substance

Additives/Adjuvants:

Chemical name:	poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-
Synonyms:	polyoxyethylene (4) lauryl ether
CAS No.:	9002-92-0
Weight percentage:	2 %

5. USE, VOLUME AND FORMULATION

The notified polymer is used as a thickening agent in personal care products, and may in future be used as an additive for plastics used in the electronics industry. It will not be manufactured in Australia. The notifier estimates an import volume of up to 5 tonnes per annum during the first five years of importation.

The notified polymer will be imported in powder form at essentially 100 % purity. The powder will normally be packed in 10 kg polyethylene lined bags. It will be reformulated in Australia by manufacturers of personal care products, such as soaps, shampoos and creams. The recommended use level for the notified polymer varies in the range of 2 – 20 %, and is typically 10 %. The final products will be packaged into small end-use containers for retail sale.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The notifier estimated that between 10 and 30 stevedoring workers, 5 – 10 transport workers and 5 – 10 warehouse workers will handle bags containing the powdered notified polymer. No exposure to these workers will occur except in the case of an accident involving damage to the packaging.

Reformulation
The notifier estimated that between 20 and 50 workers in the personal care products industry will be exposed to the notified polymer during reformulation of the notified polymer. The maximum exposure duration will be 8 hours per day, on a daily basis.

The notified polymer will be poured directly from the imported bags into the liquid formulation, in either an open or a closed mixer. The blend will be mixed using a paddle mixer, and the formulation containing < 20 % notified polymer will be packaged for consumer use. During addition of the notified polymer powder, there may be inhalation exposure to the notified polymer, due to the small particle size. Dermal and ocular contact with the powder may also occur. Following reformulation, dermal exposure to the products containing the notified polymer at < 20 % may occur.

The notifier indicated that local exhaust ventilation is recommended during the mixing process, and that workers will use dust masks. Protective eyewear will also be used for handling the pure notified polymer or concentrated solutions.

7. PUBLIC EXPOSURE

The notified polymer will be used in personal care products at up to 20 %. These products are applied to the skin or hair of consumers and may be left in contact with the skin. Therefore, public exposure is significant.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Personal care products containing the notified polymer will be applied to skin and hair. Therefore, the majority of the notified polymer is expected be washed off and enter the sewer, with the remainder disposed of in landfill as residues in empty import bags and personal care product containers. The notifier indicates that approximately 0.2 % of the notified polymer will remain the empty import bags which equates to 10 kg per annum lost to landfill.

Equipment used in the formulation of personal care products will be rinsed with water and the rinseate treated using an advanced liquid treatment system, from which the resulting sludge will either be incinerated or disposed of in landfill. At manufacturing sites where such an advanced liquid treatment system is not in use, the rinsate will be released into the sewer.

The empty import bags and personal care product containers and associated residues will be disposed of in landfill.

8.2 Fate

The majority of the notified polymer will be used in the formulation of personal care products such as soaps, shampoos and creams and will be washed off and ultimately released into the sewer. Wastes generated from the cleaning of formulation machinery may also be released into the sewer. Here, the notified polymer will adsorb onto sediments due to its expected low water solubility. Some wastes containing the notified polymer, those from advanced water treatment plants, may be incinerated producing water vapour and oxides of carbon and silicon.

Empty import bags and personal care product containers with any remaining residual solid material will be disposed of to landfill. The polymer is not expected to escape from the drums. Any polymer released in landfill will associate with the soil matrix and not leach into the aquatic compartment due to its expected low water solubility.

Polydimethylsiloxanes are unstable in landfill situations (Hamelink, 1992; Lehmann et al., 1994a; Lehmann et al., 1994b), and under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. When released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink, 1992).

The polymer is not expected to cross biological membranes, due to its high molecular weight and predicted low water solubility, and should not bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The notified polymer has been tested for skin sensitisation and for induction of point defects in bacteria. Reports on these studies have been provided by the notifier.

The notifier also provided a number of studies on analogue compounds. These include published papers on poly(dimethylsiloxane) (PDMS), covering a range of toxicity endpoints,

an number of full toxicity study reports on PDMS (for acute inhalation toxicity, eye irritation, and a 13 week feeding study), as well as a summary of a report including the results of acute oral and dermal toxicity testing. In addition, a summary of a report including the results of acute oral and dermal toxicity testing, as well as skin and eye irritation testing, was provided for Dow Corning X2-2571 Connector Fill Fluid (X2-2571). A skin irritation study report and a summary of a 1 year feeding study on Dow Corning 1107 Fluid (1107) were also provided.

