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November 2000

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**DOW CORNING 2-8822A Polymer**

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Director  
Chemicals Notification and Assessment

**FULL PUBLIC REPORT****DOW CORNING 2-8822A Polymer****1. APPLICANT**

Dow Corning Australia Pty Ltd of 21 Tattersall Rd, Blacktown, NSW (ACN 008444166) has submitted a standard notification statement in support of their application for an assessment certificate for DOW CORNING 2-8822A Polymer.

**2. IDENTITY OF THE CHEMICAL**

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

**Marketing Name:** Dow Corning 2-8822A Polymer

**Other Names:** Aminofunctional Polysiloxane

**Number-Average  
Molecular Weight (NAMW):** 23,600

**Weight-Average  
Molecular Weight:** 83,000

**Maximum Percentage of Low  
Molecular Weight Species**

**Molecular Weight < 500:** < 15% (estimation)

**Molecular Weight < 1000:** < 20% (estimation)

**3. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance at 20°C  
and 101.3 kPa:** Colourless to pale yellow liquid

**Boiling Point:** Not determined.

**Density:** 970 kg/m<sup>3</sup> at 25°C

<b>Vapour Pressure:</b>	4.2x10 <sup>-9</sup> kPa at 25°C. Vapour pressure was determined using a vapour pressure balance by method A4 of EEC directive 92/96/EEC.
<b>Water Solubility:</b>	2.2mg/L at 20°C as (CH <sub>3</sub> ) <sub>2</sub> SiO. See comments below.
<b>Partition Co-efficient (n-octanol/water):</b>	Not determined – see comments below.
<b>Hydrolysis as a Function of pH:</b>	Not determined – see comments below.
<b>Adsorption/Desorption:</b>	Not determined – see comments below.
<b>Dissociation Constant:</b>	Not determined – see comments below.
<b>Particle Size:</b>	Not applicable as polymer is a liquid.
<b>Flash Point:</b>	65°C (closed cup)
<b>Flammability Limits:</b>	Upper Explosive Limit = approximately 3.4% Lower Explosive Limit = approximately 1.2% - see comments below.
<b>Autoignition Temperature:</b>	Approximately 449°C - see comments below.
<b>Explosive Properties:</b>	Not determined.
<b>Reactivity/Stability:</b>	The notified polymer can react with strong oxidising agents. Trace quantities of formaldehyde may be released if heated to >150°C.

### Comments on Physico-Chemical Properties

For physico-chemical properties vapour pressure, water solubility, autoignition temperature and flammability limits, data were submitted by the notifier for a closely related polymer molecule, the difference being in end-blocking. The present notified polymer possesses C<sub>13-15</sub> whilst the data submitted is for a C<sub>9-11</sub> analogue, Dow Corning 2-8822 polymer. Both polymers have molecular weights over 15,000 and so the differences in carbon number of the end block should not be expected to influence physico-chemical properties.

Vapour pressure at 25°C was determined using a vapour pressure balance according to method A4 of EEC directive 92/96/EEC by extrapolation from a curve relating vapour pressure and reciprocal temperature (Tremain and Bartlett, 1997). The vapour pressure of 4.2 x 10<sup>-9</sup> kPa is low, as could be expected for polymers of this nature.

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 absorption spectroscopy. Since the polymer contains a high proportion of (CH<sub>3</sub>)<sub>2</sub>SiO groups, the solubility is reported in terms of this chemical species.

This test method based on OECD test guidelines (TG) 105 and 120 may overestimate the polymer solubility since this methodology measures the water extractable fraction, including any low molecular weight impurities which may be intrinsically soluble. The true water solubility of organosilicones is very low (Varaprath et al, 1996) and it is likely that the reported 2.2 mg/L is primarily associated with the low molecular weight cyclosiloxanes (<3%) present as residual reactants in the material. Contributions resulting from the presence of colloidal aggregates of the polymer in the water are also possible (Varaprath et al, 1996). The high molecular weight and hydrophobic nature of the molecule indicates extremely low true water solubility (Hamelink, 1992; Varaprath et al, 1996).

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

No partition coefficient, dissociation constant or adsorption/desorption data were provided, but the hydrophobic nature of most of the polymer indicates that it would have affinity for the oil phase and also adsorb to the organic component of soils and sediments (Hamelink, 1992; Lehmann et al, 1994a).

The terminal amino groups are likely to have typical amino pKa values of between 9.5 and 10.5 and consequently be protonated at environmental pH.

#### **4. PURITY OF THE CHEMICAL**

**Degree of Purity:** Approximately 96%

##### **Hazardous Impurities:**

<i>Chemical name:</i>	Octamethylcyclotetrasiloxane
<i>Weight percentage:</i>	2%
<i>CAS No.:</i>	556-67-2
<i>Comment:</i>	Causes reproductive effects in laboratory animals. Dow Corning internal exposure standard: 10ppm TWA.

##### **Non-hazardous Impurities (> 1% by weight):**

<i>Chemical name:</i>	Cyclosiloxanes, di-methyl
<i>Weight percentage:</i>	<3%
<i>CAS No.:</i>	69430-24-6
<i>Comment:</i>	Hazards not stated by notifier in submission.

