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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Dow Corning^(R) Toray Silicone BY 16-880 Fluid

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989*, and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Dow Corning^(R) Toray Silicone BY 16-880 Fluid****1. APPLICANT**

Dow Corning Australia Pty Ltd of 21 Tattersall Road BLACKTOWN NSW 2148 has submitted a limited notification statement in support of their application for an assessment certificate for Dow Corning^(R) Toray Silicone BY16-880 Fluid.

2. IDENTITY OF THE CHEMICAL

Dow Corning^(R) Toray Silicone BY16-880 Fluid is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, molecular and structural formulae, spectral data and ingredients have been exempted from publication in the Full Public Report and the Summary Report

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance. Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Trade Name: Dow Corning^(R) Toray Silicone BY16-880 Fluid

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:

light straw coloured liquid

Boiling Point:

liquid with no defined boiling point

Density:

980 kg/m³

Vapour Pressure:

0.66 kPa at 25°C

Water Solubility:

< 1.0% (see below)

Partition Co-efficient (n-octanol/water):

not determined

Hydrolysis as a Function

of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	190°C
Flammability Limits:	none known
Autoignition Temperature:	none known
Explosive Properties:	not considered to present any risk of explosion
Reactivity/Stability:	reacts with strong oxidising agents

Comments on Physico-Chemical Properties

Water solubility was stated by the notifier as <1.0%. This was in the absence of any formal tests. Siloxanes of this nature would be expected to be highly insoluble. Even with the presence of polar carboxyl groups, because of the length and weight of the hydrophobic backbone, solubility of <0.01% would be expected by the EPA.

The presence of carboxyl groups on about 2% of the polymer units may mean some dissociation in water, and slight acidity could be expected (1). While hydrolysis was not determined, there are no readily hydrolysable groups on the polymer.

The environmental properties of polydimethylsiloxane fluids have been well reviewed by Hamelink (2). Silicone fluids are surface active as a result of flexible linkages between siloxanes permitting alignment of the hydrophobic methyl substituents towards the non-polar phase (algae, sediment etc.), and the polysiloxane backbone towards the polar phase (generally water). In aqueous environments, strong adsorption of high molecular weight silicone fluids to sediment may be assumed. Low solubility and surface tension of organosilicons also tends to promote adsorption on particles (3).

As siloxanes are generally regarded as surface active compounds, partition coefficients are not particularly relevant.

4. PURITY OF THE CHEMICAL

Degree of Purity:	95%
Hazardous Impurities:	none

**Other Impurities
(> 1% by weight):**

Chemical Name	CAS No.	Weight %
dimethyl siloxanes	69430-24-6	5

Maximum content of residual monomers: estimated to be < 0.1%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used in the textile industry where it will be used as a textile softener in textile finishing processes.

The notified chemical has been confirmed for use at a final concentration of 1 - 2% at sites in Sydney, Melbourne, Wangaratta, Maitland and Wagga Wagga.

Imports of the notified chemical are estimated to be approximately 10 tonnes per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported at 95% concentration in 200 L steel drums, packed on pallets. At the wharf the pellets are loaded into trucks by means of fork lifts and cranes and transported to Dow Corning Australia's warehouse in Sydney. Twenty to 50 workers (including waterside workers, drivers and warehouse workers) will be involved in transport and handling of the material from the wharf to the warehouse and another 5 to 10 workers (warehouse workers and drivers) from warehouse to textile blending and finishing sites. As no repacking or formulation will be carried out by these workers, exposure to the chemical will result only in the event of accidental spillages.

At the emulsifying and preblending sites 20 to 100 process operators will manually feed the concentrated polymer, water and other ingredients either into high speed mixers, colloid mixers or homogenizers equipped with local exhaust ventilation. Preblended or emulsified polymer is then packed in 200 L or 20 L steel drums. The maximum exposure via inhalation is likely to occur during manual feeding and mixing where aerosol spray might escape.

