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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Dow Corning 8813 Polymer

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TABLE OF CONTENTS

| | |
|---|----|
| FULL PUBLIC REPORT..... | 3 |
| 1. APPLICANT | 3 |
| 2. IDENTITY OF THE CHEMICAL..... | 3 |
| 3. PHYSICAL AND CHEMICAL PROPERTIES | 3 |
| 3.1 Comments on Physico-Chemical Properties | 4 |
| 4. PURITY OF THE CHEMICAL..... | 4 |
| 5. USE, VOLUME AND FORMULATION | 4 |
| 6. OCCUPATIONAL EXPOSURE | 5 |
| 7. PUBLIC EXPOSURE | 6 |
| 8. ENVIRONMENTAL EXPOSURE..... | 6 |
| 8.1 Release | 6 |
| 8.2 Fate..... | 7 |
| 9. EVALUATION OF TOXICOLOGICAL DATA | 7 |
| 9.1 Skin Sensitisation (Magnusson-Kligman Test) (Dow Corning, 1988a) | 8 |
| 9.2 <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> Reverse Mutation Assay (Dow Corning , 1988b)..... | 9 |
| 9.3 Overall Assessment of Toxicological Data..... | 9 |
| 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS | 10 |
| Water Flea | 10 |
| 11. ASSESSMENT OF ENVIRONMENTAL HAZARD | 11 |
| 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS..... | 12 |
| <i>Public Health</i> | 13 |
| 13. RECOMMENDATIONS | 13 |
| 13.1 Secondary notification | 14 |
| 14. MATERIAL SAFETY DATA SHEET | 15 |
| 15. REFERENCES | 15 |

FULL PUBLIC REPORT**Dow Corning 8813 Polymer****1. APPLICANT**

Dow Corning Australia Pty Ltd of 3 Innovation Road, NORTH RYDE, NSW 2113 (ABN 36 008 444 166) has submitted a limited notification statement in support of their application for an assessment certificate for Dow Corning 8813 Polymer.

2. IDENTITY OF THE CHEMICAL

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

Other Names: Amine-Functional Polysiloxane

Marketing Name: Dow Corning 8813 Polymer

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Hazy to clear liquid

Boiling Point: The liquid has no defined boiling point.

Specific Gravity: 0.97

Vapour Pressure: Not determined.

Water Solubility: Not determined.

**Partition Co-efficient
(n-octanol/water):** Not determined.

Hydrolysis as a Function of pH: Not determined.

Adsorption/Desorption: Not determined

Dissociation Constant: Not determined

Particle Size: Not applicable for a liquid.

| | |
|----------------------------------|---|
| Flash Point: | >61°C (closed cup method). |
| Flammability Limits: | Not determined. |
| Autoignition Temperature: | Not determined. |
| Explosive Properties: | Not determined |
| Reactivity: | Stable under normal conditions; can react with strong oxidising agents; if heated to >150°C trace quantities of formaldehyde may be released. |

3.1 Comments on Physico-Chemical Properties

The vapour pressure of the notified polymer is likely to be relatively low considering its high molecular weight. The vapour pressure of the precursor polymer was calculated to be 4.2×10^{-6} Pa.

The water solubility was not determined. Based on its structure the solubility of the notified polymer is expected to be low. The notifier has indicated that silicones are classed as having low water solubilities as indicated by their high partition coefficients, typically log P equals 4-5. The precursor polymer exhibited a water solubility of 2.2 mg/L which was largely attributed to the low molecular weight cyclosiloxanes present as residual reactants in the material in spite of the amines presents.

The notified polymer contains amide linkages that could undergo hydrolysis but this is unlikely in the environmental pH range of 4 to 9.

No adsorption/desorption tests were conducted for this notification. The notified polymer is expected to be relatively immobile in soil due to its high molecular weight and expected low water solubility.

The notified polymer contains a secondary amine which would be expected to have a pKa of approximately 9-10. However, the notified polymer will not undergo dissociation due to its limited water solubility.