<i>Chemical name:</i>	Alcohols, C <sub>13-15</sub>
<i>Weight percentage:</i>	1%
<i>CAS No.:</i>	90604-31-2

**Additives/Adjuvants:** None

## **5. USE, VOLUME AND FORMULATION**

The notified polymer will be imported as a polymer fluid packed in 20 or 200L steel drums for use as a textile softener. Up to 10 tonnes/year will be imported for the first 5 years. At a textile chemical formulator, the polymer will be mixed with water and emulsifying agents. The emulsion will contain <60% w/w notified polymer. The emulsion then will be transported in 200L polyethylene lined steel drums to a textile finishing company where it will be further mixed with water and additional chemicals and applied to textile material. The applied fluid will contain <5% notified polymer.

The polymer may be also imported in 20 or 200L steel drums as an emulsion containing <60% notified polymer.

## **6. OCCUPATIONAL EXPOSURE**

### **Import, Transport and Storage**

The notified polymer will be imported in high concentration as a fluid in 20 or 200 litre steel drums with screw top bungs and stored at a Dow Corning Australia site. Drums will then be shipped unopened to a textile chemical formulator. An estimated 10-30 waterside, 5-10 transport and 5-10 warehouse workers may be exposed to the notified polymer. The potential for these workers to be exposed to the polymer is minimal under the normal conditions of transport and storage and would only occur following inadvertent puncture of the drums.

### **Formulation**

At the textile chemical formulator, an estimated 20-100 chemical industry workers will be engaged in reformulation for a maximum of 8 hours/day for 5 days/week. The polymer fluid will be blended with water and other chemicals by manually pouring the polymer into a mixing vessel. The blended polymer emulsion containing up to 60% notified polymer will then be drummed off into 200 litre polyethylene-lined containers and transported to the textile finishing company. During these transfer processes, there is potential for worker exposure predominantly via the skin and eyes following inadvertent spills and splashes. Although excessive agitation may also produce aerosols containing the notified polymer, mixing sites are expected to be fitted with forced ventilation to control the possible inhalation exposure. To control exposure, it is expected that workers will wear personal protective equipment consisting of chemical resistant goggles and gloves.

Exposure of transport workers to the reformulated polymer would only occur following inadvertent puncture of the polyethylene-lined containers.

### **Application**

At the textile finishing company, the polymer emulsion will be diluted with water and other chemicals by manually filling a dipping container and mixing to produce a final emulsion of 1-2% notified polymer to be applied to textiles. Between 20 and 100 textile industry workers working a maximum of 8 hours/day for 5 days/week will dilute the required volumes of polymer fluid and then apply the fluid to the textiles by padding. During this process, the fabric is immersed in emulsion and mechanically squeezed between rollers to recover excess emulsion.

Excessive agitation during mixing may produce aerosols containing the notified polymer. However, mixing sites are expected to be fitted with forced ventilation to control possible inhalation exposure. During emulsion transfer processes, there is the potential for worker exposure, predominantly via the skin, but also via the eyes following accidental spills and splashes. In addition, during the padding process there is the possibility of skin and eye exposure during the transfer of saturated textile to ovens where the textiles are then dried at 120-150°C. To control exposure, it is expected that workers will wear personal protective equipment consisting of chemical resistant goggles and gloves.

In the absence of adequate ventilation, workers may be exposed to polymer fumes and trace quantities of formaldehyde released if textiles are heated to >150°C. However, the heating ovens will be fitted with forced ventilation and this is expected to be adequate to control worker exposure to atmospheric contaminants.

After drying, the treated textile will be stored for further processing into garments. At this time, the notified polymer at a concentration of <1% will be firmly adsorbed to the textile material preventing any further occupational exposure.

## **7. PUBLIC EXPOSURE**

It is expected that during transport, formulation and storage, exposure of the general public to the notified polymer will be low. Public exposure will arise via dermal contact with fabric treated with the notified polymer as a textile softener in articles of clothing.

## **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. 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 maximum annual imports of 10 tonnes, 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 <5% 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 so releases will be small. Spent solution would also be passed to the sewer system and the notifier estimates around 5% (maximum 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. Discarded 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 landfills or incinerated. Discarded cloths and fabric off-cuts which have been treated with the notified polymer would also be placed into landfill or be 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 indicate that polymer 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, carbon dioxide and ammonia. Polydimethylsiloxanes are unstable in landfill situations (Hamelink, 1992; Lehmann et al, 1994a and 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 rapidly degraded through photolysis (Hamelink, 1992).

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

## 9. EVALUATION OF TOXICOLOGICAL DATA

The following data were provided for chemically similar polymers, identified as Dow Corning 2-8075, 2-8460, 929 and 2-8902.