All analogue studies are accepted as being appropriate for determination of the toxicity of the notified polymer. The toxicity of the notified polymer is expected to be similar to that of PDMS, although absorption of the notified polymer may be slower due to its higher molecular weight. The other analogue polymers are similar to starting materials in the preparation of the notified polymer.

9.1 Acute Toxicity

Summary of the acute toxicity of Dow Corning 9506 Powder and Analogues

Test	*Species*	*Test Substance*	*Outcome*	*Reference*
acute oral toxicity	rat	X2-2571	LD_{50} > 15.0 g/kg	(Dow Corning, 1981)
acute oral toxicity	rat	PDMS	LD_{50} > 15.4 g/kg	(Dow Corning, 1978)
acute dermal toxicity		X2-2571	not stated	(Dow Corning, 1981)
acute dermal toxicity	rabbit	PDMS	LD_{50} > 2.0 g/kg	(Dow Corning, 1978)
acute inhalation toxicity	rat	PDMS (thermal decomposition products)	LC_{50} > 0.99 mg/L	(Dow Corning, 1979)
skin irritation	rabbit	X2-2571	not stated	(Dow Corning, 1981)
skin irritation	rabbit	PDMS	non-irritant	(Dow Corning, 1978)
skin irritation	rabbit	1107	non-irritant	(Dow Corning, 1994)
eye irritation	rabbit	X2-2571	not stated	(Dow Corning, 1981)
eye irritation	rabbit	PDMS	slight irritant	(Dow Corning, 1978; Dow Corning, 1982)
skin sensitisation	guinea pig	notified polymer	non-sensitiser	(Dow Corning Toray Silicone Co. Ltd, 1992)

9.1.1 Oral Toxicity

Only summary reports containing acute oral toxicity results for analogue polymers were provided by the notifier. No descriptions of the experimental procedure were provided. For PDMS, the report states that LD_{50} > 15.4 g/kg (Dow Corning, 1978). For X2-2571, the report states that LD_{50} > 15.0 g/kg (Dow Corning, 1981).

9.1.2 Dermal Toxicity

Only summary reports containing acute dermal toxicity results for analogue polymers were provided by the notifier. No descriptions of the experimental procedure were provided. For PDMS, the report states that LD_{50} > 2.0 g/kg (Dow Corning, 1978). For X2-2571, the report states only that there is no indication that the material is absorbed through the skin in acutely toxic amounts (Dow Corning, 1981).

9.1.3 Inhalation Toxicity of PDMS Thermal Decomposition Products (Dow Corning, 1979)

Species/strain: rat/not specified

Number/sex of animals: 5/sex per exposure group

Observation period: 14 days

Method of administration: whole body exposure to thermal decomposition products of Dow Corning 200 Fluid, 10 cs produced at 350ºC; nominal concentrations 0.36, 0.71, 0.99, 1.40, 2.06 mg/L particulates; 6 hour exposure

Test method: in house protocol

Mortality:

Concentration	*Males*	*Females*
0.36 mg/L	1/5	2/5
0.71 mg/L	3/5	1/5
0.99 mg/L	3/5	2/5
1.40 mg/L	2/5	1/5
2.06 mg/L	2/5	1/5

Clinical observations and morphological findings: gross observations and necropsy findings indicated that the fumes were strongly irritating to the eyes, nose and throat

Comment: the majority of the deaths occurred during the first two days post exposure; the reduction in mortality at higher nominal concentrations was attributed to a change in pyrolysis conditions due to residue build-up; the levels of carbon monoxide in the chamber were monitored and were not considered to be the cause of death

	these results form part of a comparative study which also included other heat transfer fluids and mixtures of several of these
LC_{50}:	0.99 mg/L for the thermal decomposition products
Result:	thermal decomposition products of the test substance were of moderate acute inhalational toxicity in rats