4. PURITY OF THE CHEMICAL

| | |
|------------------------------|-------|
| Degree of Purity: | 95.8% |
| Hazardous Impurities: | None |
| Additives/Adjuvants: | None |

5. USE, VOLUME AND FORMULATION

The notified polymer will be imported as a polymer fluid packed in 20 or 200 L 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 2-20% w/w notified polymer. The emulsion will be transported in 200 L polyethylene lined steel drums to a textile finishing company where it will be further mixed with water and additional chemicals and applied to textiles. The applied fluid will contain 1-2% notified polymer.

The polymer may be also imported in 20 or 200 L steel drums as an emulsion containing 2-20% notified polymer.

6. OCCUPATIONAL EXPOSURE

Introduced notified polymer will be emulsified with water and emulsifying agents, prior to transport in 200 L polythene-lined steel drums to a textile finishing company. There it will be mixed with water and other chemicals and applied to textiles by padding or dipping, followed by drying at $>150^{\circ}\text{C}$ and storage prior to manufacture into garments. For “optimal performance”, Dow recommends 0.5-0.75% silicone treatment owf (on-the-weight of fabric), leading to a fabric application concentration of approximately 1-2% of notified polymer.

According to the MSDS supplied, spills should be dealt with in accordance with local, State, and Federal regulations. Residues may require the use of steam, solvents or detergents to remove the slip hazard associated with silicones. Large spills should be contained with dykes, and if possible, recovered by pumping. Persons cleaning spills should wear appropriate protective equipment to prevent eye, skin and inhalation contact.

Import, Transport and Storage

The notified polymer will be imported at a high concentration fluid in 20 or 200 litre steel drums with screw top bungs, stored at a Dow Corning Australia site, and 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 exposure of workers involved in transport of the notified polymer is minimal under the normal conditions of transport and storage and would only occur following 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 2-20% 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 due to spills and splashes. The viscosity of Dow Corning 8813 is $80\text{ cm}^2/\text{s}$. Mixing sites are expected to be fitted with forced ventilation to control the inhalation exposure as excessive agitation may produce aerosols containing the notified polymer. Workers are expected to wear personal protective equipment consisting of goggles and chemical resistant gloves.

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 inhalation exposure. During emulsion transfer processes, there is the potential for worker exposure, predominantly via the skin, but also via the eyes due to 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 goggles and chemical resistant gloves.

In the absence of adequate ventilation, workers may be exposed to polymer fumes and trace quantities of formaldehyde may be released if textiles are heated to >150°C. However, the heating ovens will be fitted with forced ventilation 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% is reported to be firmly adsorbed to the textile material preventing any further occupational exposure. No test data on fixation rates were provided.

7. PUBLIC EXPOSURE

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

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Given the likely low water solubility of the notified polymers, it is expected to remain bound to the textile and not be released during washing. The notifier indicates that approximately 0.25% of the notified polymer will remain the “empty” import drums which equates to 250 kg per annum lost to landfill. The notifier further indicates that approximately 0.25% of the 50% polymer emulsion will remain the “empty” reformulation drums which equates to 125 kg per annum lost to landfill.

Equipment used in the formulation and application of the textile softener will be rinsed with water and the rinseate treated using an advanced liquid treatment system, from which the resulting sludge will either be incinerated or disposed of in landfill. At manufacturing sites where such an advanced liquid treatment system is not in use, the rinseate will be released

directly into the sewer. Therefore the notifier expects that at each site, 0.5 kg of the notified polymer will remain in the mixing equipment while 0.0075 kg of the notified polymer will remain in the textile treating equipment.

The “empty” import drums and will be disposed of in landfill. At the end of their useful life, the garments which have been made from the textiles treated with the softener containing the notified polymer will also be disposed of in landfill.

8.2 Fate

The majority of the notified polymer will be used to treat textiles which will ultimately be disposed of in landfill. It is unlikely that the notified polymer will leach from the textile due to its low water solubility, however, if it did it would become associated with the soil matrix and not leach into the aquatic compartment. Wastes generated from the cleaning of formulation machinery will be released into the sewer. Here, the notified polymer will adsorb onto sediments due to its expected low water solubility. Some wastes containing the notified polymer may be incinerated producing water vapour and oxides of carbon and silicon.

