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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

DOW CORNING @2-8630 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 Human Services and Health.

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA

Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA

Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT
DOW CORNING ®2-8630 FLUID

1. APPLICANT

Dow Corning Australia Pty Ltd, 21 Tattersall Road , Blacktown, NSW 2148

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, DOW CORNING ®2-8630 FLUID is not considered to be hazardous. Therefore, the details of chemical name, CAS number, molecular formula, structural formula and spectral data have been exempted from publication in the Full Public Report and Summary Report.

Other name: Amino-functional polysiloxane

Trade name: Dow Corning ® 2-8630 Fluid

Number-average molecular weight: 42140

Weight-average molecular weight: 71160

Maximum percentage of low molecular weight species (molecular weight < 1000): None

Method of detection and determination:

Infra-red Spectroscopy; Nuclear Magnetic Resonance Spectroscopy; Gel Permeation Chromatography;

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Clear to hazy straw coloured liquid

Odour: Ammonia

Glass-transition Temperature: Not provided

Specific Gravity: 0.98 at 25°C

Vapour Pressure: <0.67 kPa at 25°C

Vapour Density: >1

Water Solubility: <1.0 g/L at 20°C

Fat Solubility: Not provided

Partition Co-efficient (n-octanol/water) $\log P_{o/w}$:	Not provided, not relevant to surface active substances
Hydrolysis as a function of pH:	The polymer carries terminal ethoxy substitution that is susceptible to hydrolysis, particularly at alkaline pH
Adsorption/Desorption:	Silicones are strongly surface active and sorb strongly to soils, where they undergo catalytic transformation
Dissociation Constant pKa:	Not applicable
Flash Point:	>23 °C closed cup
Flammability Limits:	Not determined
Combustion Products:	Oxides of nitrogen and carbon, silicon dioxide, traces of incompletely oxidised carbon compounds and formaldehyde
Pyrolysis Products:	Not provided
Decomposition Temperature:	150°C
Autoignition Temperature:	Not determined
Explosive Properties:	Not likely to explode
Reactivity/Stability:	Oxidising agents can cause a reaction; ethyl alcohol forms upon contact with water, moisture or humid air; hazardous polymerisation will not occur
Particle size distribution: range - μm	Not applicable

4. PURITY OF THE CHEMICAL

Degree of purity:	93.9%
Toxic or hazardous impurity/impurities:	None

Non-hazardous impurity/impurities (> by weight):

- | | |
|---------------------------|---------------------------|
| Chemical name: | Cyclosiloxanes, di-methyl |
| CAS No.: | 69430-24-6 |
| Weight percentage: | 5% |
- | | |
|---------------------------|---------|
| Chemical name: | Ethanol |
| CAS No.: | 64-17-5 |
| Weight percentage: | 1% |

Maximum content of residual monomer(s): None

Additive(s)/Adjuvant(s): None

5. INDUSTRIAL USE

Dow Corning ® 2-8630 Fluid is a textile softener which will be imported into Australia in liquid form for use in textile mills. The estimated yearly import is 10 tonnes/year.

6. OCCUPATIONAL EXPOSURE

Following importation, Dow Corning ® 2-8630 Fluid will be emulsified by mixing with water and emulsifying agents in either a high speed mixer, colloid mill or homogeniser. After emulsification, other chemicals used in the textile industry may be blended with the notified chemical to form emulsions containing 1-20% w/w of the notified chemical which will then be sold to the textile finishing industry. Storage and transportation of the emulsion will be in 20 or 200L steel drums. At the textile finishers, the emulsion will be decanted in the required quantities and diluted with water with the possible addition of other chemicals before application to textiles by padding or dipping. Application baths will contain <1% of the notified chemical. The treated textiles will then be dried at 120-150°C and stored for further processing into garments.

No details have been provided regarding the machineries to be used in the emulsifying, blending, application to textiles and drying operations. However it can be concluded that if personal protection measures, engineering controls and good work practices are not implemented in the work place, workers may come into direct contact with the notified chemical and exposure of workers handling the pure chemical may be high. Exposure to the notified chemical in the emulsion form is likely to be low based on the strengths of the emulsions to be prepared. After the textiles have been dried, exposure to the notified chemical will be very low as it will have become firmly attached to the textiles.