9.1.4 Skin Irritation of Dow Corning 1107 Fluid (Dow Corning, 1994)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 male
Observation period:	3 days
Method of administration:	semi-occlusive patch; test material used as received; dose 0.5 mL; 4 hour exposure
Test method:	OECD TG 404
Comment:	all Draize scores at 1, 24, 48 and 72 hours were zero
Result:	the test substance was non-irritating to the skin of rabbits

9.1.5 Skin Irritation; Additional Reports

Only summary reports containing skin irritation results for the analogue polymers PDMS and X2-2571 were provided by the notifier. Draize scores were provided for PDMS (Dow Corning, 1978). No descriptions of the experimental procedure were provided. For PDMS, the report states that all Draize scores at 24 and 72 hours for abraded and non-abraded rabbit skin were zero. For X2-2571, the report states that dermal exposure may produce no effect, or, at most, very slight redness (Dow Corning, 1981).

9.1.6 Eye Irritation of PDMS (Dow Corning, 1982)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 male per test material
Observation period:	3 days
Test materials:	PDMS; 2 cs, 100 cs, 500 cs, 1000 cs, 12500 cs
Method of administration:	0.1 mL test material was instilled in the conjunctival sac of the right eye of each animal; the left eye served as control; treated eyes were not irrigated
Test method:	not stated

Results: no effects on the cornea or iris were observed; conjunctival effects were limited to redness (grade 1); the number of animals showing conjunctival redness for each test material at each observation time are tabulated below

	Time after instillation				
Test material	***1 hour***	***6 hours***	***1 day***	***2 days***	***3 days***
	Conjunctival redness incidence				
PDMS, 2 cs	3/3	0/3	0/3	0/3	0/3
PDMS, 100 cs	3/3	1/3	0/3	0/3	0/3
PDMS, 500 cs	3/3	3/3	1/3	0/3	0/3
PDMS, 1000 cs	3/3	3/3	2/3	0/3	0/3
PDMS, 12500 cs	3/3	3/3	3/3	2/3	0/3

Comment: higher viscosity grades of PDMS showed more persistent irritation; the irritation scores in all cases were below the levels leading to classification as eye irritants

Result: the test materials were non-irritating to slightly irritating to the eyes of rabbits

9.1.7 Eye Irritation; Additional Reports

Only summary reports containing eye irritation results for the analogue polymer X2-2571 were provided by the notifier (Dow Corning, 1981). An additional summary report on eye irritation for PDMS was also provided; this included Draize scores (Dow Corning, 1978). No descriptions of the experimental procedures were provided. For PDMS, the report states that all Draize scores at 24, 48, 72 hours and 7 days for effects on the cornea, iris and conjunctiva were zero (3 rabbits). For X2-2571, the report states that ocular exposure may produce slight redness for a few hours.

9.1.8 Skin Sensitisation (Dow Corning Toray Silicone Co. Ltd, 1992)

Species/strain: guinea pig/Hartley

Number of animals: 10 female per group(test and control)

Induction procedure:

test group:
day 1 on a prepared area of skin from the shoulder region of test animals, three pairs of intradermal injections were administered as follows:

1. 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % v/v in water;
2. 0.1 mL 10 % test substance in water;

3. 0.1 mL 10 % test substance emulsion in water 50 % v/v with FCA

day 7 — local irritation was induced at the shaved test site by application of 0.2 g of sodium lauryl sulphate in petroleum jelly

day 8 — test substance (25 % in water) was applied by occlusive patch between the sites that received the intradermal injections for 48 hours

control group:

day 1 — on a prepared area of skin from the shoulder region of test animals, one pair of intradermal injections of 0.1 mL of Freund's Complete Adjuvant (FCA) 50 % v/v in water was administered

day 7 — no treatment indicated

day 8 — no treatment indicated

Challenge procedure:

day 22 — test substance (25 %, 10 % and 5 % in water) was applied by occlusive patch to three clipped sites on the belly for 24 hours

Test method: Japanese Test Guideline Yakusin 1 No. 24

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	*24 hours**	*48 hours**	*24 hours*	*48 hours*
25 %	**0/10	0/10	0/10	0/10
10 %	0/10	0/10	0/10	0/10
5 %	0/10	0/10	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Result: the notified polymer was non-sensitising to the skin of guinea pigs

9.2. Repeated Dose Toxicity

9.2.1 13-week Repeated Dose Toxicity of PDMS (Dow Corning, 1995)