### 9.1 Acute Toxicity

*Summary of the Acute Toxicity of Analogues 2-8075, 2-8460, 929 and 2-8902.*

<i>Test</i>		<i>Test Substance</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
Acute toxicity	oral	2-8075	Rat	LD <sub>50</sub> > 5000 mg/kg	DeVries and Siddiqui (1981d)
Acute toxicity	dermal	2-8075	Rabbit	LD <sub>50</sub> > 2000 mg/kg	DeVries and Siddiqui (1981b)
Acute toxicity	inhalation	929	Rat	LD <sub>50</sub> > 0.412 mg/L	Duchosal (1994);
		2-8460	Rat	LD <sub>50</sub> > 0.27 mg/L	Braunhofer (1995);

	2-8902	Rat	LD50 > 1.16 mg/L	Sullivan and Rajendran (1997)
Skin irritation	2-8075	Rabbit	Severe irritant	DeVries and Siddiqui (1981a)
Eye irritation	2-8075	Rabbit	Moderate irritant	DeVries and Siddiqui (1981c)
Skin sensitisation	2-8902	Guinea pig	Weakly sensitising	Findlay and Bradshaw (1997);
	2-8075	Guinea pig	Not sensitising	Blaszczak (1999)

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### 9.1.1 Oral Toxicity (DeVries and Siddiqui, 1981d)

<i>Species/strain:</i>	Rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Test substance:</i>	Dow Corning 2-8075
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	Gavage
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	none
<i>Clinical observations:</i>	none
<i>Morphological findings:</i>	none
<i>LD<sub>50</sub>:</i>	> 5000 mg/kg
<i>Result:</i>	The test substance was of very low acute oral toxicity in rats

### 9.1.2 Dermal Toxicity (DeVries and Siddiqui, 1981b)

<i>Species/strain:</i>	Rabbits/New Zealand white
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Test substance:</i>	Dow Corning 2-8075
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	Single 2000 mg/kg dose of neat test substance applied to intact skin and held in place for 24 hours by a porous gauze dressing.



<i>Test method:</i>	OECD TG 402
<i>Mortality:</i>	One male animal died on day 4 of the study following slight diarrhoea. Although a cause of death was not established definitively, it was considered not related to the test substance.
<i>Clinical observations:</i>	One male animal showed slight diarrhoea during the early part of the study. This was considered not related to the test substance. Two male animals exhibited slight weight loss during the course of the study.
<i>Morphological findings:</i>	The rabbit with diarrhoea that died on day 4 showed distension of the caecum and black patches on the liver and lungs. Terminal sacrifice of all surviving animals revealed no gross pathological alterations.
<i>LD<sub>50</sub>:</i>	> 2000 mg/kg
<i>Result:</i>	The test substance was of low dermal toxicity in rats

### **9.1.3 Inhalation Toxicity (Duchosal, 1994; Braunhofer, 1995; Sullivan and Rajendran, 1997)**

The use of Dow Corning 2-8075 as a surrogate for assessing the inhalational toxicity of the notified polymer 2-8822A was considered inappropriate because of the decreased viscosity of 2-8075 (150 cst vs 1500 cst) which makes this polymer more easily aerosolised and thus bioavailable. Therefore, inhalation toxicity data were provided for 3 analogues of the notified polymer with similar viscosities or amine contents. The analogues were tested as emulsions. Compared to the notified polymer 2-8822A, the analogue Dow Corning 2-8460 possesses similar viscosity but higher amine content (2.3 mole % vs 0.68 mole % in 2-8822A) while the analogues Dow Corning 929 and 2-8902 possess similar amine content – approximately 0.5 mole %.

#### **9.1.3.1 Analogue 2-8460 (Braunhofer, 1995)**

<i>Species/strain:</i>	Rat, Sprague-Dawley
<i>Number/sex of animals:</i>	10 males, 10 females
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	4 hour inhalation (nose only). Group 1 (5 males, 5 females) received 0.044mg/L air and Group 2 (5 males, 5 females) received 0.271mg/L air (highest achievable concentration).
<i>Test method:</i>	OECD TG 403
<i>Mortality:</i>	Group 1: 0% males, 0% females

Group 2: 40% males, 20% females

<i>Clinical observations:</i>	Body weight gains in Group 1 were unaffected by treatment. Body weight gains in surviving animals in Group 2 were either absent (one animal) or reduced in the first week of observation. Weight gains were normal in the second week. No clinical signs were observed in any animal in Group 1 or Group 2 during exposure or in Group 1 during the observation period. In Group 2, hunched posture (10 animals), dyspnea (10 animals) or ruffled fur (10 animals) were most pronounced on day 2, persisting until death or until day 3 (6 animals) or day 4 (1 animal).
<i>Morphological findings:</i>	In Group 1, 4 animals showed red coloured pulmonary foci. In Group 2, animals showed dark red pulmonary discolouration (3 spontaneous deaths), incompletely collapsed lungs (7 animals) or dark red pulmonary foci (3 animals).
<i>LC<sub>50</sub>:</i>	> 0.27mg/L
<i>Result:</i>	The test substance was of moderate acute inhalational toxicity in rats.