A biodegradation study was conducted using the related polymer Q2-8413 according to OECD TG 301B – Ready Biodegradability; CO₂ Evolution Test (ABC Laboratories Inc. 2000).

Activated sludge, obtained from the Columbia Wastewater treatment plant in Columbia, Missouri, was mixed with the test substance or standard material (sodium benzoate) at a final concentration of 20 mg/L. The biodegradation of sodium benzoate was over 91% after 28 days, indicating the test conditions were valid. After 28 days at 22 °C, the biodegradation of the test substance was determined to be approximately 13%, which indicates the notified polymer is not readily biodegradable in aerobic environments. According to Guideline 301B, a substance cannot be considered to be readily biodegradable as it failed to satisfy the 10 day window criterion whereby 60% degradation must be attained within 10 days of the degradation exceeding 10%. However, despite the low apparent rate for biodegradation, it is expected that if placed into landfill the polymer would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes could be expected to produce carbon dioxide, methane and water.

“Empty” import and reformulation drums with any remaining residual material, will be disposed of to landfill. Here, the polymer is not expected to escape from the drums but if it did, it would become associated with the soil matrix and not leach into the aquatic compartment due to its expected low water solubility.

Polydimethylsiloxanes are unstable in landfill situations (Hamelink, 1992; Lehmann *et al*, 1994a and 1994b), and under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. When released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink 1992).

The polymer is not expected to cross biological membranes, due to its high molecular weight and predicted low water solubility, and as such should not bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier provided reports of skin sensitisation study and bacteria reverse mutation study on Dow Corning X2-8357. Dow Corning X2-8357 is of a similar chemical structure to Dow Corning 8813 polymer, and these toxicological data are accepted as analogue data for the notified polymer.

9.1 Skin Sensitisation (Magnusson-Kligman Test) (Dow Corning, 1988a)

Test materials: Dow Corning X2-8357

Species/strain: Guinea pig/Hartley

Number of animals: Test group: 20 male;
Negative control group: 20 male;
Positive control group: 10 male.

Induction procedure:

test group:
day 0 3 pair of intradermal injections (0.1 mL):

- 1:1 mixture of Freund's Complete Adjuvant (FCA) and water;
- 5% test material in Dow Corning 244 Fluid (244 Fluid);
- 10% test material (in Dow Corning 244 Fluid) in a 1:1 mixture of Freund's Complete Adjuvant (FCA) and water.

day 7 Topical Induction:
A 48-hour dermal occluded application of undiluted test material.

control groups: Negative control group was treated with Dow Corning 244 Fluid and the positive control group received 1-chloro-2,4-dinitrobenzene (DNCB) in propylene glycol.

Challenge procedure:

day 21 A 24 hour occluded application of 50% test material in Dow Corning 244 Fluid to one flank, and the vehicle to the other side flank.

Test method: OECD TG 406

Challenge outcome:

| Challenge concentration | Test animals | | Negative Control animals | | Positive control animals | |
|--------------------------------|---------------------|------------------|---------------------------------|------------------|---------------------------------|------------------|
| | 24 hours* | 48 hours* | 24 hours* | 48 hours* | 24 hours* | 48 hours* |
| 50% | **0/20 | 0/20 | 0/20 | 0/20 | 10/10 | 10/10 |

* time after patch removal

** number of animals exhibiting positive response (Draize scores ≥ 1)

Comment: None of the animals in the test or negative control group had positive responses to the test material.

The positive control group responded appropriately.

Result: The test material was not sensitising the skin of guinea pigs under the experimental conditions.

9.2 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Dow Corning , 1988b)

Test materials: Dow Corning X2-8357

Strains: *S. typhimurium*: TA98, TA100, TA1535 and TA1537;
E. coli: WP2

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Concentration range: 312.5, 625, 1 250, 2 500 and 5 000 µg/plate with and without the S9-mix (vehicle: DMSO).

Positive control (with the absence of S9-mix):
Sodium azide for TA1535 and TA100;
9-Amino acridine for TA1537;
2-Nitrofluorene for TA98
N-methyl-N-nitro-N-nitrosoguanidine for WP2.

Positive control (with the presence of S9-mix):
2-Anthramine for all strains.