Species/strain: rat/CDF (F-344) CrlBr

Number/sex of animals: 8 groups each 15/sex

Test material: PDMS, 350 cs

Method of administration: test material was administered daily by gavage (2 dose groups; test material used as received) and in diet (4 dose groups); the diet control group remained untreated; the gavage control group received water by gavage daily

Dose/Study duration: gavage: 0, 500 and 2500 mg/kg/day
diet: 0, 5000, 10000, 25000, 50000 ppm
measured dietary intake:

nominal (ppm)	5000	10000	25000	50000
males (mg/kg/day)	312	618	1590	3347
females (mg/kg/day)	352	716	1790	3824

Test method: OECD TG 408

Clinical observations:
One male and two females in the 2500 mg/kg/day gavage group were found dead on day 12; the male had exhibited rales on the preceding day, while no prior clinical observations were noted for the females.

Yellow matting at the base of the tail occurred occasionally in the 2500 mg/kg/day gavage males, and infrequently in the 2500 mg/kg/day gavage females during weeks 8-13. Yellow urogenital matting was noted infrequently at increased incidence over the dietary control in all treated groups and in the gavage control.

Corneal opacities, noted as corneal crystals, were observed in all groups including both control groups, commencing in week 1 and appearing in both eyes of all animals by the end of week 3; the initial incidence was highest in the dietary treated groups, followed by the dietary control, the gavage treated groups and the gavage control. Findings of corneal opacity had also been made in the pre-treatment opthalmic examination. The severity of the corneal opacity at week 3 appeared to be greater in the treated groups, in a dose dependent manner. The severity indexes were lowest for the control groups, and elevated in all treated groups. Severity was comparable between the treated and control groups at the week 12 examination. Based on severity, the dietary and gavage groups which received similar levels of test material (500 mg/kg/day and 5000 ppm, and 2500 mg/kg/day and 25000 ppm, respectively) showed similar degrees of corneal opacity in examinations at week 3 and week 12.

No persistent trends in body weights were observed. The 50000 ppm dietary group showed significantly higher food consumption from weeks 4-5 (males) and weeks 2-3 (females) to the study end; statistically increased food consumption was also observed in the 25000 ppm

dietary females in weeks 4-5.

Clinical chemistry/Haematology
These measurements were performed only on the dietary administration groups. No significant differences in haematology, serum chemistry or urinalysis parameters between the treated and control groups were reported.

Gross pathology:
For the animals which died on day 12, dark red lobes in the lungs and reddened mediastinal lymph nodes were observed in all cases; the male showed reddened adrenal glands and mandibular lymph nodes and dark red contents in the ileum; one female showed dark red contents in the duodenum and jejunum.

No significant treatment related lesions were reported for the animals which survived to necropsy; all observations were scattered or appeared at similar frequency in the treated and control groups.

Slight but significant absolute liver and kidney weight differences were observed in the 50000 ppm females; no similar finding was made for the males. Relative brain weights for the 25000 and 50000 ppm females were significantly decreased, although no difference in absolute brain weights was observed. Apart from a difference in absolute left testes weight in the 5000 ppm males, with no corresponding change in the right testes weight or in higher dose groups, no other significant organ weight findings were made.

Histopathology:
Suppurative inflammation of the corneal epithelium increased in a dose dependent manner in the treated groups compared with the control groups. The incidences are tabulated below:

	ppm					mg/kg/day		
	0	5000	10000	25000	50000	0	500	2500
Males	1	3	6	8	11	0	2	12
Females	0	2	5	5	7	0	6	9

The severity also increased with dose; moderate grades were only recorded for the 500 mg/kg/day, 2500 mg/kg/day and 50000 ppm groups.

Other corneal lesions, including neovascularisation and graulatomatous inflammation of the corneal stroma and hyperplasia of the corneal epithelium, were observed in a scattered manner with no evident dose relationship in the treated but not control animals.

Full histopathological examination was only performed on the dietary control and 50000 ppm dietary groups; selected tissues were examined in the other dietary groups. No other treatment related findings were reported; all observations were scattered or appeared at similar frequency in the treated and control groups.