7. PUBLIC EXPOSURE

The public may come into contact with the notified polymer when fabrics containing it are used or worn. However, once incorporated into the fabric and dried, the chemical undergoes crosslinking to form cured silicone polymer, presumably with relatively inert properties. Therefore, public exposure to the notified polymer should be minimal.

8. ENVIRONMENTAL EXPOSURE

. Release

The notified substance is imported as a 100% polymer fluid that will be sold to textile chemical formulators. The formulators will prepare aqueous emulsions containing 1-20% of the notified substance using standard procedures (high speed mixer, colloid mill or homogeniser). The emulsions may be blended with other textile finishing chemicals before distribution to customers in closed 20 or

200 L lined steel drums. No estimate was provided of losses during formulation, but these would not be expected to be significant from a simple blending process. Drum residues and equipment washings will be discharged as aqueous waste.

The substance is likely to be used by textile mills situated in coastal and inland cities throughout Australia (eg Sydney, Melbourne, Wangaratta, Maitland and Wagga Wagga).

The notifier states that accidental discharge from the application bath or residuals in the spent treatment bath may enter sewers, at a worst case concentration in the order of 1%. A microemulsion of the notified silicone underwent 99% exhaustion onto fabric during 60 minutes, but the degree of stripping that will occur under actual conditions of use is unclear. Treatment baths need to be emptied and refilled as the emulsions they contain become spent or contaminated, but the frequency with which this may occur is not apparent in the submission. However, high molecular weight silicone fluids are removed during sewage treatment, with little, if any, discharged in waste waters (1). Sludge containing residues of the notified substance may be incinerated or landfilled.

Another possible route for environmental exposure to the modified silicone is wash off from treated fabric, but this is not expected to occur at a significant rate because of the strong affinity of silicones for textile surfaces.

. Fate

The notified substance is likely to undergo transformation in aqueous media because of the presence of hydrolytically labile terminal ethoxy substituents. This transformation would generate another silicone with similar properties.

Amounts and concentrations of the notified substance and its transformation products likely to enter sewers are unclear. These silicones are hydrophobic but carry hydrophilic substituents. 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, nitrogen and silicon, while disposal to landfill would immobilise them.

Silicones undergo clay catalysed rearrangement in soils to water soluble hydroxy functional low molecular weight oligomers, and volatile cyclics and trimethylsiloxy end-blocked oligomers (2). The rearrangement is much more rapid in dry soils (3) but is not known to occur in aquatic sediment. It is thought that soil moisture coating the clay particles may limit contact with hydrophobic silicones, thus retarding the reaction.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Dow Corning ® 2-8630

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ >2000mg/kg	(4)
Acute dermal toxicity	Rat	LD ₅₀ >2000 mg/kg	(5)
Skin Irritation	Rabbit	slight irritant	(6)
Eye irritation	Rabbit	slight irritant	(8)

9.1.1 Oral Toxicity (4)

This study was carried out in accordance with the *OECD Guidelines for the Testing of Chemicals No:401*.

A single dose of 2000 mg/kg of Dow Corning® 2-8630 was administered by gavage to 10 (5 males and 5 females) Sprague-Dawley albino rats. The animals were observed for 14 days post-exposure. No deaths were observed during the study. Food consumption and gain in bodyweight were unaffected. Necropsy revealed no treatment related changes.

The results of this study indicate an acute oral LD₅₀ of >2000 mg/kg for Dow Corning® 2-8630 in male and female rats.

9.1.2 Dermal Toxicity (5)

This study was carried out in accordance with the *OECD Guidelines for the Testing of Chemicals No:402*.

A single dose of 2000 mg/kg of Dow Corning® 2-8630 was administered by occlusive application to the shaved dorsal area of each of 10 (5 males and 5 females) albino New Zealand White rabbits for 24 hours. The animals were observed twice daily for a period of 14 days post-exposure. No deaths were noted during the study. Food consumption and gain in bodyweight were unaffected. Necropsy revealed no treatment related changes.