#### **9.1.3.2 Analogue 929 (Duchosal, 1994)**

<i>Species/strain:</i>	Rat, Sprague-Dawley
<i>Number/sex of animals:</i>	5 males, 5 females
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	4 hour inhalation (nose only). Group 1 (5 males, 5 females) received 0.356mg/L air and Group 2 (5 males, 5 females) received 0.412mg/L air.
<i>Test method:</i>	OECD TG 403
<i>Mortality:</i>	None
<i>Clinical observations:</i>	All animals gained weight at the normal rate except one female in Group 2 which failed to gain weight during the first week of observation. Except for eye bleeding in one male in Group 1, no clinical signs were noted.
<i>Morphological findings:</i>	The lungs of most animals in both groups were incompletely collapsed. This finding was attributed to anaesthesia and considered not related to the test substance.
<i>LC<sub>50</sub>:</i>	>0.412mg/L

*Result:* The test substance was of low acute inhalational toxicity in rats.

#### **9.1.3.3 Analogue 2-8902 (Sullivan and Rajendran, 1997)**

*Species/strain:* Rat, Sprague-Dawley

*Number/sex of animals:* 10 males, 10 females

*Observation period:* 15 days

*Method of administration:* 4 hour inhalation (whole body) of test substance at 1.16mg/L air (highest achievable concentration).

*Test method:* OECD TG 403

*Mortality:* None

*Clinical observations:* All animals gained weight during the study. Clinical signs observed consisted of hypoactivity and wet inguinal fur (all animals), redness around nose fur (9 animals) and dyspnea (8 animals).

*Morphological findings:* No gross lesions were observed in any animals except one male which exhibited three distal end foci (approximately 2mm in diameter), two in the left and one in the apical lobes of the lung.

*LC<sub>50</sub>:* > 1.16 mg/L

*Result:* The test substance was of low acute inhalational toxicity in rats.

#### **Overall Conclusions from Acute Inhalation Toxicity Studies:**

The analogue 2-8460 possessing similar viscosity and increased amine content to the notified polymer 2-8822A showed moderate acute inhalational toxicity. However, analogues 929 and 2-8902 with similar amine content showed low acute inhalational toxicity. The viscosities of these latter analogues are unspecified. Therefore, the notified polymer 2-8822A should be considered to be of moderate acute inhalational toxicity.

#### **9.1.4 Skin Irritation (DeVries and Siddiqui, 1981a)**

*Species/strain:* Rabbits/New Zealand white

*Number/sex of animals:* 6 males

*Test substance:* Dow Corning 2-8075

*Observation period:* 21 days

*Method of administration:* Single dose of 0.5mL test material applied to intact skin and then covered with a porous gauze dressing. After 4 hours, the test material was removed and the skin washed with tap water.

*Test method:* OECD TG 404

*Draize scores:*

<i>Time after Treatment</i>							
	<i>60 min</i>	<i>24 hrs</i>	<i>48 hrs</i>	<i>72 hrs</i>	<i>7 days</i>	<i>14 days</i>	<i>21 days</i>
<b><i>Erythema and Eschar</i></b>							
<b><i>Mean Scores</i></b>	2 <sup>a</sup>	3.8	3.5	3.2	2.3	0.5	0
<b><i>Oedema</i></b>							
<b><i>Mean Scores</i></b>	1.7	2.5	1.5	0.8	0	0	0

<sup>a</sup> see Attachment 1 for Draize scales

*Comments:* Individual animal data were not provided by the notifier. All animals showed severe redness with slight eschar and slight swelling which persisted for several days. This irritation was resolved by day 21.

*Result:* The test substance was severely irritating to the skin of rabbits.

### 9.1.5 Eye Irritation (DeVries and Siddiqui, 1981c)

*Species/strain:* Rabbits/New Zealand white

*Number/sex of animals:* 6 male

*Test substance:* Dow Corning 2-8075

*Observation period:* 14 days

*Method of administration:* 0.1mL of test substance was instilled in the right eye of each rabbit; untreated left eyes served as controls. Treated eyes of 3 animals were washed at 4 seconds and for the remaining 3 animals, eyes were washed at 30 seconds.

*Test method:* OECD TG 405

*Draize scores:*

	<i>Time after Treatment</i>					
	<i>1 hr</i>	<i>24 hrs</i>	<i>48 hrs</i>	<i>72 hrs</i>	<i>7 days</i>	<i>14 days</i>
<b><i>Corneal Opacity</i></b>	0.7 <sup>a</sup>	1	1	1	0	0
<b><i>Iridal Inflammation</i></b>	0	0.7	0.3	0.3	0	0
<b><i>Conjunctival Irritation</i></b>						
<b><i>Redness</i></b>	2.3	2.3	2	1.7	0.7	0
<b><i>Chemosis</i></b>	3.3	3.7	2	1.7	0	0

<sup>a</sup> see Attachment 1 for Draize scales

*Comment:* Individual animal scores were not provided by the notifier. A very slight pain response was exhibited by all 6 animals after application of the test substance. All animals exhibited slight to moderate conjunctival redness and swelling through the first 24 hours and 3 animals continued to show irritation after 7 days. Diffuse areas of corneal opacity were observed in 4 animals after 24 hours, but all corneas appeared normal at 7 days. Two rabbits showed slight iridal congestion. The degree of irritation was slightly less in the eyes that were washed after 4 seconds compared to 30 seconds.