Comment:
Corneal opacities are stated to be spontaneous in the strain of rats used, and were observed prior to treatment as well as during the study. The severity of the corneal effects was found to be increased by treatment at week 3, and microscopic findings at necropsy indicated the presence of suppurative inflammation of the corneal epithelium in treated animals at a much higher incidence than in control animals. Other lesions observed in the treated groups were not observed in the control groups. The study authors cite a study on PDMS fluids where dietary administration at 10 % resulted in anal leakage of the test substance and similar eye lesions. Matting at the base of the tail in the present study indicated that anal leakage may be occurring at 50000 ppm (5 %), and the study authors conclude, on the basis of corneal findings occurring in the gavage groups as well as the dietary administration groups, that grooming may be spreading this material to the eyes, where local irritant effects are observed.

Result:
Apart from corneal effects, which are attributed to local irritant effects, no significant treatment related effects were observed in the dietary administration groups. The No Observed Effect Level (NOEL) for systemic toxicity by dietary administration is therefore determined to be > 50000 ppm (3347 mg/kg/day for males, 3824 mg/kg/day for females). Due to the restricted scope of the gavage study, no NOEL could be determined, however mortalities were observed at 2500 mg/kg/day.

9.2.1 1-year Repeated Dose Toxicity of Dow Corning 1107 Fluid (Dow Corning, 1966)

A summary only of this report was submitted. This contained tables of mean values for the parameters examined, and summary tables of pathological results. Individual data were not available for independent verification. A synopsis of the main conclusions is presented below.

Species/strain:	rat/FDRL
Number/sex of animals:	5/sex/group (treatment groups) 10/sex (control group)
Method of administration:	test material administered daily as an admixture in diet
Dose/Study duration:	dietary levels 0, 0.05 %, 1.0 % for 12 months
Test method:	in house protocol

Clinical observations:
One male and one female of the control groups died during the last 10 weeks of the study; the cause of death was determined to be acute pulmonary infections.

No abnormalities in general appearance or behaviour of any of the treated animals was reported. The body weight increase for the 1 % females was significantly reduced during the last 13 weeks of the study; a reduction in food intake for this group was also reported.

Clinical chemistry/Haematology
No significant treatment related effects on haematology, urinalysis or clinical chemistry

were reported.

Gross pathology:
No dose related trends were reported except for an increase in thyroid weight in both sexes for both treatment levels. A number of scattered observations which were considered incidental were reported.

Histopathology:
An apparent increase in the incidence of thyroid hyperplasia was observed in the treated groups relative to the controls. This finding was made in three out of twenty control animals, six out of ten animals at 0.05 % and nine out of ten animals at 1.0 %.

Comment:
The study authors stated that a low level of thyroid hyperplasia is not unusual in the strain of rats used. Due to the brevity of the report and the uncertain significance of the macroscopic and microscopic thyroid findings, no NOEL could be determined.

Result:
A NOEL was not determined in this study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Dow Corning Toray Silicone Co. Ltd, 1996)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537 *Escherichia coli*: WP2 *uvrA*
Metabolic activation:	rat liver S9 fraction from animals pretreated with phenobarbital and 5,6-benzoflavone, 10 % (v/v) in standard cofactors
Concentration range:	range finding: 0, 10, 50, 100, 500, 1000, 5000 μg/plate main test: 0, 313, 625, 1250, 2500, 5000 μg/plate test material was suspended in acetone
Positive controls:	with S9: TA98, TA100, TA1537: benzo[α]pyrene 5.0 μg/plate TA1535: 2-aminoanthracene 2.0 μg/plate WP2 *uvrA*: 2-aminoanthracene 10 μg/plate without S9: TA98: 2-(2-furyl-3-(5-nitro-2-furyl)acrylamide 0.1 μg/plate TA100, WP2*uvrA*: 2-(2-furyl-3-(5-nitro-2-furyl)acrylamide 0.01 μg/plate TA1535: sodium azide 0.5 μg/plate TA1537: 9-aminoacridine 80 μg/plate
Test method:	Japanese Test Guideline Yakusin 1 No. 24

Comment:	scoring was carried out on both the range finding and main tests; all tests were performed in duplicate; precipitation was noted in all tests at or above 313 μg/plate no antibacterial effects of the test material were observed no significant increases in the numbers of revertant colonies over the controls were observed at any concentration either in the presence or absence of metabolic activation; the positive controls in all cases caused significant large increases in the number of revertant colonies, indicating that the test system responded appropriately
Result:	the notified polymer was non mutagenic under the conditions of the test

9.4 Published Toxicological Information on PDMS

A number of published studies on the toxicology of commercial silicones were provided by the notifier. These are closely related to the notified polymer.