The results of this study indicate an acute dermal LD₅₀ of <2000 mg/kg for Dow Corning® 2-8630 in male and female rabbits.

9.1.3 Skin Irritation (6)

This study was carried out in accordance with the *OECD Guidelines for Testing Chemicals No:404*.

A single dose of 0.5 ml of Dow Corning® 2-8630 was administered by occlusive application to the intact shaved dorsal skin of each of four New Zealand White rabbits for four hours. The test sites were examined at 1, 24, 48 and 72 hours post-exposure. Effects were graded according to Draize (7). Twenty-four hours post-exposure, very slight erythema was observed in all 4 test animals and slight oedema was seen in one animal. These symptoms had disappeared by 48 hours post-exposure.

The results of this study indicate that Dow Corning® 2-8630 is a slight skin irritant in rabbits at the concentration tested.

9.1.4 Eye Irritation (8)

This study was carried out in accordance with the *OECD Guidelines for Testing Chemicals No: 405*.

A single dose of 0.1ml of Dow Corning® 2-8630 Fluid was instilled into one eye of each of six New Zealand White rabbits. The untreated eye of each rabbit served as the control. Three of the treated eyes were washed 30 seconds after exposure. The other three treated eyes were left unwashed. Both eyes of each rabbit were tested with fluorescein dye and were examined for staining 24, 48 and 72 hours after exposure. The effects were graded according to Draize (7). Some slight redness of the conjunctiva was seen in all three unwashed eyes 24 and 48 hours post-exposure but such effects were not observed by 72 hours post-exposure. Two of the washed eyes also showed signs of slight redness of the conjunctiva one and 24 hours post-exposure but were normal by 48 hours.

Results of this study indicate that Dow Corning® 2-8630 Fluid is a slight eye irritant in rabbits at the concentration tested.

9.2 Genotoxicity

9.2.1 Salmonella typhimurium Reverse Mutation Assay (9)

This study was carried out in accordance with the *OECD Guidelines for the Testing of Chemicals, "Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay" No: 471*.

Dow Corning® 2-8630 at dose levels of 312.5, 625, 1250, 2500 and 5000 µg/plate was tested in two independent experiments for gene mutations using *Salmonella typhimurium* strains TA-98, TA-100, TA-1535 and TA-1537, and *E. coli* strain WP2, both in the presence and absence of a metabolising system (S9-mix). The positive controls used were sodium azide, 9-aminoacridine, 2-nitrofluorene, N-methyl-N-nitro-N-nitrosoguanidine and 2-anthramine. The solvent, absolute ethanol served as the negative control.

In both the experiments, the test substance did not induce statistically significant dose-related or twice the solvent control value increases in the observed number of revertant colonies in the *Salmonella typhimurium* and *E. Coli* strains tested in the presence or absence of S9-mix. On the other hand, the positive controls induced marked increases.

The results of this study suggest that Dow Corning® 2-8630 was not mutagenic under the test conditions reported.

9.3 Overall Assessment of Toxicological Data

Dow Corning® 2-8630 has low acute oral and dermal toxicity (oral LD₅₀ in rats: >2000 mg/kg ; dermal LD₅₀ in rats : >2000 mg/kg). It is a mild eye and skin irritant. It is not mutagenic. Its high molecular weight renders it unlikely to cross biological membranes to bring about any systemic effects.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* (10) in relation to the following acute toxicity studies: acute oral toxicity; acute dermal toxicity; skin irritation; and eye irritation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for polymers of NAMW >1 000 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. Water soluble (miscible or self-dispersing) polyamines of molecular weight above 1000 can exert toxicity on fish by binding to gill membranes, although toxicity is mitigated by dissolved organic carbon in natural waters (11). Further mitigation in natural surface waters of any toxic potential will be provided by the surface active properties of the polydimethylsiloxane backbone, which will favour precipitation of the notified substance with sediment.

