

File No: EX/51(PLC/189)

23 February 2004

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in DOW CORNING 9040 Silicone Elastomer Blend

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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

**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

FULL PUBLIC REPORT	5
1. APPLICANT.....	5
Original Holder of Assessment Certificate (First Applicant)	5
Second Applicant	5
2. IDENTITY OF THE CHEMICAL	5
Weight-average MW	5
% MW < 1000.....	5
% MW < 500.....	5
Method	5
3. POLYMER COMPOSITION AND PURITY	6
Synonym	6
4. PLC JUSTIFICATION	6
5. PHYSICAL AND CHEMICAL PROPERTIES.....	6
Result	6
Comments	6
5.1. Comments on Physico-Chemical Properties.....	7
6. USE, VOLUME AND FORMULATION	8
7. OCCUPATIONAL EXPOSURE.....	8
Exposure details.....	8
Controls indicated by notifier	8
<i>Formulation</i>	8
<i>Transport and storage</i>	9
8. PUBLIC EXPOSURE.....	9
9. ENVIRONMENTAL EXPOSURE	9
9.1. Release	9
9.2. Fate.....	10
10. EVALUATION OF HEALTH EFFECTS DATA.....	11
Chemical	11
Health hazards.....	11
Constituents.....	11
Hazardous impurities	11
Additives/adjuvants.....	11
10.1 Acute Toxicity	11
Summary of the acute toxicity of Polymer in DOW CORNING 9040 Silicone	11
10.1.1 Oral Toxicity (Dow Corning, 1999d)	12
10.1.2 Dermal Toxicity (Dow Corning, 1999b)	12
10.1.3 Skin Irritation (Dow Corning, 1999a).....	13
10.1.4 Eye Irritation (Dow Corning, 1999c).....	13
10.1.5 Skin Sensitisation (Dow Corning, 1999e)	14
10.2 Genotoxicity.....	14
10.2.1 <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay (Dow Corning, 1999f).....	14
10.3 Toxicological Information on Related Silicones	15
10.4 Overall Assessment of Toxicological Data.....	16
11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA	16
12. ENVIRONMENTAL RISK ASSESSMENT	16
13. HEALTH AND SAFETY RISK ASSESSMENT	17

13.1.	Hazard assessment	17
13.2.	Occupational health and safety	17
13.3.	Public health.....	17
14.	MSDS AND LABEL ASSESSMENT.....	18
14.1.	MSDS.....	18
14.2.	Label	18
15.	RECOMMENDATIONS	18
16.	REQUIREMENTS FOR SECONDARY NOTIFICATION	19
17.	REFERENCES	19

FULL PUBLIC REPORT

Polymer in DOW CORNING 9040 Silicone Elastomer Blend

1. APPLICANT

Original Holder of Assessment Certificate (First Applicant)

An Assessment Certificate for the notified polymer known by the name Polymer in DOW CORNING 9040 Silicone Elastomer Blend was granted to Dow Corning Australia Pty Ltd (ABN 91 008 396 245) of Macquarie University Research Park; 3 Innovation Rd, North Ryde NSW 2113.

The Assessment Report for Polymer in DOW CORNING 9040 Silicone Elastomer Blend is identified by the sequence number PLC/189 (Synthetic Polymer of Low Concern Notification).

Second Applicant

Since granting of the abovementioned Assessment Certificate, Procter & Gamble Australia Pty Ltd (ABN 36 008 444 166) of 320 Victoria, Rydalmere NSW 2116 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for Polymer in DOW CORNING 9040 Silicone Elastomer Blend. Dow Corning Australia Pty Ltd. has agreed to this extension.

Information submitted by Procter & Gamble Australia Pty Ltd pertains to the introduction of the notified polymer for use in as a viscosity modifier in personal care products. Introduction volumes will be up to 100 kg per year, imported as the finished product.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Trade names: DOW CORNING 9040 Silicone Elastomer Blend

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
> 15500	not stated	0	0	based on starting

The notifier did not supply a GPC trace or slice data but indicated that the polymer has a high number average molecular weight (expected to be around 1,000,000 g/mol) and that the all material is expected to have molecular weight greater than 15,500 g/mol.