Test method: OECD TG 419 & 420

Comment: Under the conditions of the study, the test material caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes.

All positive controls responded appropriately.

Result: The test material was non mutagenic under the conditions of the test.

9.3 Overall Assessment of Toxicological Data

The notifier provided an abstract of acute toxicity on Dow Corning X2-8357 (Dow Corning, 1988c). Dow Corning X2-8357 was of very low acute oral toxicity (LD50>15 g/kg) in rats. In a primary eye irritation study, it caused slight conjunctival redness and very slight corneal

injury which had resolved by 24 hours. A dermal irritation study showed that the test chemical caused slight redness after a single 24 hour semi-occluded dermal exposure. Repeat prolonged dermal contact also caused slight redness. Species used in skin and eye irritation studies were not stated.

A report of skin sensitisation study in guinea pigs on Dow Corning X2-8357 was provided. Dow Corning X2-8357 was not a skin sensitiser in the Magnusson and Kligman maximisation test.

A report of Ames study on Dow Corning X2-8357 was provided. No evidence of mutagenicity was detected for Dow Corning X2-8357 in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2, at concentrations of up to 5 000 µg/plate, with and without metabolic activation (rat S9 mix).

The MSDS supplied for the notified polymer states that it may cause irritation to the mouth, throat and stomach and may be a moderate eye and skin irritant. Studies of structurally related aminofunctional siloxanes show a high inhalation toxicity with LC50<0.5 mg/L over 4 hours. However, the notifier provided evidence that aminofunctional siloxane polymers of viscosity greater than 1500cP cannot be aerosolised during normal handling and use. Due to the high viscosity of the notified polymer (8000 cP), Dow Corning 8813 Polymer will not be aerosolisable during the proposed handling and use situations. Therefore, it is not considered necessary to label the notified polymer with the risk phrase R23 (Toxic by inhalation).

The available toxicological data for the notified polymer are limited. Based on the information submitted, the notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies for Dow Corning Q2-8413 Polymer were provided by the notifier.

| <i>Test</i> | <i>Species</i> | <i>Results</i> |
|------------------------------------|------------------------------------|---|
| Acute Immobilisation | Water Flea <i>Daphnia magna</i> | No mortalities experienced at a nominal loading of 11.5 g/L |
| Microtox Test | <i>Vibrio fischeri</i> | 5 and 15 min EC ₅₀ > 90 mg/L. |
| Respiration Inhibition of Bacteria | Sewage sludge bacteria | EC ₅₀ > 100 mg/L. |

The immobilisation tests with *Daphnia* (Dow Corning 1999a) were performed under static conditions with observations performed at 24 and 48 hours. The test was performed in

duplicate using 10 daphnids per flask at a temperature of 22 °C. The tests were conducted using both the water accommodation fraction (WAF) and the water soluble fraction (WSF). The WAF (containing trace impurities that partition into the aqueous phase) was prepared by adding the notified polymer (23 g) to water (2 L) and the resulting solution stirred for 24 hours. The mixture was allowed to stand for 24 hour prior to the removal of the aqueous phase. The water soluble fraction (WSF) was prepared by filtering the aqueous phase through a 0.45 µm filter prior to use. After 48 h, no immobilised daphnids were observed in any of the test vessels though there was a low level of entrapment (<10%) in the WAF beakers. The data indicates the notified polymer is not toxic to *Daphnia* up to the limit of its water solubility. The concentration of the notified polymer in each test solution was not determined, however, these solutions were analysed for elemental silicone. After 48 h the concentration of silicone in the test solutions was approximately 1.2 ppm (down from an initial 3 ppm) which is well below the nominal loading of 11.5 g/L.

A report detailing tests on respiration inhibition of sewage sludge bacteria was also submitted (ABC Laboratories Inc. 1999). The 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 then aerated for 3 hours at 20 °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.

A reference test conducted with 3,5-dichlorophenol inhibited bacterial respiration 0 % at a test concentrations of 3.2 mg/L and 10 mg/L, and 59% at 32 mg/L, and this would indicate that the bacterial culture used in the test was viable.

