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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in 2-8822

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Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9466 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in 2-8822

1. APPLICANT

Dow Corning Australia Pty Ltd of 21 Tattersall Road BLACKTOWN NSW 2148 has submitted a limited notification statement for an assessment certificate for Polymer in 2-8822.

2. IDENTITY OF THE CHEMICAL

Polymer in 2-8822 is considered to be hazardous based on the nature of the chemical and the analogue data provided. However, the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	amino functional polydimethyl siloxane
Trade Name:	Dow Corning$^{(R)}$ 2-8822 polymer
Method of Detection and Determination:	infrared (IR) spectra and Gel Permeation Chromotography (GPC)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	light, straw-coloured liquid with an amine like odour
Boiling Point:	not determined
Specific Gravity:	970 $kg.m^{-3}$ at 25°C
Vapour Pressure:	4.2 $x10^{-6}$ Pa at 25°C
Water Solubility:	2.2 $mg.L^{-1}$ as $(CH_3)_2SiO$ (see comments below)
Partition Co-efficient (n-octanol/water):	not determined (see comments below)

Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see comments below)
Dissociation constant:	not determined (see comments below)
Flash point:	113°C (closed cup)
Flammability limits:	lower: 1.2%v/v; upper: > 3.4% v/v
Autoignition temperature:	449 °C
Explosive properties:	None
Reactivity/stability:	notified polymer can react with strong oxidising agents; thermal breakdown during fire or very high heat conditions may evolve: carbon oxides, traces of incompletely burned carbon compounds, silcon dioxide, nitrogen oxides and formaldehyde

Comments on Physico-Chemical Properties

All physico-chemical data provided (including molecular weight determinations) were acquired at Dow Corning corporate facilities using corporate test methods.

Water solubility was estimated by mixing the polymer with water, filtering to remove suspended matter followed by extraction into a mixed organic solvent. This extract was then analysed for Si using atomic adsorption spectroscopy. Since the polymer contains a high proportion of $(CH_3)_2SiO$ groups, the solubility is reported in terms of this chemical species. This test method is based on OECD guidelines 105 and 120 and may significantly overestimate the polymer solubility since this test methodology really measures the water extractable fraction, including the low molecular weight impurities which may have significant intrinsic solubility. The true water solubility of organosilicones is very low (1) and it is likely that the reported 2.2 $mg.L^{-1}$ is primarily associated with the low molecular weight cyclosiloxanes present as residual reactants in the material. Contributions resulting from the presence of colloidal aggregates of the polymer in the water are also possible (2). The high molecular weight and hydrophobic nature of the molecule indicates extremely low (1, 2) true water solubility.

Although no hydrolytic degradation data was provided, the compound is unlikely to undergo hydrolysis in the usual environmental pH region (4<pH<9). Low water solubility would also detract from any tendency for hydrolysis. Nevertheless it is likely that hydrolytic cleavage of the siloxane groups are instrumental in bonding the polymer to the fabric during the high temperature (120^0C) drying process (see below).

No partition coefficient or adsorption/desorption data was provided, but the hydrophobic nature of most of the polymer indicates that it would have affinity for the

oil phase, and also adsorb the organic component of soils and sediments (2, 3).

The terminal amino groups are likely to have typical amino pKa values of between 9.5 and 10.5, and consequently be protonated in the usual environmental pH region (4<pH<9), giving these terminal groups a positive charge.

4. PURITY OF THE CHEMICAL

Degree of purity: 96%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): see residual monomers

Maximum Content of Residual Monomers:

Chemical Name	*CAS No.*	*Weight %*
Cycolsiloxanes - dimethyl	69430-24-6	3
Isodecyl alcohol	68256-86-3	1

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer will be imported as polymer fluid (approximately 100% notified polymer) in 20 L and 200 L steel drums for use as a textile softener. The polymer fluid will be emulsified by Dow Corning Australia Pty Ltd, or a customer by mixing it with water and emusifying agents. The polymer emulsion will then be sold to the textile finishing industry where it will be further blended with other chemicals commonly used in the textile industry, such as inorganic salts, dye stuffs and finishing resins. The imported polymer fluid containing the notified polymer may also be sold as imported, without preblending to the textile industry.

The estimated quantity of the notified polymer to be imported is 10 tonnes per annum the first five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported as a polymer solution and stored at a Dow Corning Australia site before transportation by road and rail to formulators or distributors. The potential for worker exposure is minimal under normal conditions for storage and transport.