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

Purity (%): 12 % in commercial product

Additives/adjuvants:

Chemical name	Synonym	CAS no.	% weight
decamethylcyclopentasiloxane	cyclomethicone	541-02-6	88

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	clear to slightly translucent paste	
Boiling point	not determined	no well defined melting or boiling point exists (see comments below)
Density	960 kg/m ³ at 25°C	
Water solubility	not soluble	based on solubility data for polymers of similar structure and molecular weight, the water solubility is expected to be less than 1 mg/L (see comments below)
Particle size	not applicable	the polymer is only used in liquid form
Flash point	76°C	polymer formulation
Explosive properties	not explosive	
Stability/reactivity	stable under normal	

	environmental conditions	
Hydrolysis as function of pH	not determined	see comments below
Partition coefficient	not determined	see comments below
Adsorption/desorption	not determined	see comments below
Dissociation constant	no dissociable groups are present	see comments below

5.1. Comments on Physico-Chemical Properties

The polymer particles have a wide molecular weight distribution (15,500 to > 1,000,000 g/mol), so a sharp melting point is unlikely. In any case, when dispersed in decamethylcyclotetrasiloxane the particles are in the form of a swollen gel for which melting point has little significance.

Although no data was supplied with the notification, the water solubility of silicone polymers such as the notified material is usually very low and the notifier indicated that the water solubility of a polydimethylsiloxane with molecular weight 1,200 g/mol was determined as 1.6 mg/L, while for a similar polymer with molecular weight 25,000 g/mol the water solubility was 0.17 mg/L and on further increase in MW to 56,000 g/mol the water solubility was 0.076 mg/L (Watanabe, 1984). As the average MW of the new polymer is stated as around 1,000,000 g/mol the water solubility is expected to be significantly less than 0.076 mg/L. Also, the new polymer will be used with a high proportion of decamethylcyclotetrasiloxane in cosmetic preparations, and a report provided by the notifier (Chu, 1987) indicated that the solubility of the closely related octamethylcyclotetrasiloxane was determined as 0.05 mg/L.

The notifier supplied some information concerning the partition coefficient which is briefly commented on here. Chu (1987) determined the value of Log P_{ow} for octamethylcyclotetrasiloxane as around 5.1, which could be expected for a compound of this chemical nature which contains a high proportion of hydrocarbon and is essentially non polar. Although the new polymer is of a much greater molecular weight and is essentially linear, it contains the same silane groups and it is considered that on a molecular level the physical interactions between water and the polymer would be similar to those between water and octamethylcyclotetrasiloxane. Consequently, it is likely that Log P_{ow} for the polymer would also be around 5, indicating strong preference of the material for organic phases compared with water.

No adsorption/desorption data for soil (Log K_{oc}) were provided in the submission, but there are well established correlations between the value of Log P_{ow} and Log K_{oc} for a wide variety of chemical classes. For example, Lyman et al (1990) list a number of Quantitative Structure Activity Relationships (QSARs) between Log K_{oc} and Log P_{ow} . Although none of the equations quoted by Lyman et al (1990) are strictly applicable for silicone polymers, it is generally true that high values for Log P_{ow} imply correspondingly large values for Log K_{oc} .

Consequently, since Log P_{ow} is expected to be around 5 for the new polymer it is likely that Log K_{oc} will also be high, indicating that the polymer will have high affinity for the organic component of soils and sediments.

The compound contains no acidic or basic functionalities, so dissociation constant data are not applicable. The Si-O bonds are stable under most environmental conditions, and the polymer is not expected to be easily degraded when released.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer will be used as a viscosity modifier in personal care products, such as antiperspirants and deodorants. It will be imported in the formulation DOW CORNING 9040 Silicone Elastomer Blend, which contains 12 % notified polymer in cyclomethicone. The finished personal care products will contain between 0.1 and 1 % notified polymer.

Manufacture/Import volume:

The notifier estimates that the import volume will be up to 10 tonnes notified polymer in the first year, increasing to 40-50 tonnes per annum after three years.

Formulation details:

The notified polymer will be imported as a formulation DOW CORNING 9040 Silicone Elastomer Blend, containing 12 % notified polymer (w/w) in cyclomethicone. The formulation will be stored by the notifier before transport to personal care product manufacturers. The product will be reformulated at a number of sites in Australia to produce consumer personal care products, containing up to 1 % (w/w) notified polymer. The resin dispersion will be imported in 18.1 kg and 181 kg steel drums. The imported formulation will be poured into open or enclosed mixing equipment and incorporated usually with a paddle mixer. The finished personal care products will be packaged for consumer use.

