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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Rhodorsil 21645

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FULL PUBLIC REPORT**Rhodorsil 21645****1. APPLICANT**

Rhodia Australia Pty Ltd. of 100 York Street, South Melbourne, VIC 3205 (ACN 004 693 038) has submitted a limited notification statement in support of their application for an assessment certificate for Rhodorsil 21645. No exempt information has been requested.

2. IDENTITY OF THE CHEMICAL

Chemical Name: alpha, omega-dimethylpoly di-Me, Me[3-(2,2,6,6-tetramethyl piperidin-4-yloxy)propyl]siloxane

Chemical Abstracts Service (CAS) Registry No.: 171543-65-0

Other Names: amino alkoxy polydimethyl siloxane
siloxanes and silicones, di-Me, Me 3[(2,2,6,6-tetramethyl-4-piperidinyloxy)propyl-

Marketing Name: Rhodorsil 21645

Molecular Formula: $(\text{CH}_3)_3\text{SiO}[(\text{CH}_3)(\text{C}_{12}\text{H}_{24}\text{NO})\text{SiO}]_n[(\text{CH}_3)_2\text{SiO}]_m\text{Si}(\text{CH}_3)_3$

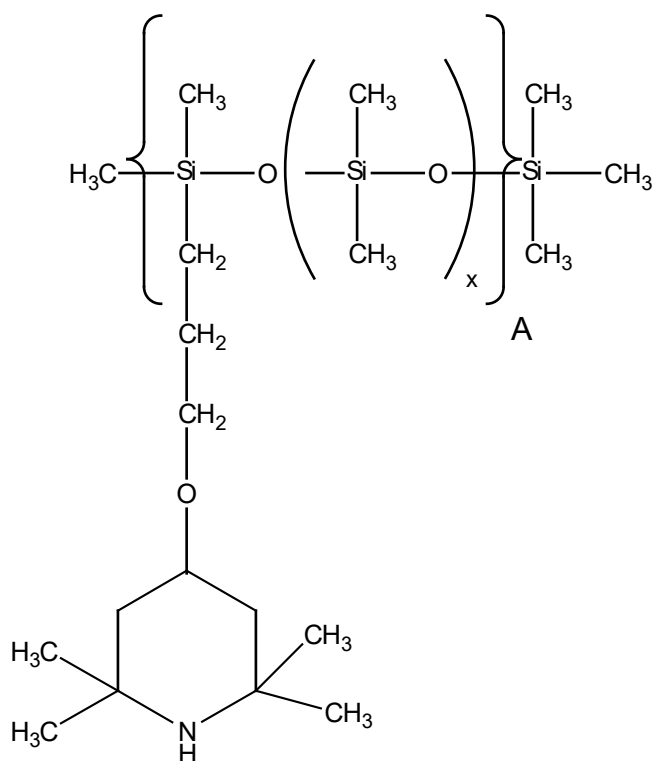
Number-Average Molecular Weight (NAMW): 43900

Weight-Average Molecular Weight: 89000

Maximum Percentage of Low Molecular Weight Species

Molecular Weight < 500: 2 %
Molecular Weight < 1 000: 3.3 %

Structural Formula:



The notified material is a complex condensation product containing two major types of functionality. From the information provided by the notifier, the major portion of the molecule is a large methylated siloxane chain with around 480 $(\text{CH}_3)_2\text{SiO}$ units, while pendant propylpiperidyl groups are present in the polymer in the approximate mole ratio piperidine: $(\text{CH}_3)_2\text{SiO}_2$ of 1:96. Several different sets of GPC data were submitted which provided estimates for the Number Average Molecular Weight (NAMW) of the polymer between 7400 and 44000, but the most reliable appears to be that providing the higher estimates. Nevertheless, it is likely that the molecular weight distribution varies between production batches, and the stated NAMW of 43900 should be taken as indicative only. The GPC traces also indicate the presence of some low molecular weight material although this was not identified. Again, the proportions of this in the polymer probably vary considerably between batches and one set of GPC data indicated 3.3 % of this particular material had a molecular weight below 1000, and around 2 % below 500.

The product is stated to contain < 2 % of relatively low molecular weight cyclodimethyl siloxanes which are residuals from production of the linear polydimethylsiloxane moiety.