At the textile finishing sites 20 to 100 process workers will decant the emulsion containing the notified chemical to containers and diluted with water and other ingredients under local exhaust ventilation. The emulsion containing 1 - 2% of the notified chemical is transferred manually to a treatment bath where the fabric is allowed to pass. The treated fabric is then dried at a temperature range of 120 - 150°C and stored for a short period to ensure maximum attachment of the notified chemical to the fabric. Exposure during these operations will be low due to low concentration of the notified chemical in the emulsion.

The duration of exposure for chemical industry process workers and textile industry process workers is approximately 8 hours per day, 5 days per week .

7. PUBLIC EXPOSURE

The notified polymer will be used in clothing textiles and therefore, public contact with the polymer is expected to be widespread. However, given that the polymer will undergo crosslinking on drying to form a completely cured silicone polymer, migration of the polymer from the fabric is unlikely to occur. In addition, the number-average molecular weight (NAMW) 31700 for the notified polymer, suggests that if contact were to occur, dermal absorption is unlikely.

8. ENVIRONMENTAL EXPOSURE

Release

During blending/emulsifying operations, losses are not expected to be significant due to the simple blending process. Residues from drums and equipment will be washed down and carried into liquid industrial waste. For companies without an advanced liquid waste recycling system, residues may be washed to sewer.

At the textile finishing company, the drums will be opened and the emulsion diluted with water, and possibly other chemicals.

Fabric is passed through an emulsion in a treatment bath containing around 1-2% of the notified chemical. The concentration of the chemical in the emulsion will depend on the "pick-up" (the amount of treating bath the fabric absorbs when passed through). If pick-up is relatively poor (the notifier indicates 50%), the concentration of the chemical in the bath will be 2% to enable a 1% silicone treatment owf (on-the-weight of the fabric). Pick up varies depending on the fabric, and the recommended level of application of 0.2 - 1% silicone owf.

Consequently, entry to the sewer system due to discharge of the treating bath may be at 1 or 2%. This will be diluted further within the mill due to other wash waters, prior to entering the sewer system. Wash waters within textile mills can typically be between 1 and 3 ML. A predicted environmental concentration is given in the Environmental Hazard section of this report.

After proceeding through the bath, the fabric is dried, usually between 120 - 150°C. Dry material is then stored for processing into textile products. A further possible route for release to the environment by the notified chemical is wash off from treated fabric, but this is not expected to occur at a significant rate because of the hydrophobic nature of the silicone, and the affinity of silicones for textile surfaces.

Fate

Amounts and concentrations of the notified substance likely to enter sewers are unclear. High molecular weight silicone fluids are removed during sewage treatment, with little, if any, discharge in waste waters (2). The notified silicones are hydrophobic but carry relatively hydrophilic substituents (polar carboxyl groups).

The length of the hydrophobic backbone and the relatively low number of hydrophilic substituents suggest that they will be promptly removed from solution by adsorption onto sludge with little, if any, likely to be contained in treated waste waters. Sludge containing the notified substance may then be incinerated or landfilled. Incineration would destroy the silicones and liberate oxides of carbon and silicon, while disposal to landfill would immobilise them.

In all soils, polydimethylsiloxanes (PDMS) degrade extensively to low-molecular weight, water soluble products. Clay surfaces catalyse the rearrangement of PDMS to oligomeric forms with the rearrangement being much more rapid in dry soils (4). At present there is no evidence for biodegradation in the aquatic environment, though non-biological decomposition has been demonstrated (3).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for polymers with NAMW > 1000 under the Act. However, the following studies on skin irritation for Toray Silicone BY 22-840 Fluid and eye irritation for 3-aminopropyl methyl, dimethyl, ethoxy terminated (Dow Corning^R X2-8630) were submitted. Both chemicals are similar in composition to the notified chemical.