In addition, Procter & Gamble Australia Pty Ltd will import the notified polymer at up to 100 kg per year. It will be imported as a component of Olay Regenerist moisturisers, cream and serum, at concentrations of 1.1% and 1.7% respectively.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Formulation		
<i>Personal care product formulation (20-50 workers)</i>		
dermal	12 % solution, 8 h/day on a daily	exhaust ventilation

basis; workers may be exposed to drips and spill of polymer solution safety eyewear

Transport and storage

Stevedoring industry (10-30 workers)

none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident; exposure to 0.1 – 1 % notified polymer may occur during packaging of personal care products.	none
------	--	------

Transport workers (5-10 workers)

none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident	none
------	--	------

Warehouse workers (5-10 workers)

none	12 % solution, up to 8 h/day on a daily basis; no exposure expected except in case of accident	none
------	--	------

Procter and Gamble will be importing the notified chemical as a component in finished goods only at a concentration of 1.1% and 1.7%. No exposure to the notified chemical is expected during transport and storage except in the event of an accident where the packaging may be breached.

8. PUBLIC EXPOSURE

It is expected that during transport, storage and formulation into personal care products, exposure of the general public will be low.

Personal care products containing the notified polymer at 0.1%-1.7% will be sold to the public. Application of one or more of the products containing the notified polymer is likely to occur on a daily basis, consequently the only limit on exposure is likely to be the commercial success of these products. Exposure during use of antiperspirants and deodorants will occur primarily via the dermal route, with the chances of accidental ocular, oral and inhalation exposure being largely determined by the mode of application, eg spray aerosol or roll-on.

Exposure during the use of moisturising products is expected to be confined to the dermal route although inadvertent exposure via the ocular and oral route may occasionally occur.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

The notifier indicated that an estimated 1 % of residual polymer would remain in the drums and in the mixing equipment after use. Assuming a maximum annual importation of 50 tonnes of notified polymer, around 500 kg of the polymer would remain in the empty drums and mixing vessels. The notifier stated that this material would probably be released into the sewer system, and due to its hydrophobic nature would become associated with sewer sludge. Periodically this sludge is removed from sewer lines and placed into landfill or incinerated.

The polymer will be used in a variety of personal care products, and it is likely that some residual formulation will be left in containers and disposed of with domestic garbage. The notifier did not provide any estimates of the quantity of polymer likely to be released in this manner, but this could be quite high, and 25 % may be typical. Assuming annual imports of 50 tonnes of the polymer, this indicates disposal of around 12.5 tonnes of polymer with garbage. The garbage would be either placed into landfill or be incinerated.

Almost all of the polymer will be released as a consequence of use in personal care products, mostly to sewer systems.

Consequently up to 75 % of the notified polymer (annually 37.5 tonnes) may be released to sewer. Most of the remainder (12.5 tonnes) would be placed into landfill with domestic garbage, although some may be incinerated.

As the new polymer is always used in association with decamethylcyclotrisiloxane, this will have the same release patterns. Consequently up to 420 tonnes of silicone material will be released to the environment each year.

9.2. Fate

The majority of the notified polymer will be used in cosmetic applications, and consequently most is expected to be released into the environment – primarily into sewer systems. The polymer has little affinity for water and is consequently likely to become associated with the sediments in sewer trunks or in sewage sludge at treatment works. Most sewer sludge is placed into landfill, although some may be incinerated. Incineration will destroy the polymer with production of water vapour and oxides of carbon while the silicon component will be converted to silica then become associated with ash or furnace slag.

No data on biodegradation were submitted and the notifier indicated in the Material Safety Data Sheet (MSDS) for the 9040 Silicone Elastomer Blend that, due to very low water solubility, standard tests for biodegradation were not applicable. Silicone materials are not expected to be biodegradable, and it is likely that the released polymer (together with the associated decamethylcyclotrisiloxane) will be reasonably persistent once released.