*Result:* The test substance was moderately irritating to the eyes of rabbits.

#### **9.1.6 Skin Sensitisation (Findlay and Bradshaw, 1997; Blaszcak, 1999)**

As well as for Dow Corning 2-8075, skin sensitisation data were provided for another analogue Dow Corning 2-8902 possessing a similar amine content of approximately 0.5 mole% to the notified polymer.

##### **9.1.6.1 Analogue 2-8075 (Blaszcak, 1999)**

Species/strain: Guinea pigs, Dunkin Hartley albino

Number of animals: 15 males, 15 females for main study; 10 males, 10 females for controls

Induction procedure: In the main study, three pairs of intradermal injections in the shaved shoulder region as follows:

Test group:  
day 1

- 0.1mL of 1:1 FCA/water

- 0.1mL of 5% v/v test substance in polyethylene glycol
  - 0.1mL of 5% v/v test substance in 1:1 FCA/water
- Irritation control group:  
day 1
- 0.1mL of 1:1 FCA/water
  - 0.1mL of polyethylene glycol alone
  - 50% polyethylene glycol in 1:1 FCA/water

*Day 8:* Twenty-four hours before test patch application, the clipped areas were rubbed with 0.5mL of 10% sodium lauryl sulfate in petrolatum. On day 8, approximately 0.2mL of neat test substance on a 2 x 4 cm filter patch was applied to the test sites under occlusive dressing for 48 hours.

*Challenge (day 22):* Fourteen days after application of the induction patch, 0.1mL of neat test substance alone on a 2 x 2 cm filter patch was applied to the test sites under occlusive dressing for 24 hours.

*Test method:* OECD TG 406

*Challenge outcome:*

<i>Challenge concentration</i>	<i>Test animals</i>		<i>Control animals</i>	
	<i>24 hours*</i>	<i>48 hours*</i>	<i>24 hours</i>	<i>48 hours</i>
100%	2/20**	1/20	0/10	0/10
* time after patch removal				
** number of animals exhibiting positive response (greater than irritation controls)				

*Result:* The test substance was weakly sensitising to the skin of guinea pigs.

#### 9.1.6.2 Analogue 2-8902 (Findlay and Bradshaw, 1997)

*Species/strain:* Guinea pigs, Dunkin Hartley albino

*Number of animals:* 30 males for main study; 10 males for controls

*Induction procedure:* In main study, three pairs of intradermal injections in the shaved shoulder region as follows:

- Test group:  
day 1
- 0.1mL of 2% v/v test substance in water
  - 0.1mL of 1:1 FCA/saline
  - 0.1mL of 2% w/v test substance in 1:1 FCA/saline
  -
- Irritation control group:  
day 1
- 0.1mL of water
  - 0.1mL of 1:1 FCA/saline
  - 50% water in 1:1 FCA/saline

*Day 8:* On day 8, approximately 1.5mL of 10% test substance in water on a 2 x 4 cm filter patch was applied to the test sites under occlusive dressing for 48 hours.

*Challenge (day 22):* Fourteen days after application of the induction patch, 0.3mL of 2% test substance in water on a 2 x 2 cm filter patch was applied to the test sites under occlusive dressing for 24 hours.

Test method: OECD TG 406

*Challenge outcome:*

<i>Challenge concentration</i>	<i>Test animals</i>		<i>Control animals</i>		
	<i>24 hours*</i>	<i>48 hours*</i>	<i>24 hours</i>	<i>48 hours</i>	
2%	0/20**	0/20	0/10	0/10	
*	time		after	patch	removal
** number of animals exhibiting positive response					

*Result:* The test substance was not sensitising to the skin of guinea pigs.

### Overall Conclusions for Skin Sensitisation:

On the basis of data from analogues with similar or higher amino functionality, the notified polymer is considered to be a weak skin sensitiser.

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Isquith and Miller, 1981)

*Strains:* Salmonella typhimurium TA-1535, 1537, 1538, 98, 100; Escherichia coli WP2 uvr A.

*Test substance:* Dow Corning 2-8075

*Concentration range:* Test compound: 312.5, 625, 1250, 2500, 5000µg/plate with/without rat liver S9 metabolic activation. Positive controls were sodium azide, 9-amino acridine, 2-nitrofluorene, N-methyl-N-nitro-n-nitrosoquandine, 10µg/plate. In addition, positive controls with S9 used 2-anthramine, 10µg/plate.

*Comment:* For the Salmonella strains TA1538 and TA98, cytotoxicity was observed at the highest dose, with and without S9

activation. No increase in mutant counts was observed at any dose with any strain. The positive controls tested appropriately.

*Test method:* OECD TG 471, 472

*Result:* No evidence of genetic activity was observed.