Based on the structural formula depicted above the Functional Group Equivalent Weight (FGEW) for the amine groups is estimated as approximately 7000. The polymer contains approximately 0.2% of amino nitrogen.

Weight Percentage of

Ingredients:

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight %</i>
cyclotetrasiloxane, octamethyl-	556-67-2	94.54
piperidine, 4-[3-(dichloromethylsilyl)propoxy-2,2,6, 6-tetramethyl-, hydrolysed, polymerised	137898-96-5	4.467
siloxanes and silicones, dimethyl	63148-62-9	0.993

Method of Detection and Determination:

infrared spectroscopy

Spectral Data:3570, 3510, 2880, 2820, 1370, 1330, 1290, 1280, 1170, 1040-920 (br), 770, 725, 705, 625, 610, 590 cm⁻¹**3. PHYSICAL AND CHEMICAL PROPERTIES****Appearance at 20 °C & 101.3 kPa:** clear colourless to slightly hazy viscous liquid**Boiling Point:** not determined (see comments below)**Specific Gravity:** approximately 974 kg/m³**Vapour Pressure:** < 0.01 kPa at 20°C**Water Solubility:** very slightly soluble; for an analogue polymer
pH 10 1.65×10^{-2} g/L
pH 7 7.68×10^{-3} g/L
pH 1 2.85×10^{-1} g/L at 20°C**n-octanol Solubility:** 2.54 g/L at 20°C**Viscosity:** 10000 to 100000 cps at 25°C**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:** 104 °C (closed up) not flammable; combustible**Flammability Limits:** not determined (see comments below)**Autoignition Temperature:** > 400 °C

Explosive Properties:	not explosive
Reactivity/Stability:	stable under normal environmental conditions

3.1. Comments on Physico-Chemical Properties

The solubility of the Rhodorsil 21645 in water was not determined, but that of an apparently chemically similar polymer with a NAMW of around 76400 (Rhodorsil 21650) was determined at pH 1, 7 and 10 using the methods of OECD TG 105 and OECD TG 120 (Roth, 1997). Although not specified in the notification statement, it is assumed that Rhodorsil 21650 has essentially the same structure as Rhodorsil 21645, but as depicted in the structural diagram above has higher values for A and/or x.

The water solubility of Rhodorsil 21650 oil was determined by vigorously mixing the polymer with water at 30°C, allowing to stand at 20°C for at least 120 hours then filtering (0.45 micron) to remove suspended matter. Six replicate determinations were made at each pH, and the aqueous phase was then analysed for Si using inductively coupled plasma (ICP) spectroscopy. Since the polymer contains around 30 % silicon the water solubilities of the silicone oil were estimated from the silicon content of the solutions determined by ICP. The mean solubilities at pH 1, 7 and 10 were 285, 7.68 and 16.5 mg/L respectively. Due to the smaller NAMW of the notified polymer compared with the tested polymer, it is possible that the new polymer may have concomitantly higher water solubility.

Although no hydrolytic degradation data was provided, the compound is unlikely to undergo hydrolysis in the usual environmental pH region of 4 to 9. Low water solubility would also reduce the likelihood of 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°C) drying process used during application of the notified polymer.

The solubility of the polymer in n-octanol was also determined (with six replicates) using the protocols of OECD TG 105 by stirring an excess of the Rhodorsil 21650 in n-octanol at 30°C for an extended period (up to 144 hours), then allowing the mixture to equilibrate at 20°C for at least 24 hours (Roth, 1997). The mixture was centrifuged and the n-octanol layer removed for analysis of the dissolved Rhodorsil 21650. The analysis was performed gravimetrically by determining the residue left after the n-octanol had been removed through evaporation at 110°C in a nitrogen stream. The mean of the six determinations established the solubility of the test material in n-octanol as 2.54 g/L at 20°C.

The n-octanol/water partition coefficient was not determined. However, this may be crudely estimated from the ratio of the solubility in n-octanol to that in water. Taking the water solubility at pH 7 as 7.7 mg/L, and that in n-octanol as 2.54 g/L, the value for Log P_{ow} at 20°C is estimated as 2.5. While the polymer is primarily composed of hydrophobic (CH₃)₂SiO₂ groups, the presence of the amine groups provides some affinity for water.