The very low water solubility and hydrophobic nature of polydimethylsiloxanes indicates that material placed into landfill would be immobilised through association with soil and sediment particles (Hamelink, 1992; Lehmann et al., 1994a). However, over time the polymer and its degradation products could be expected to decompose to simpler species, with eventual production of silicate and landfill gases such as methane and carbon dioxide. Polydimethylsiloxanes are unstable in landfill situations (Hamelink, 1992; Lehmann et al.,

1994a; Lehmann et al., 1994b), and in 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).

Due to its insolubility in water and high molecular weight, the polymer will have little potential for bioaccumulation.

10. EVALUATION OF HEALTH EFFECTS DATA

The health hazards of the constituents and hazardous impurities, additives and adjuvants are tabulated below.

Chemical	Health hazards	Regulatory controls
Constituents		
the identities of residual monomers have been exempted from publication in the Full Public Report	all are present at below the cutoffs for classification of the notified polymer as hazardous	none
Hazardous impurities		
none present		
Additives/adjuvants		
cyclomethicone	low toxicity and irritant potential (Rowe, 1948)	none

10.1 Acute Toxicity

Summary of the acute toxicity of Polymer in DOW CORNING 9040 Silicone Elastomer Blend (12 % notified polymer)

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 2000 mg/kg	(Dow Corning, 1999d)
acute dermal toxicity	rat	LD ₅₀ > 2000 mg/kg	(Dow Corning, 1999b)
skin irritation	rabbit	non-irritating	(Dow Corning, 1999a)
eye irritation	rabbit	slight irritant	(Dow Corning, 1999c)
skin sensitisation	guinea pig	non-sensitising	(Dow Corning, 1999e)

10.1.1 Oral Toxicity (Dow Corning, 1999d)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	gavage; dose 2000 mg/kg
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	no deaths occurred during the study
<i>Clinical observations:</i>	no clinical signs of toxicity were observed
<i>Morphological findings:</i>	no macroscopic abnormalities were observed
<i>Comment:</i>	one animal had a slight weight loss during the second week of the study
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the product containing the notified polymer was of very low acute oral toxicity in rats

10.1.2 Dermal Toxicity (Dow Corning, 1999b)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	semi-occlusive patch; 24 hr exposure; material used as supplied; dose 2000 mg/kg
<i>Test method:</i>	OECD TG 402
<i>Mortality:</i>	no deaths occurred during the study
<i>Clinical observations:</i>	no clinical signs of toxicity were observed
<i>Morphological findings:</i>	no macroscopic abnormalities were observed
<i>Comment:</i>	one female had a slight weight loss during the first week of the study
<i>LD₅₀:</i>	> 2000 mg/kg

Result: the product containing the notified polymer was of low dermal toxicity in rats

10.1.3 Skin Irritation (Dow Corning, 1999a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 female

Observation period: 3 days

Method of administration: semi-occlusive patch; 4 hr exposure; material used as supplied; dose 0.5 mL

Test method: OECD TG 404

Comment: all animals were free of dermal irritation throughout the study; all Draize scores were zero

Result: the product containing the notified polymer was not irritating to the skin of rabbits

10.1.4 Eye Irritation (Dow Corning, 1999c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 male

Observation period: 3 days

Method of administration: a single dose of 0.1 mL of test substance was placed in the conjunctival sac of one (right) eye of each of the test animals; the untreated eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	<i>Time after instillation</i>											
<i>Animal</i>	<i>1 hour</i>			<i>1 day</i>			<i>2 days</i>			<i>3 days</i>		
<i>Cornea</i>	all Draize scores were zero											
<i>Iris</i>	all Draize scores were zero											
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	1	0	0	1	0	0	0	0	0

¹ see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Result: the product containing the notified polymer was a slight irritant to the eyes of rabbits