9.1 Acute Toxicity

Summary of the acute toxicity of Cyanex 272 Extractant

Test	Species	Outcome	Reference
skin irritation	rabbit	slight to moderate irritant	5
eye irritation	rabbit	slight to moderate irritant	6

9.1.1 Skin Irritation (5)

<i>Species/strain:</i>	humans
<i>Test type:</i>	human skin insult patch test
<i>Test material:</i>	100% cotton fabrics treated with the microemulsion containing 1-2% of the notified chemical; dried at 105°C for 5 minutes; cured at 130°C for 2 minutes
<i>Number of tests:</i>	20 patch tests were performed
<i>Observation period:</i>	not identified
<i>Method of administration:</i>	treated fabric attached to skin for a specific time period

i

Result: < 24 hours; slight irritant; 24 - 48 hours moderate irritant

9.1.2 Eye Irritation (6)

Species/strain: Albino rabbit

Number/sex of animals: 6 males

Observation period: 72 hours

Method of administration: 0.1 mL into conjunctival sac of one eye. For 3 animals the treated eyes were not irrigated; for 3 animals the treated eyes were irrigated for 30 seconds after instillation

Draize scores (7) of unirrigated eyes:

Time after instillation

Animal	1 day			2 days			3 days			4 days			7 days		
Cornea	o^a	a^b		o^a	a^b		o^a	a^b		o^a	a^b		o^a	a^b	
1	0			0			0			-			-		
2	0			0			0			-			-		
3	0			0			0			-			-		
Iris															
1		0			0			0			-			-	
2		0			0			0			-			-	
3		0			0			0			-			-	
Conjunctiv a	r^c	c^d	d^e	r^c	c^d	d^e	r^c	c^d	d^e	r^c	c^d	d^e	r^c	c^d	d^e
1	1	1	-	1	1	-	0	0	-	-	-	-	-	-	-
2	2	2	-	1	1	-	0	0	-	-	-	-	-	-	-
3	1	1	-	1	1	-	0	0	-	-	-	-	-	-	-

ⁱ see Attachment 1 for Draize scales

^a opacity ^b area ^c redness ^d chemosis ^e discharge

Irrigated eyes: no corneal or iridial effects; 1 animal exhibited no conjunctival redness or chemosis, 2 animals exhibited slight redness and chemosis on day 1

Test method: in accordance with OECD Guidelines for

Testing of Chemicals (8)

Result: slight to moderate irritant

9.2 Overall Assessment of Toxicological Data

A skin irritation study carried out using a dermal patch test and an ocular study on rabbits using compositionally similar chemicals, indicated the notified chemical to be a slight to moderate skin and eye irritant.

On the basis of submitted analog data, the notified chemical will not be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] in relation to skin and eye irritation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for polymers of NAMW > 1000 according to the Act. The high molecular weight and low solubility of the substance suggest that it will not cross biological membranes, and will therefore be of low toxicity.

Polydimethylsiloxane (PDMS) fluids in intimate contact with many soils undergo siloxane bond redistribution and hydrolysis, resulting in the formation of low molecular weight cyclic and linear oligomers (9). Cyclic oligomers will include octamethylcyclotetrasiloxanes (OMCTS), and toxicity figures are presented below

Table 1 - Toxicity of Octamethylcyclotetrasiloxane in Aquatic Sediments. (10)

Species	Testing Medium	NOEC
Midge (<i>Chironomus tentans</i>)	Water only	15 µg/L
	Sediment-Low organic content	65 mg/L

Sediment- medium organic content	120 mg/L
	54 mg/L
sediment- high organic content	

Toxicity is clearly reduced in the presence of sediment or particulate organic carbon. Volatility also serves as another avenue to limit aquatic exposure of low MW oligomers.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated, a poor "pick up" of the chemical by fabric could result in only 50% being absorbed by the fabric. The remaining chemical is likely to be diluted within the washwaters from other textile mill operations such as dyehouse wash waters, prior to discharge to sewer. A Predicted Environmental Concentration (PEC) has been based on the following parameters:

Expected annual consumption:	10 tonnes	
No. of sites:	5	
Average quantity per site:	2000 kg	
Production days per year:	300	
Quantity of chemical used per day:	6.7 kg	
Worst case "pick-up" rate:	50%	
Quantity of chemical entering mill effluent:	3.35 kg	
Concentration in mill by wash waters (1 ML):	3.35 mg.L ⁻¹	
Concentration in water treatment works:	city (250:1)	country (5:1)
	13.4 ppb	0.67 ppm
Concentration in receiving waters:	city (10:1)	country (2:1)
	1.34 ppb	0.34 ppm