High molecular weigh dimethylsilicone fluids were found to be very low in acute oral toxicity (Rowe et al., 1948), and repeated feeding for one month at doses up to 20 g/kg did not cause discernable ill effects; administration by intraperitoneal, intradermal and subcutaneous effects showed these materials to be essentially inert. No skin irritation or corneal damage was observed, although transitory conjunctival irritation was seen. Low toxicity was observed for formulated silicone compounds and crosslinked resins.

Similar results were reported in a study of polydimethylsiloxane fluids (Calandra et al., 1976). It was stated that no evidence of carcinogenicity was observed in long term studies (up to 2 years in rats and dogs). Skin sensitisation was not observed in a number of human repeated insult patch tests. No ill effects were reported for several inhalation studies of aerosols of high molecular weight silicones.

In a number of reproductive studies on high molecular weight dimethylsilicones (Kennedy Jr et al., 1976), an apparent dose related incidence of foetal mortality was observed in rats, and a slight increase in a foot deformity (non dose related) in rabbits were observed. Other studies in rats, mice and rabbits showed no teratogenic effects or induction of dominant lethal mutations.

9.5 Overall Assessment of Toxicological Data

The notified polymer is a very high molecular weight unreactive silicone with low water solubility. Toxicological studies on related unreactive silicones such as PDMS may therefore serve as appropriate analogue studies for indicating the toxicological properties of the notified polymer.

Studies on the genotoxicity and skin sensitising potential of the notified polymer were

submitted by the notifier. These showed that the notified polymer was not genotoxic and was not a skin sensitiser in the tests systems used. In addition, no indication of skin irritation was observed in the sensitisation study. While only a single study on the genotoxicity of the notified polymer was submitted, long term carcinogenicity results for the analogue PDMS are presented in one of the published references provided by the notifier, and these results do not indicate carcinogenic potential. Inhalation toxicity data was provided for the thermal decomposition products of PDMS, but not for PDMS itself. This showed that the decomposition products are of moderate inhalation toxicity.

A wide range of toxicological results on PDMS fluids of different molecular weights were provided. These indicated that silicones of this type are of very low oral toxicity in rats, low dermal toxicity in rats or rabbits, non-irritant to rabbit skin, and at most slightly irritating to rabbit eyes (possibly due to the hydrophobic nature of the material). In a 13 week feeding study, a NOEL of > 50000 ppm was established for 350 cs PDMS fluid, although there was evidence for chronic eye irritant effects due to repeated exposure during grooming. The published longer term studies showed low toxicity, including for human sensitisation, carcinogenicity and reproductive and developmental effects.

The studies on silicones similar to the starting materials for preparation of the notified polymer, Dow Corning X2-2571 Connector Fill Fluid and Dow Corning 1107 Fluid, showed these to also be of low acute toxicity; however a 1 year feeding study using Dow Corning 1107 Fluid showed possible thyroid effects at a level of 0.05 % in food. The more reactive groups present in this analogue polymer would be expected to be consumed in reaction of a similar polymer to produce the notified polymer.

Based on the above results, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substance* (Approved Criteria) (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will be incorporated into personal care products such as soaps and shampoos and will be washed off and ultimately released into the sewer. Here, the notified polymer will adsorb onto sediments due to its expected low water solubility.

Some waste containing the notified polymer will be disposed of in landfill, where it is expected that the polymer would associate with the soil matrix and not leach from the soil because of its expected low solubility in water. Some wastes containing the notified polymer, those from advanced water treatment plants, may be incinerated producing water vapour and oxides of carbon and silicon.

Polydimethylsiloxanes are unstable in landfill and on dry sediments (Hamelink, 1992; Lehmann et al., 1994a; Lehmann et al., 1994b) because under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile

and enter the atmosphere. However, when released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink, 1992). Therefore in landfill, the notified polymer would eventually degrade and pose little risk to the environment.