<i>Strains:</i>	<i>Salmonella typhimurium</i> TA98, TA100, TA1535 and TA1537; <i>Escherichia coli</i> WP2uvrA(pKM101) and WP2 (pKM101)
<i>Metabolic activation:</i>	10 % rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors
<i>Concentration range:</i>	0, 1.0, 3.3, 6.7, 10, 33, 67, 100, 333, 667, 1000 µg/plate, dissolved in tetrahydrofuran and plated as a 25 µL aliquot
<i>Positive controls:</i>	<p>with S9:</p> <p>TA98, TA100, TA1535, TA1537: 2-aminoanthracene 1.0 µg/plate</p> <p>WP2uvrA: 2-aminoanthracene 10 µg/plate</p> <p>WP2: sterigmatocystin 100 µg/plate</p> <p>without S9</p> <p>TA98: 2-nitrofluorene 1.0 µg/plate</p> <p>TA100,TA1535: sodium azide 1.0 µg/plate</p> <p>TA1537: 9-aminoacridine 75 µg/plate</p> <p>WP2uvrA, WP2: methyl methanesulphonate 1000 µg/plate</p>
<i>Test method:</i>	OECD TG 471 and 472 (plate incorporation method)
<i>Comment:</i>	<p>all concentrations were tested in triplicate and concurrent positive and negative controls responded appropriately, except for an unacceptable positive control value in the initial test of TA100 in the presence of S9; this assay was repeated</p> <p>no precipitation or reduction in background lawn was observed in any of the tests</p> <p>increases of 2.3 fold were observed for TA1537 both in the presence (at 1000 µg/plate) and absence (at 33 and 100 µg/plate) of S9 in the initial assay; no dose response was observed and no equivalent increases were observed in the confirmatory assay</p>
<i>Result:</i>	the product containing the notified polymer was non mutagenic under the conditions of the test

10.3 Toxicological Information on Related Silicones

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 weight dimethylsilicone fluids were found to be very low in acute oral toxicity (Rowe, 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, 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, 1976), an apparent dose related incidence of dose related 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.

10.4 Overall Assessment of Toxicological Data

The notified polymer is of very low acute oral toxicity and low dermal toxicity. It is not a skin irritant or a skin sensitiser, and ocular irritant effects are slight and were found to clear after two days. No evidence of mutagenicity was observed in a bacterial assay.

Published information about the general class of polymer including the notified polymer indicates that these are of low toxicity.

The notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSESSMENT

Almost all of the new polymer is expected to be released to the environment as a consequence of its use in personal care products. Most is expected to be released to the sewer, although some may be placed directly into landfill with domestic garbage. The polymer is not biodegradable and that portion released to the sewer (estimated as up to 37.5 tonnes per annum) will become associated with sewer sludge due to its hydrophobic nature. Although all the polymer is expected to be released, the use pattern is such that the release will be diffuse and at relatively low levels. For example, if all the annual import of 50 tonnes were to be released to the sewer system, assuming that each individual in Australia produced 150 L of sewage each day, and taking the national population as 19,000,000 the Predicted Environmental Concentration (PEC) in the sewage is estimated as 48 µg/L. However, as indicated previously this will become associated with sludge, and this will ultimately also be

placed into landfill, although some may be incinerated. It is also expected that around 12.5 tonnes of polymer may be directly released to the soil compartment through disposal of partly emptied containers in domestic garbage.

Silicone polymers are stable under moist conditions, but it is expected that prolonged residence in dry landfills would eventually degrade the polymer to landfill gases and silica, while incineration would destroy the material, also with production of silica.

No ecotoxicity data were supplied, but silicone polymers are not known to be toxic to aquatic organisms, and in any case the low rate of release and expected association of the polymer with sediments would mitigate any toxic effects. The polymer is not expected to bioaccumulate.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer is of very low acute oral toxicity and low dermal toxicity. It is not a skin irritant or a skin sensitiser, and a very slight ocular irritant. No evidence of mutagenicity was observed in a bacterial assay. The notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the polymer solution or the personal care products containing this polymer, or during retail sale of the products. There will be exposure during production of the personal care products.

During the reformulation and packaging processes, the main exposure route for the notified polymer will be dermal. The polymer solution and final products will be viscous, and ready formation of aerosols is not expected. The polymer is not expected to be hazardous by dermal exposure as the high molecular weight will preclude absorption through the skin. The engineering controls and personal protective equipment specified in the notification (local exhaust ventilation and protective eyewear) will provide protection against the notified polymer. No significant OHS risks are expected due to the low toxicity of the notified polymer.