The notified polymer, as the imported polymer fluid, will be converted to an oil/water emulsion containing between 10 and 20% of the notified polymer. This initial blending process will be carried out by 20 to 100 textile workers using either high speed mixers or colloid mills. During transfer of the notified polymer to the blending vessels there is the potential for occupational exposure with the skin being the most likely route of exposure.

The blended material will then be transported by road and rail to the textile finishing industry. In some cases the polymer fluid may be transported to some distributors without preblending. In both circumstances the notified polymer, as the polymer solution or blended material will be packed into closed 200 L (or 20 L) steel drums.

At the textile finishing company the polymer fluid or blended material emulsion, containing the notified polymer, will be diluted further by the addition of other standard chemicals such as inorganic salts and dyes. The final aqueous emulsion applied to textiles will contain below 1% of the notified polymer. Application onto the textile either will be by a continuous or batch process. In the continuous process the fluid or blended material is placed in a trough and the fabric passed through the liquid. The textile will be circulated in the bath and during this process the textile absorbs the notified polymer (polymer emulsion) leaving only small amounts of residue in the bath, maybe 10% or less. Excess liquid is squeezed out by rollers and the remaining water will evaporate during the drying and curing process which is carried out in ovens at temperatures of between 120 and 150 °C. During this process the notified polymer bonds to the textile. There is the potential for dermal exposure when the wet textile, which has absorbed the notified polymer, is transferred to the ovens. There is also the potential for incidental contact during the finishing process when the textile is treated with the liquid.

During drying the notified polymer cross-links to form a completely cured silicon polymer, obviating further occupational exposure.

Workers should be aware that harmful degradation products may be released during the curing process and therefore they should take appropriate precautions to minimise exposure including adequate ventilation.

7. PUBLIC EXPOSURE

Textiles treated with the notified polymer will be used in the clothing industry, and as such dermal contact with treated clothing will occur. Minimal amounts of the notified chemical are expected to be released from the treated fabrics during wearing or washing, and the NAMW is greater than 10 000. As such there should be negligible

exposure of the public.

Minor public exposure may result from disposal of the unused products which contain the notified polymer, or accidental spillage of the products during transport, formulation and storage. However, adequate measures are described by the notifier to minimise the risk of public exposure during formulation, disposal, or in the event of accidental spillage.

8. ENVIRONMENTAL EXPOSURE

Release

Some of the imported polymer will remain in the drums after production of the emulsion, and this is estimated to be 0.25% or 0.5 kg in a 200 L drum. These residues will be washed out and passed to a waste treatment plant at the Dow Corning facility. However, where emulsion is prepared at the textile mills or by other chemical formulators, it is likely that drum residuals will be discharged directly to sewer systems. If the 0.25% residual in the drums estimated by the notifier is accepted, then with annual imports of 10 tonne, a maximum 25 kg of notified material could be discharged to sewer via this route.

Some polymer is also likely to be released through discharge of “spent” bath solution containing 1 to 2% of the polymer. The textiles “pick up” between 50 and 100% of the bath solution prior to drying, and it is likely that these solutions are continually replenished in a closed system and hence releases will be small. Spent solution would also be passed to the sewer system and the notifier estimates around 5% (500 kg per annum) of the imported polymer would be released via this route.

Fate

Most of the material will be chemically bonded to textiles and its fate will consequently be that of the textile. However, it is probable that degradation of the polymer to lower molecular weight oligomers will occur over time as a result of washing and other processes. The resultant molecules are likely to be discharged to sewer with grey water from laundries. Old textile is likely to be placed into landfill or incinerated.

Polymer and degradation products which enter sewer systems will be adsorbed onto the organic component of sediments, and are likely to eventually become associated with waste sludge from sewage plants. This would either be deposited into landfill or incinerated.

Incineration would destroy the polymer with production of silica, water vapour and oxides of carbon and nitrogen.

The very low water solubility and hydrophobic nature of polydimethylsiloxanes indicates that when placed into landfill the material would be immobilised through association with soil and sediment particles (2, 3). 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, carbon

dioxide and ammonia.

Polydimethylsiloxanes are unstable in landfill situations (2, 3, 4), 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 (2).

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

9. EVALUATION OF TOXICOLOGICAL DATA

The Act does not require provision of toxicology data for polymers where the NAMW exceeds 1 000. However, the following data were provided for a chemically similar polymer, identified as Dow Corning 2-8075 Amino Functional Fluid. Individual animal data were not provided, summary reports only were cited.