This calculation is not particularly meaningful for such strongly surface active compounds, which tend to undergo essentially complete removal through sorptive processes during waste water treatment. The exercise does confirm however that concentrations of the modified silicone fluid, or its derivatives, entering the aquatic environment should be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not considered hazardous in relation to its physico-chemical properties other than in contact with strong oxidising agents. Major toxicological

concerns associated with the notified chemical will be its potential slight to moderate skin and eye irritation. Adverse systemic effects (from dermal absorption) are unlikely due to the high NAMW of the notified polymer. In addition the level of residual monomers in the notified polymer are unlikely to present a health hazard. However, dimethyl siloxanes present as an impurity (5%) carries an exposure limit of 10 ppm (time weighted average).

As the polymer is available in liquid form, inhalation, skin and eye contact will be the main source of occupational exposure during emulsifying and preblending operations. During these operations the use of local exhaust ventilation would minimise inhalational exposure due to aerosol spray. However, should ventilation methods be inadequate exposure may be further controlled with personal protective equipment including respiratory protection would further reduce exposure.

The risk of adverse effects at textile finishing sites is expected to be low, due to low exposure levels and the high molecular weight of the notified polymer.

Fabrics treated with the notified polymer will be used in the manufacture of clothing, and therefore, public contact with the notified polymer is expected to be widespread.

13. RECOMMENDATIONS

To minimise occupational exposure to Dow Corning^(R) Toray Silicone BY16-880 Fluid the following guidelines and precautions should be observed during decanting, mixing and packaging at chemical processing sites and use at textile finishing sites:

- carried out under local exhaust ventilation
- if engineering controls and work practices are insufficient to reduce exposure to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;
 - eye protection should be selected and fitted in accordance with AS 1336 (11) to comply with AS/NZS 1337 (12)
 - industrial clothing must conform to the specifications detailed in AS 2919 (13) and AS 3765.1 (14)
 - impermeable gloves or mittens conforming to AS 2161 (15)
 - all occupational footwear should conform to AS/NZS 2210 (16)
- 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 material safety data sheet (MSDS) should be easily accessible to employees.
- the notified polymer should not be used to treat fabrics that are expected to be in contact with human skin for prolonged periods, in view of its potential to cause slight to moderate skin irritation.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

- 1 Brown, WH (1982). *Introduction to Organic Chemistry*, Third Edition. p 261.
- 2 Hamelink, JL (1992), *Silicones in the Handbook of Environmental Chemistry*, Vol 3: Detergents, N.T. de Oude (ed).
- 3 World Health Organisation, 1986. Reports and Studies No 29. *Review of Potentially Harmful Substances: Organosilicon Compounds (Silanes and Siloxanes)*.
4. Lehmann, RG, Varaprath, S, Annelin, RB & Arndt, JL "Degradation of Silicone Polymer in a Variety of Soils." *Environmental Toxicology and Chemistry* 1995, **14**,pp 1299-1305.
5. Data on file, *Human Skin Insult Patch Study: Doe Corning Toray Silicone BY 16-880*, Japan. .
6. Stanton E., Siddiqui W.H., 1987, : *Eye Irritation to the Rabbit*, Report No: 7430, Health and Research Centre Gruppe, Germany.
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9. Buch, RR & Ingebrigtsen, DN "Rearrangement of Poly(dimethylsiloxane) Fluids on Soil. *Environmental Science and Technology*, 1979, Vol 13, pp 676 - 679.
10. Kent, DJ, McNamara, PC, Putt, AE, Hobson, JF & Silberhorn, EM Octamethylcyclotetrasiloxane in Aquatic Sediments: Toxicity and Risk Assessment. *Ecotoxicology and Environmental Safety*. 1994, **29**, pp 372 - 389.
11. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.
12. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
13. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing Clothing*, Standards Association of Australia Publ., Sydney.
14. Standards Australia 1990, *Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals*, Standards Association of Australia Publ., Sydney.
15. Australian Standard 2161-1978, *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.
16. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
17. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

Attachment 1

The Draize Scale 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 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