13.3. Public health

An analogous chemical to the notified polymer showed some evidence of effects on reproduction in rats, following subcutaneous administration (Kennedy, 1976). The use of the

notified polymer at 0.1%-1.7% in personal care products means that a small amount will be applied to the skin for each use. Likely skin application sites, such as underarms, possess large numbers of sweat glands, and consequently there is potential for increased dermal absorption at these sites. This is not of concern in this case, as the notified polymer is of high molecular weight (NAMW > 15500) and is unlikely to penetrate biological membranes, suggesting limited systemic absorption following normal use.

The low concentration and limited systemic absorption would eliminate any potential toxic hazard from normal use of the polymer in personal care products. There will be minimal public exposure during transport, storage and formulation into personal care products.

Based on the above information, it is considered that Polymer in DOW CORNING 9040 Silicone Elastomer Blend is unlikely to pose a significant hazard to public health when used in the proposed manner.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994b). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994a). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

To minimise occupational exposure to Polymer in DOW CORNING 9040 Silicone Elastomer Blend, the following guidelines and precautions should be observed:

- Safety eyewear should be used during occupational use of the products containing the notified polymer;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical 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).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the Director of Chemical Notification and Assessment must be informed if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern, and secondary notification may be required under subsection 64(1). 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.

17. REFERENCES

Calandra JC, Keplinger ML, Hobbs EJ, et al. (1976) Health and Environmental Aspects of Polydimethylsiloxane Fluids. *Polymer Preprints*, 17 (1): 12.

Chu HK (1987) The n-Octanol/Water Partition Coefficient of Octamethylcyclotetrasiloxane, Project No. 1362-12 (Series No. I-0005-1666), Dow Corning Corporation Toxicology Department.

Dow Corning (1999a) DOW CORNING 9040 Silicone Elastomer Blend: Acute Dermal Irritation/Corrosion Study in Rabbits, Project No. 1999-I0000-46165, Dow Corning Corporation, Health & Environmental Sciences.

Dow Corning (1999b) DOW CORNING 9040 Silicone Elastomer Blend: Acute Dermal Toxicity Study in Rabbits, Project No. 1999-I0000-46260, Dow Corning Corporation, Health & Environmental Sciences.

Dow Corning (1999c) DOW CORNING 9040 Silicone Elastomer Blend: Acute Eye Irritation/Corrosion Study in Rabbits, Project No. 1999-I0000-46259, Dow Corning Corporation, Health & Environmental Sciences.

Dow Corning (1999d) DOW CORNING 9040 Silicone Elastomer Blend: Acute Oral Toxicity Study in Rats, Project No. 1999-I0000-46222, Dow Corning Corporation, Health & Environmental Sciences.

Dow Corning (1999e) DOW CORNING 9040 Silicone Elastomer Blend: Skin Sensitization Study (Buehler Test Method), Project No. 1999-I0000-46455, Dow Corning Corporation, Health & Environmental Sciences.

Dow Corning (1999f) Genetic Evaluation of DOW CORNING 9040 Silicone Elastomer Blend in the Bacterial Reverse Mutation Assay, Project No. 1999-I0000-46532, Dow Corning Corporation, Health & Environmental Sciences.

Kennedy Jr GL, Keplinger ML, Calandra JC, et al. (1976) Reproductive, Teratologic and Mutagenic Studies with Some Polydimethylsiloxanes. Journal of Toxicology and Environmental Health, 1 : 909-920.

Hamelink J (1992) Silicones. In: N. T. d. Oude ed. The Handbook of Environmental Chemistry, Vol 3: Detergents.

Lehmann RG, Varaprath S & Frye CL (1994a) Degradation of silicone polymers in soil. Environ. Toxicol. Chem., 13 (7): 1061-1064.

Lehmann RG, Varaprath S & Frye CL (1994b) Fate of Silicone Degradation Products (Silanols) in Soil. Environ. Toxicol. Chem., 13 (11): 1753-1759.

Lyman WJ, Reehl WF & Rosenblatt DH (1990) Handbook of Chemical Property Estimation Methods. American Chemical Society, Washington DC.

National Occupational Health and Safety Commission (1994a) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Rowe VK, Spencer HC & Bass SL (1948) Toxicological Studies on Certain Commercial Silicones. Journal of Industrial Hygiene and Toxicology, 30 (6): 332-352.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand.

Watanabe et al N (1984) Sci. Total Environ., 38 : 167.

Attachment 1

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

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, *J. Pharmacol. Exp. Ther.* 82 : 377-390

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.