The notifier submitted a report (12) on toxicity testing with *Daphnia magna* in a static system. A dose related mortality response was observed, with a 48 h LC50 of 44 ppm, indicative of slight toxicity. Mortalities were thought to be due at least in part to entrapment of the test organisms by the strongly surface active test substance, as has been reported elsewhere. Entrapment occurred on the sides of the test vessels, and on a Nitex screen installed to prevent entrapment in the surface film. Similar effects would not be expected in natural environments where a variety of other surfaces provide opportunities for deposition of silicones.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

No estimates were provided of typical amounts and concentrations of this modified silicone likely to be discharged from textile factories. In the worst case situation of accidental discharge of the bath to the sewer, the daily budget of fabric conditioner may be released all at once, at a concentration in the order of 1%. Assuming 10% of total use at an inland location where production occurs on 300 days each year, the worst case daily discharge would be around 3.3 kg. Passage through sewage treatment works, assuming daily flow of 5 ML, would dilute this discharge to below 1 ppm.

Calculations such as the above indicating the degree of dilution of textile waste streams before they reach the environment are not particularly meaningful for such strongly surface active compounds, which tend to undergo essentially complete removal through sorptive processes during waste water treatment. However, the above exercise confirms that unacceptable concentrations of the new modified silicone fluid should not enter the environment.

Silicone polymers are a well studied class of compound used in a variety of applications, many of which entail discharge to sewage systems as emulsions. Dow Corning; 2-8630 Fluid will also enter sewers, but is not expected to enter aquatic environments in significant quantities because of its removal with sludge during treatment. The predicted environmental hazard is low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is a high molecular weight polymer so it is unlikely to cross biological membranes to bring about systemic effects. However, animal studies have shown that it is a mild eye and skin irritant so care must be taken in preventing contact with the eyes and skin especially during prolonged exposure to the notified chemical. It has a low vapour pressure therefore irritation of the upper respiratory tract through inhalation is unlikely. So far, no work-related health effects have been reported and there are no known health conditions for which use of the notified chemical should be avoided.

In the work-place, ethanol formed on contact of the notified chemical with water, moisture or humid air, will present the main health risk to workers. Although the amount of ethanol which can evolve is unlikely to be high, workers who handle the emulsification of the pure chemical with water should take care in avoiding contact with it. The work-place should be well ventilated. Exposure to ethanol in excess of its exposure standard of TWA 1000 ppm (13) may cause headache, eyes, nose and throat irritation; and with prolonged exposure, drowsiness, lassitude, loss of appetite and the inability to concentrate (14).

The notified chemical and ethanol are flammable substances so it is necessary that the work-place be well ventilated and flame, sparks and heat eliminated.

Under normal use conditions when control measures are in place, the notified chemical is not expected to present any acute significant health or safety hazard to workers.

While public contact with materials treated with the notified polymer may occur, public exposure to the notified polymer is expected to be negligible, since the high molecular weight polymer self crosslinks to form a stable and inert coating after application to the fabric.

13. RECOMMENDATIONS

To minimise occupational exposure to Dow Corning® 2-8630 the following guidelines and precautions should be observed:

- . enclosed systems should be used when splashings or spillages are anticipated;
- . good work practices should be implemented to avoid spillages and splashings;
- . storage should be in sealed robust containers and in accordance with relevant State or Territory Dangerous Goods legislation due to the notified chemical being a moderately hazardous flammable product;
- . the work-place should be well ventilated;

- . if engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment which complies with Australian Standards (AS) should be worn such as:
 - . splash-proof safety goggles (AS 1337) - *Eye Protectors for Industrial Applications* (15); and
 - . in the event of prolonged exposure elbow length impervious gloves (AS 2161) - *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)* (16);
- . should there be an accidental spillage or leakage, eliminate sources of ignition and ventilate the area affected. Mop, wipe or soak up spill with an inert absorbent and contain for disposal according to State regulations;
- . a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for Dow Corning ® 2-8630 was provided in Worksafe Australia format (17).

This MSDS was provided by Dow Corning Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Dow Corning Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Dow Corning ® 2-8630 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

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14. N. Irving Sax, Richard J Lewis., Dangerous Properties of Industrial Materials, 7th Edition, Van Nostrand Reinhold, New York, 1989.
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