A rapid screening test (Dow Corning Corporation 1999b) conducted against a luminescent marine bacteria *Vibrio fischeri* whose light output after exposure to test materials has apparently been correlated with acute toxicity of the test material to freshwater fish and invertebrates. This test was also performed using the test material Dow Corning Q2-8413 at nominal concentrations up to 90 mg/L, and gave a 5 minute and a 15 minute EC₅₀ of greater than 90 mg/L with corresponding No Observed Effect Level (NOEL) of 90 mg/L for both times. However, since there was no discussion of how to actually correlate these results with toxicity to aquatic species, the relevance of this result to “real world” aquatic toxicity is unclear.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will be used to treat textiles which will ultimately be disposed of in landfill. It is unlikely that the notified polymer will leach from the textile due to its low water solubility, however, if it did it would become associated with the soil matrix and not leach into the aquatic compartment. Wastes generated from the cleaning of formulation machinery will be released into the sewer. Here, the notified polymer will adsorb onto sediments due to its expected low water solubility. Some wastes containing the notified polymer, those advanced water treatment plants, may be incinerated producing water vapour and oxides of carbon and silicon. Some sludge containing the notified polymer will be disposed of in landfill, where it is expected that the polymer would become associated with the soil matrix and will not leached from the soil because of its expected low solubility in

water.

Polydimethylsiloxanes are unstable in landfill and on dry sediments (Hamelink, 1992; Lehmann *et al*, 1994a and 1994b) because under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. However, when released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink 1992). Therefore in landfill, the notified polymer would eventually degrade and as such poses little risk to the environment.

Based on annual imports of 10 tonnes/annum used at 5 sites across Australia the local Predicted Environmental Concentration (PEC) for both city and country are estimated below.

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

The ecotoxicity data indicates the notified polymer is not toxic to *Daphnia* up to the limit of its water solubility. The hydrophobic nature of the notified polymer indicates that most would adsorb onto particles of sediment and sludge (Hamelink 1992; R.G. Lehmann *et al.*, 1994), and would therefore not remain in the water compartment and be available for assimilation by aquatic organisms.

Therefore, the environmental exposure and overall environmental hazard from the notified polymer is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Extrapolating from the analogue toxicity studies, notified polymer is predicted to be of very low acute oral toxicity in rats. It could be a slight eye and skin irritant but not a skin sensitiser. Evidence of mutagenicity is unlikely to be found in bacteria with and without metabolic activation. Based on available information, the notified polymer is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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 2-20% 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 1-2%. 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. Therefore, when workers are decanting the notified polymer or polymer emulsions, appropriate measures must be taken to minimise exposure by the dermal and ocular routes. Local exhaust ventilation should be provided during transfer and mixing processes and 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. Given the low concentration of notified polymer in the clothing fabric (up to 2%), the skin irritation hazard is likely to be low. There will be minimal public exposure from transport, storage, reformulation and industrial use.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to 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 exposure to formaldehyde vapour.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Spills should be dealt with in accordance with local, State, and Federal regulations. Residues require the use of steam, solvents or detergents to remove the slip hazard associated with silicones
 - The polymer is likely to be acutely toxic by inhalation, so the generation of aerosols should be avoided.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
Protective eyewear
Chemical resistant industrial clothing
Footwear
Impermeable gloves
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.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Atmospheric monitoring should be conducted to measure workplace concentrations during formulation and use of the notified polymer. Employers should ensure that NOHSC exposure standards for formaldehyde are observed.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act;
 - If the notified polymer is used in a manner that may generate aerosols, acute inhalation toxicity data must be provided for assessment.or
- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 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. REFERENCES

ABC Laboratories Inc. (1999) Report number 1999-I0000-47719: "Activated Sludge Respiration Test of Dow Corning Q2-8413 Conditioning Additive" (unpublished report submitted by Dow Corning).

ABC Laboratories Inc. (2000) Study number 9249: Determination of ready biodegradability of Dow Corning Q2-8413; CO₂ Evolution Test, (unpublished report submitted by Dow Corning).

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.

Dow Corning (1988a) Guinea pig maximization test with Dow Corning X2-8357, Dow Corning Corporation, USA.

Dow Corning (1988b) Genetic evaluation of Dow Corning X2-8357 in bacterial reverse mutation assays, Dow Corning Corporation, USA.