Toxicity For Dow Corning 2-8075

9.1 Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50}> 5 000 $mg.kg^{-1}$	(5)
acute dermal toxicity	rabbit	LD_{50}> 2 000 $mg.kg^{-1}$	(6)
skin irritation	rabbit	severe irritant	(7)
eye irritation	rabbit	moderate irritant	(8)

9.1.1 Oral Toxicity (5)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, as a clear yellow liquid tested as supplied at a dose level of 5 000 mg/kg
Clinical observations:	no adverse effects were observed throughout the study
Mortality:	nil

Morphological findings:	no abnormalities detected
Test method:	based on OECD Guidelines for testing animals (9)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	the test material is considered to be of low oral toxicity in rats

9.1.2 Dermal Toxicity (6)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 000 $mg.kg^{-1}$ of neat test substance (liquid) applied to intact skin and held in place for 24 hours by a semi-occlusive dressing
Clinical observations:	one of the males had slight diahorrea during the early part of the study but this was considered not to be compound related; no abnormalities observed in the remaining animals
Mortality:	one male rabbit died of the fourth day following slight diahorrea; this was considered not to be compound related and the remaining animals survived until the end of the study
Morphological findings:	a distended caecum, black patches on the lung and liver were found in the rabbit that died on day 4 of the study; examination of all surviving animals did not reveal any gross alterations in the tissues and organs examined
Test method:	based on OECD Guidelines for Testing animals (9)
Result:	the test material is of low dermal toxicity in rats

9.1.3 Skin Irritation (7)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	21 days
Method of administration:	0.5 mL of neat test substance was applied to intact skin of six rabbits and held in place using a semi-occlusive dressing for 4 hours; the chemical was removed and the animals observed for 21 days for signs of erythema, eschar and oedema
Test method:	based on OECD Guidelines for Testing Chemicals (9)
Draize scores:	evaluation of responses was determined using Draize scoring system (10) but individual animal data were not provided by the notifier; severe redness with slight eschar and swelling was observed in all rabbits; these effects gradually reduced in severity and all signs of irritation had reversed by day 21
Result:	the test material is a severe skin irritant

9.1.4 Eye Irritation (8)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	14 days
Method of administration:	0.1 mL of undiluted test substance was instilled into the right eye of each rabbit, the left eye remaining untreated and serving as a control; treated eyes of three of the six rabbits were washed at 4 seconds and the remaining animals after 30 seconds
Test Method:	based on OECD Guidelines for Testing Chemicals (9)
Observations:	evaluation of responses was determined using Draize scoring system (10) but individual animal data were not provided by the notifier; a very slight pain response was exhibited by all animals after installation of the test

substance; transient diffuse areas of corneal opacity were observed in four out of six animals after 24 hours but this reversed by day 7; slight iridial effects were observed in two rabbits; no signs of ocular irritation were observed 14 days after treatment; the degree of irritation was slightly less in those animals where irrigation occurred at 4 seconds after treatment compared with irrigation 30 seconds after treatment

Result: the test material was considered to be a moderate irritant to the rabbit eye

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (11)

Strains: *S.typhimurium TA 98,TA 100,TA 1535 TA 1537 TA 1538; E.coli WP2 uvr A*

Concentration range: 312.5 - 5 000 μg/plate with or without rat liver S9; dilutions were prepared in dimethylsulfoxide and positive controls; sodium azide, 9-amino acridine, 2-nitrofluorene, N-methyl-N-nitro-N-nitrosoquanidine, 10 μg/plate; in addition positive controls with S9 used 10μg/plate 2-anthramine; no data were cited for *E.coli* strains

Test method: in accordance with OECD Guidelines for Testing Chemicals (9)

Result: the test material was non-mutagenic in bacteria; controls gave appropriate responses

9.3 Overall Assessment of Toxicological Data

On the basis of toxicology data provided on a chemically similar polymer, the notified polymer is likely to be of low oral and dermal toxicity to rats with LD_{50} values of greater than 5 000 and 2 000 $mg.kg^{-1}$ respectively. The notified polymer is likely to be non-mutagenic but would be classified as hazardous as a skin and eye irritant according to the criteria of Worksafe Australia (12) .

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not required for polymers of NAMW greater than 1 000 according to the Act, the notifier provided the following ecotoxicological data generated for a 35% water emulsion of a compound with comparable molecular weight and containing similar functionalities to those in the notified material. This material is known as DOW CORNING 2-8075 Amino Functional Fluid, and contains an identical amino functionality to that of the notified material. Since ecotoxicological properties will be associated primarily with the amino groups, this is acceptable.

ECOTOXICITY FOR DOW CORNING 2-8075

Test	***Species***	***Results (Nominal)***
Acute toxicity to Rainbow trout	*Salmo gairdneri*	LC_{50} (96h) = 6.1 $mg.L^{-1}$
Acute immobilisation to Water fleas	*Daphnia magna*	LC_{50} (96h) = 1.0 $mg.L^{-1}$

The tests on rainbow trout were performed using static test methodology with the test material introduced as a 35% emulsion. The test was conducted over 96 hours, and test solutions were replaced after 48 hours. The results indicate the test material to be moderately toxic to this species.