#### **9.4 Overall Assessment of Toxicological Data**

Based on analogue data provided for a structurally similar polymer (2-8075), the notified polymer is expected to have very low acute oral toxicity in rats (oral LD<sub>50</sub>>5000mg/kg) and low dermal toxicity in rabbits (LD<sub>50</sub>>2000mg/kg).

Acute inhalational toxicity studies using an analogue of similar viscosity but increased amine content to the notified polymer (2-8460) showed moderate acute inhalational toxicity (LD<sub>50</sub>>0.27mg/L) with a mortality rate of 30% at the highest achievable concentration of 0.27mg/L. Studies using analogues of similar amine content (929 and 2-8902) showed low acute inhalational toxicity (LD<sub>50</sub>>0.412mg/L and >1.16mg/L respectively). The Material Safety Data Sheet (MSDS) for the notified polymer warns that recent inhalation studies of aerosols of structurally related aminofunctional siloxanes show a high order of toxicity (LC<sub>50</sub><0.5mg/L) and that repeated inhalation or oral exposures produce an increase in liver size. Therefore, by extrapolation, the notified polymer should be classified as a hazardous substance with the risk phrase R23 - Toxic by Inhalation (National Occupational Health and Safety Commission, 1999).

In the rabbit, 2-8075 is a severe skin irritant inducing severe erythema with slight eschar and swelling persisting for several days. In this respect, the notified polymer should be classified as a hazardous substance with the risk phrase R38 – Irritating to Skin (National Occupational Health and Safety Commission, 1999).

2-8075 induced moderate irritation in rabbit eyes. Slight to moderate conjunctival redness and swelling were observed up to 7 days after application, the degree of irritation being slightly less in eyes washed after 4 seconds compared to eyes washed after 30 seconds. Diffuse areas of corneal opacity and iridal irritation were observed in some animals after 24 hours, but all corneas and irises appeared normal after 7 days. The notified polymer should be classified as a hazardous substance with the risk phrase R36 – Irritating to eyes (National Occupational Health and Safety Commission, 1999).

On the basis of data from analogues with similar (2-8902) or higher amino functionality (2-8075), the notified polymer is considered to be a weak skin sensitiser.

2-8075 showed no evidence of mutagenicity in a *Salmonella typhimurium* and *Escherischia coli* reverse mutation assay.

No repeated dose toxicity data were provided.

### **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**



The notifier provided ecotoxicological data for rainbow trout and daphnia generated for a 35% water emulsion of a siloxane polymer with comparable molecular weight and containing similar functionalities including an identical amino functionality to those in the notified material. This polymer is known as Dow Corning TX-81-2001-17 or 2-8075 Amino Functional Fluid. Ecotoxicological properties will be associated primarily with the amino groups, so the analogue is acceptable for ecotoxicological analyses. Tests on Rainbow trout and daphnia were conducted according to US EPA test protocols EPA 660/3-75-009.

Bacterial tests were conducted using Dow Corning Q2-8220.

#### Summary of Ecotoxicity for Dow Corning TX-81-2001-17 (2-8075) and Q2-8220

Test	Species	Results (Nominal)
Acute Toxicity to Rainbow Trout with 35% emulsion. Method US EPA	<i>Salmo gairdneri</i>	LC <sub>50</sub> (96 h)= 6.1 mg/L
Acute Immobilisation to Water Fleas with 35% emulsion. Method US EPA	<i>Daphnia magna</i>	LC <sub>50</sub> (48 h)=1.0mg/L
Acute Immobilisation to Water Fleas. Acetone "carrier" solvent Method US EPA	<i>Daphnia magna</i>	LC <sub>50</sub> (48 h)=1.4mg/L
Respiration Inhibition of Bacteria with test material Dow Corning Q2-8220. Method OECD TG209.	Sewage sludge bacteria	EC <sub>50</sub> >100 mg/L
Microtox Test with test material Dow Corning Q2-8220.	<i>Vibrio fischeri</i>	5 min. EC <sub>50</sub> = 80 mg/L

#### Fish

An abstract of a test report for acute toxicity to Rainbow trout (Annelin and Zimmerman, 1981b) was submitted, which indicated that the tests were performed using static test methodology. The test material was assumed to be a 35% emulsion, although neither this nor the nature of the emulsifying agent were definitively stated in the abstract of the test report. Reports of exactly the same test data were submitted for Dow Corning 2-8075 and these alluded to the 35% emulsion.

The test was conducted over 96 hours at 12°C, and test solutions were replaced after 48 hours. Four test concentrations containing between 1 and 10 mg/L (nominal concentration) of the test polymer were used, together with a control. Although only 8% had died after 24 hours exposure to the highest nominal concentration, over 50% were dead after 24 hours exposure to a 1.8 mg/L concentration and all were dead after 96 hours exposure at the highest concentration. No details of sub-lethal effects were given. The pH of the test solutions was around 7.5, while dissolved oxygen levels were between 7.5 and 8.5 mg/L. The results were analysed using probit analysis to give the 96 hour LC<sub>50</sub> of 6.1 mg/L, indicating the test material to be moderately toxic to this species.