Based on annual imports of up to 5 tonnes per annum, up to 99.8 % of which is eventually released to sewer, the daily release on a nationwide basis to receiving waters is estimated to be 13.67 kg/day. Assuming a national population of 18,000,000 and that each person contributes an average 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 1.85 μg/L.

Amount of the notified polymer entering sewer annually	4990 kg
Population of Australia	18 million
Amount of water used per person per day	150 L
Number of days in a year	365
Estimated PEC	1.85 μg/L (1.85 ppb)

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 0.2 μg/L. If used in one capital city such a Sydney (pop. 3500000), the PEC of the notified polymer released to receiving waters would be 9.5 μg/L.

No ecotoxicological data were provided for this notification. However, the hydrophobic nature of the notified polymer indicates that most would adsorb onto particles of sediment and sludge (Hamelink, 1992; Lehmann et al., 1994a), and would therefore not remain in the water compartment and be available for assimilation by aquatic organisms. Furthermore, Nabholz et al. (1993) have pointed out that the interaction between this class of compound and the dissolved and suspended organic matter in natural waters can significantly mitigate toxicity of these compounds through reducing effective exposure to sensitive organisms.

Therefore, the environmental exposure and overall environmental hazard from the notified polymer is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on study reports on the skin sensitising potential and genotoxicity of the notified polymer, and on published work and study reports on analogues of the notified polymer, Dow Corning 9506 Powder is expected to be of low toxic hazard to humans. The notified polymer is not classified as a hazardous substance in accordance with the Approved Criteria.

The MSDS for Dow Corning 9506 Powder indicates that the primary hazards are expected to be due to the dusty nature of the notified polymer, as imported. The majority of particles are in the respirable range (< 10 μm), and it is indicated that the dust may irritate the eyes, nose and throat. The NOHSC exposure standard for dusts in general of 10 mg/m^3 should be adhered to in handling the notified polymer in powder form.

Occupational Health and Safety

Exposure to the notified polymer is expected to primarily occur during reformulation to

produce personal care products. Dust exposure is likely during pouring of the powder from bags into the mixer where the final products are produced. After reformulation, the notified polymer will be in the form of products intended for dermal application by the public, and exposure would not be expected to cause harmful effects.

The notifier indicated that local exhaust ventilation is recommended during the mixing process, and that workers will use dust masks. Protective eyewear will also be used for handling the pure notified polymer or concentrated solutions.

Public Health
There will be significant public exposure to the notified polymer as will be used in personal care products. The concentration in products would be less than 20 %. Since products of this nature are commonly known to cause irritation to the eyes, and the fact that the notified polymer is only a low eye irritant, the notified polymer is unlikely to contribute significantly to the eye irritation of the product.

Assuming the notified polymer is used in sunscreen at 20 %, a 60 kg woman applying 8 g of sunscreen 3 times per day over a two week period will be exposed to 80 mg/kg/day of the polymer. With 10 % absorption this will result in a daily exposure of 8 mg/kg/day which is well below the NOAEL of 3824 mg/kg/day. Thus dermal exposure is unlikely to pose a significant hazard to human health.

There is a slight chance of ingestion of the notified polymer. A 10 kg child ingesting 5 mL of a 20 % solution would receive a dose of approximately 100 mg/kg bw which is significantly below the lethal dose (LD_{50} > 15400 mg/kg bw) for an analogous polymer (Dow Corning, 1978). The polymer has a low acute oral toxicity and the quantities consumed would be minimal. Based on this, the notified polymer is unlikely to pose a significant hazard to public health following normal use.

13. RECOMMENDATIONS

To minimise occupational exposure to Dow Corning 9506 Powder the following guidelines and precautions should be observed:

- The NOHSC exposure standard for dusts in general of 10 mg/m^3 should be adhered to in handling the notified polymer in powder form; if work practices and engineering controls do not reduce dust exposure sufficiently, respiratory protection should be used;

- Safety eyewear should be used during occupational use of the products containing the notified polymer;

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly and then be put into containers for disposal;

- A copy of the MSDS should be easily accessible to employees.

If products containing the notified polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999),

workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992) for respirators, guidance may be obtained in AS/NZS 1715 (Standards Australia/Standards New Zealand, 1994a) and AS/NZS 1716 (Standards Australia/Standards New Zealand, 1994b), or other internationally acceptable standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified polymer may be required. No other specific conditions are prescribed.

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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