Dow Corning (1988c) Acute toxicological properties and industrial handling hazards of Dow Corning X2-8357, Dow Corning Corporation, USA.

Dow Corning Coporation (1999a) Report number 1999-I0000-47818: Acute Toxicity Tests of the Water Soluble Fractions and Water Accommodating Fractions of Dow Corning Q2-8413 Polymer with *Daphnia Magna* under Static Conditions, Midland, USA, (unpublished report submitted by Dow Corning).

Dow Corning Coporation (1999b) Report number 1999-I0000-47818: "*Vibrio fischeri* Bioluminescence [Microtox®] Test of Dow Corning Q2-8413 Conditioning Additive", (unpublished report submitted by Dow Corning).

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

R.G. Lehmann, S. Varaprath and C.L. Frye 1994. "Degradation of silicone polymers in soil". *Environ. Toxicol. Chem.* 13 (7): 1061-1064.

R.G. Lehmann, S. Varaprath and C.L. Frye 1994. "Fate of Silicone Degradation Products (Silanols) in Soil". *Environ. Toxicol. Chem.* 13 (11): 1753-1759.

J.V. Nabholz, P. Miller and M. Zeeman "Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five," *Environmental Toxicology and Risk Assessment, American Society for Testing and Materials, ASTM STP 1179*, W.G. Landis, J.S. Hughes, and M.A. Lewis Eds. Philadelphia, 1993, pp 40-55.

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

National Occupational Health and Safety Commission (1995). Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003 (1995)]. In: Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

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

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

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

Standards Australia/Standards New Zealand (1994b) Australian/New Zealand Standard 1715-1994, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994c) Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Sydney, Standards Association of Australia.

Attachment 1

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

| <i>Erythema Formation</i> | <i>Rating</i> | <i>Oedema Formation</i> | <i>Rating</i> |
|---|---------------|---|---------------|
| No erythema | 0 | No oedema | 0 |
| Very slight erythema (barely perceptible) | 1 | Very slight oedema (barely perceptible) | 1 |
| Well-defined erythema | 2 | Slight oedema (edges of area well-defined by definite raising) | 2 |
| Moderate to severe erythema | 3 | Moderate oedema (raised approx. 1 mm) | 3 |
| Severe erythema (beet redness) | 4 | Severe oedema (raised more than 1 mm and extending beyond area of exposure) | 4 |

The Draize scale (Draize *et al.*, 1944) for evaluation of eye reactions is as follows:

CORNEA

| <i>Opacity</i> | <i>Rating</i> | <i>Area of Cornea involved</i> | <i>Rating</i> |
|--|---------------|--------------------------------|---------------|
| No opacity | 0 none | 25% or less (not zero) | 1 |
| Diffuse area, details of iris clearly visible | 1 slight | 25% to 50% | 2 |
| Easily visible translucent areas, details of iris slightly obscure | 2 mild | 50% to 75% | 3 |
| Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 moderate | Greater than 75% | 4 |
| Opaque, iris invisible | 4 severe | | |

CONJUNCTIVAE

| <i>Redness</i> | <i>Rating</i> | <i>Chemosis</i> | <i>Rating</i> | <i>Discharge</i> | <i>Rating</i> |
|---|---------------|---|---------------|--|---------------|
| Vessels normal | 0 none | No swelling | 0 none | No discharge | 0 none |
| Vessels definitely injected above normal | 1 slight | Any swelling above normal | 1 slight | Any amount different from normal | 1 slight |
| More diffuse, deeper crimson red with individual vessels not easily discernible | 2 mod. | Obvious swelling with partial eversion of lids | 2 mild | Discharge with moistening of lids and adjacent hairs | 2 mod. |
| Diffuse beefy red | 3 severe | Swelling with lids half-closed | 3 mod. | Discharge with moistening of lids and hairs and considerable area around eye | 3 severe |
| | | Swelling with lids half-closed to completely closed | 4 severe | | |

IRIS

| <i>Values</i> | <i>Rating</i> |
|---|---------------|
| Normal | 0 none |
| Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light | 1 slight |
| No reaction to light, haemorrhage, gross destruction | 2 severe |

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

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