#### Daphnia

An abstract of a test report for acute toxicity of the same 35% emulsion of TX-81-2000-17 to daphnia (Annelin and Zimmerman, 1981a) was also submitted. Two duplicate tests on

daphnia were conducted over 48 hours at 22°C using five test concentrations containing between 1 and 10 mg/L (nominal concentration) of the test polymer, together with controls.

Approximately 25% immobility was observed after 48 hours exposure to a nominal 0.56 mg/L concentration in both tests, and 100% immobility after 48 hours exposure to 5.6 mg/L concentration. No details of sub-lethal effects were given in the summary reports. The pH of the test solutions was around 7.8, while dissolved oxygen levels were between 6.0 and 8.0 mg/L. The data was analysed using probit analysis and gave the 48 hour LC50 values of 1 mg/L (95% confidence 0.6-1.4 mg/L) and 1.1 mg/L (95% confidence 0.7-1.5 mg/L) respectively. These two data sets exhibited excellent reproducibility and the result indicates that the material is moderately to highly toxic to the daphnia.

In addition to these tests, a second report on the acute toxicity of TX-81-2000-17 to Daphnia was submitted (Annelin and Zimmerman, 1982), using a solution of the polymer in acetone to introduce the polymer into the test medium. The test was performed at 22°C using 21 daphnia, and nominal test concentrations of 0 (control), 0.001, 0.01, 0.1 and 1.0 mg/L. Significant mortality (immobilisation) was observed at only the highest nominal concentration (1.0 mg/L), with 25% immobilisation after 24 hours exposure, and approximately 70% immobilisation after 48 hours. The data were analysed using probit analysis to provide the LC50 figure of 1.4 mg/L. This result is not dissimilar to that obtained with the emulsion, and indicates at least moderate toxicity to this species.

## **Algae**

No test data were submitted with the notification. See further discussion below.

## **Sewage Bacteria**

A test report on respiration inhibition of sewage sludge bacteria was submitted (Heim, 1999). The test was conducted in duplicate with the test material Dow Corning Q2-8220. The chemical identity of this material was not specified, but the material was described as an amino functional fluid and is presumed to be chemically similar to the notified polymer.

This test material was added to the artificial sewage media at nominal loadings of 0 (control) 20, 40, 60, 80 and 100 mg/L. The test flasks were inoculated with sewage sludge bacteria and aerated for 3 hours at  $20 \pm 2^\circ\text{C}$ . Following aeration, the rate of oxygen consumption was measured for the dispersions, and compared with that in the controls. None of the tests indicated any significant inhibition of bacterial respiration compared with the controls, and it was concluded that the test material is not toxic to sewage bacteria up to the limits of its water solubility.

In contrast to tests with Dow Corning Q2-8220, a reference test conducted with 3,5-dichlorophenol inhibited bacterial respiration by 2.2% at a test concentration of 3.2 mg/L, and 65% at 32 mg/L, indicating that the bacterial culture used in the test was viable.

## **Microtox Test**

This is a rapid screening test conducted against a luminescent marine bacteria *Vibrio fischeri* where light output after exposure to test materials is correlated with acute toxicity of the test material to freshwater fish and invertebrates. This test was performed using Dow Corning Q2-8220 at nominal concentrations up to 90 mg/L, and gave a 5 minute EC50 of 80 mg/L and a 15 minute EC50 of 75 mg/L with corresponding No Observed Effect Level (NOEL) of 22.5

mg/L in both cases. However, since there was no discussion of how to correlate these results with toxicity to aquatic species, together with the failure of the notifier to properly establish structural chemical relationships between Dow Corning Q2-8220 and the new polymer, the relevance of this result to “real world” aquatic toxicity is questionable.

### **Summary of Ecotoxicity Data**

The ecotoxicity data for the notified polymer indicate the test substance Dow Corning TX-81-2001-17 is moderately to highly toxic to the two freshwater aquatic species tested. The structural similarities between the notified material and the Dow Corning TX-81-2001-17 indicate that the notified polymer could be expected to exhibit similar ecotoxicological properties. This is supported by the literature (Nabholz et al, 1993). No test reports on toxicity to algae accompanied the notification, but it is likely that the amine functionality would also make the notified material at least as toxic to these organisms (Nabholz et al, 1993; Boethling and Nabholz, 1997).

## **11. ASSESSMENT OF ENVIRONMENTAL HAZARD**

The polymer is at least moderately toxic to fish ( $LC_{50} = 6.1$  mg/L) and highly toxic to daphnia ( $LC_{50} = 1.0$  mg/L), and the scientific literature (Boethling and Nabholz, 1997) indicates that it is likely to be at least highly toxic to algae. Consequently, it is appropriate to estimate 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. Once diluted with other sewage (assume dilution factor 1:2) then a predicted environmental concentration (PEC) of 0.5 mg/L is calculated for the sewage treatment plant (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 indicates a potential environmental hazard from the predicted release of residuals, since the margin of safety is low ( $Q=0.5$ ). However, the hydrophobic nature of the notified polymer indicates that most would adsorb onto particles of sediment and sludge (Hamelink 1992; Lehmann et al, 1994), and would not remain in the water compartment and be available for assimilation by biota. Furthermore, Nabholz et al (1993) have pointed out that the interaction between this class of compound and the dissolved and suspended organic matter in natural waters can significantly mitigate toxicity of the compounds through reducing effective exposure to sensitive organisms.