Two duplicate tests on *Daphnia* were conducted over 48 hours and gave an LC_{50} of 1 $mg.L^{-1}$. The two data sets exhibited excellent reproducibility and the result means the material is moderately to highly toxic to the *Daphnia.*

The ecotoxicity data for the notified polymer indicate the test substance DOW CORNING 2-8075 (also known as TX-81-2001-17) is moderately to highly toxic to the two aquatic species tested. The structural similarities between the notified material and the DOW CORNING 2-8075 indicate that the notified polymer could be expected to exhibit similar ecotoxicological properties. This is supported by the literature (13).

No test reports on toxicity to algae accompanied the notification, but it is likely that the amine functionality would make the notified material toxic to these organisms (13) also.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is likely to be highly toxic to aquatic life, and consequently it is appropriate to make some estimates of the environmental concentration resulting from release from typical usage patterns.

A medium sized country textile mill may discharge 200 ML per annum of waste effluent, and assuming this plant used 2 tonnes per annum of the notified polymer, of which 10% is discharged (the notifier stated 5% would be released), then the average concentration of the polymer in the textile mill effluent would be 1 $mg.L^{-1}$. Once diluted with other sewage (assume dilution factor 1:2) then a PEC (predicted environmental concentration) of 0.5 $mg.L^{-1}$ is calculated for the STP effluent assuming no assimilation of the polymer into sediments or sludge. In view of the

ecotoxicity data described above - particularly for daphnia, this PEC appears to indicate a potential environmental hazard from the predicted release of residuals. However, the hydrophobic nature of the notified polymer indicates that most would adsorb onto particles of sediment and sludge (2, 14), and would not therefore remain in the water compartment and be available for assimilation by biota. Furthermore, Nabholz et al (15) 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 the compounds.

Polymer released into the sewage system as a result of disposal of drum residuals or of spent process solution (emulsion) from textile mills is likely to be adsorbed into sediments within the sewer mains and to eventually be incorporated into waste sludge from sewage treatment operations. This would be placed into landfill or incinerated.

The environmental hazard from the notified polymer is expected to be low when the material is used in the usual manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will be imported into Australia as a polymer fluid (approximately 100% notified polymer), for use as a textile softener. Animal studies on an analogue indicate the notified chemical would be classified as a skin and eye irritant.

The occupational health risk posed to waterside, warehouse and transport workers is negligible, as exposure to the notified chemical will only occur in the event of an accident.

The notified polymer will be imported as a polymer fluid containing approximately 100% polymer. The polymer fluid will be supplied to textile chemical formulators who will prepare aqueous emulsions containing up to 40% of the notified polymer. These emulsions will be further blended/diluted by the addition dyes, inorganic salts etc before applying it to textiles; at this stage the notified chemical will be present at less than 1%. The processes used for emulsification and blending are automated which will minimise the potential for exposure to the notified polymer and the occupational health risks are considered to be low.

If skin or eye contact occurs irritation is likely and in the case of skin responses may be severe, therefore when workers are decanting the notified polymer or emulsions containing the notified polymer appropriate measures should be taken to minimise exposure. The notified polymer will be at very low concentrations when it is applied to textiles and workers are considered to be at negligible risk if exposure occurs.

There is negligible health risk for workers handling dry textiles. The polymer will have crosslinked during curing and will irreversibly bound to the textile.

During curing harmful degradation products may be released e.g. formaldehyde, the notifier has stated that adequate ventilation will be provided to reduce the potential

for exposure (see recommendations section).

It is unlikely that the notified polymer will pose a significant hazard when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in 2-8822 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (16) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (17);
- Impermeable gloves or mittens should conform to AS 2161(18) ;
- All occupational footwear should conform to AS/NZS 2210 (19) ;
- 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.

In addition, during the curing process harmful degradation products including formaldehyde are released. To minimise exposure to formaldehyde the NOHSC occupational exposure standard should be adhered to (20) and adequate ventilation provided.

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* (21).

This MSDS was provided for the product containing the notified polymer, 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.

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified polymer, or if additional information becomes available on adverse environmental effects of the polymer. No other specific conditions are prescribed.

16. REFERENCES

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17. 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, Sydney/Wellington.

18. Standards Australia 1978, Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves), Standards Association of Australia, Sydney.

19. Standards Australia/Standards New Zealand 1994, Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

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21. 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