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 eventually be incorporated into waste sludge from sewage treatment operations. This would be placed into landfill or incinerated. Prolonged residence in landfills would eventually degrade the polymer to landfill gases and silica, while incineration would destroy the material, also with production of silica.

The environmental hazard from the notified polymer is expected to be moderate when the material is used in the usual manner. However, large accidental or otherwise unplanned

releases of the new polymer to environmentally sensitive receiving waters may be very detrimental to aquatic life.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

### **Hazard Assessment**

A toxicity profile was derived for the notified polymer using structural analogue data. Based on analogue toxicity, the notified polymer is expected to have very low acute oral toxicity and low acute dermal toxicity.

Extrapolating from abstracts of analogue acute inhalational toxicity studies, the notified polymer should be classified as a hazardous substance with the risk phrase R23 - Toxic by Inhalation (National Occupational Health and Safety Commission, 1999).

Considering analogue skin and eye irritation studies, the notified polymer should be classified as a hazardous substance with the risk phrase R38 – Irritating to Skin (National Occupational Health and Safety Commission, 1999) and the risk phrase R36 – Irritating to eyes (National Occupational Health and Safety Commission, 1999).

On the basis of data from analogues with similar or higher amino functionality, the notified polymer is considered to be a weak skin sensitiser.

### **Occupational Health and Safety**

The notified polymer will be imported as a polymer fluid containing approximately 100% polymer. The occupational health risk posed to waterside, warehouse and transport workers is negligible, unless exposure to the notified polymer occurs accidentally, when respiratory, skin and eye protection would be needed for workers cleaning up spillage.

The polymer fluid will be supplied to textile chemical formulators who will prepare aqueous emulsions containing <60% of the notified polymer. These emulsions will be further blended/diluted by the addition of water, dyes and other agents before being applied to textiles. At this stage the notified polymer will be present at <5%. Emulsification and blending are largely automated which will minimise the potential for exposure to the notified polymer. However, initial manual decanting of drums of polymer fluid and emulsions is required and this is accompanied by the possibility of spillage and dermal and ocular exposure of workers.

Given the toxicity profile of the notified polymer, if skin or eye contact occurs, irritation is likely. Skin irritation may be severe. Therefore, when workers are decanting the notified polymer or polymer emulsions, appropriate measures must be taken to minimise exposure by the dermal, ocular and inhalation routes. Local exhaust ventilation should be provided during transfer and mixing processes and chemical resistant overalls, goggles and gloves should be worn. The polymer is likely to be acutely toxic by inhalation, so the generation of aerosols should be avoided. The provision of local exhaust ventilation is essential to prevent a health risk to workers during the transfer and mixing processes and when handling treated, undried fabric.

Textiles treated with the notified polymer will be cured in drying ovens. During curing, harmful degradation products may be released eg. formaldehyde. The notified polymer will be present at low concentrations when it is applied to textiles and drying ovens should be fitted with forced ventilation. Adequate ventilation during the drying and curing process is required to ensure a low health risk to workers from possible exposure to polymer vapours and degradation products.

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

### **Public Health**

Public exposure will arise via dermal contact with fabric treated with the dried notified polymer as a textile softener in articles of clothing. There are no work-related diseases or injuries associated with the notified polymer. Given the low concentration of notified polymer in the clothing fabric, the hazards regarding skin irritation and sensitisation are likely to be low. There will be minimal public exposure from transport, storage, reformulation and industrial use. Therefore, based on this information, it is considered that the notified polymer is unlikely to pose a significant risk to public health when used in the proposed manner.

## **13. RECOMMENDATIONS**

To minimise occupational exposure to Dow Corning 2-8822A Polymer, the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer;
- Local exhaust ventilation must be provided during transfer and mixing processes. Ventilation should also be provided during the heat curing process to minimise polymer vapours and employers should ensure that NOHSC exposure standards for formaldehyde are observed (National Occupational Health and Safety Commission, 1995). Where engineering controls and work practices do not reduce vapour exposure to safe levels, an organic vapour respirator should be used in addition to the personal protective equipment indicated above;
- 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 polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

Nomination of the notified polymer to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC *List of Designated Hazardous Substances* is recommended.

#### **14. MATERIAL SAFETY DATA SHEET**

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

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

#### **15. REQUIREMENTS FOR SECONDARY NOTIFICATION**

Under the Act, secondary notification of the notified polymer may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Specifically, if annual imports of the new polymer exceed 10 tonnes, the notifier should provide data on adsorption/desorption on soils and sediments, and on toxicity of the polymer to green algae. Notwithstanding the above requirement, acute ecotoxicity data for daphnia, green algae and fish should be submitted when available.

No other specific conditions are prescribed.

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## Attachment 1

The Draize Scale 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 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