No adsorption/desorption data was provided, with the notifier claiming that this information could not be obtained despite repeated attempts. Given that the material has a moderate value for Log P_{ow} (2.5) and moderate water solubility, it is expected to have only moderate affinity for soils and sediments and is likely to be mobile in these media.

No data on the dissociation constant of the polymer was provided in the notification, but the secondary amine group in the piperidine ring could be expected to have similar basicity to that of 2,2,6,6-tetramethyl piperidine, which has a pKa of 11.07 (CRC, 1977). Consequently, the amino nitrogen is expected to be very basic and would be protonated (hence cationic) in the environmental pH region of 4 - 9.

A study provided by the notifier in respect of inhalation toxicity (Bergeron, 1999) found that the pure notified polymer cannot be sprayed as an aerosol, but rather extrudes from the spray nozzle as strands, due to its high viscosity.

The notified polymer has a high flash point and spontaneous ignition temperature, indicating the product presents a low fire hazard as a class C2 combustible liquid.

4. PURITY OF THE CHEMICAL

Degree of Purity: approximately 98 %

Hazardous Impurities: none present.

**Non-hazardous Impurities
(> 1% by weight):** none present

Maximum Content of Residual Monomers:

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight %</i>
cyclotetrasiloxane, octamethyl-	556-67-2	2.0
piperidine, 4-[3-(dichloromethylsilyl)propoxy- 2,2,6, 6-tetramethyl-, hydrolysed, polymerised	137898-96-5	0.001

Additives/Adjuvants: none present

5. USE, VOLUME AND FORMULATION

The notified polymer is used for formulation of non-yellowing textile softening emulsions and micro emulsions. It is typically used on cellulosic and man made fibres on woven, knitted and non-woven fabrics where softening and lubrication are required without any resultant yellowing.

The notified polymer is imported as the pure oil, with no additives, in 200 L steel drums. It will be reformulated in Australia to produce a microemulsion textile softener which contains 15 % notified polymer, water and emulsifier. This will be packaged in 200 L stainless steel drums for use within Australia, or 150 L HDPE drums for export. The textile softener is used in textile finishing plants at a dilution of 1 – 5 g/L (0.015 – 0.075 % notified polymer).

The notifier estimates that the import volume will be 5,500 kg/annum during the first five

years of importation.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

Waterfront, transport and warehouse workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage of the paint or resin solution. Handling, transporting and storage of drums of notified polymer and finished emulsion at the reformulation plant will involve 4 workers for 1 hours per day, 20 days per year. Handling, transporting and storage of drums of finished emulsion at the textile plants will involve 4 workers for 1 hours per day, 20 days per year.

Reformulation

The reformulation of pure notified polymer oil to produce the microemulsion textile softener will occur at one site. The notifier states that the equipment used in the sampling, dispensing and compounding operations will be a closed system, or a system designed not to create aerosols or a spill hazard. Dermal exposure to the polymer will be possible at several points throughout the process; charging the polymer oil into the mixer, removal and testing of quality control samples, and drips and spills during drum filling.

Reformulation will involve quality assurance staff, manufacturing operators and packaging operators. The notifier expects that 2 quality assurance staff will handle the notified polymer. Sampling and testing of the pure notified polymer will occur for 4 hours per day, 3 days per year, and sampling and testing of the finished emulsion will occur for 1 hour per day, 10 days per year. Small quantities of notified polymer are expected to be handled under laboratory conditions.

The reformulation process will involve 5 manufacturing operators, who will be involved in dispensing pure notified polymer and blending operations for 1 hour per day, 10 days per year. Dermal exposure to drips and spills of the pure notified polymer may occur during connection and disconnection of transfer hoses while drums of notified polymer are being changed during dispensing operations. After reformulation, the finished emulsion will be handled by 2 packaging operators, for 2 hours per day, 10 days per year. Dermal exposure to drips and spills of the emulsion, containing 15 % notified polymer, may occur while changing and closing drums on the filling line.

Workers will wear impervious gloves and goggles.

End Use

The notified polymer will be used at up to 20 fabric treatment sites in Australia. The emulsion will be dosed into the fabric treatment tanks at a rate of 1 to 5 g/L, and it is estimated that between 90 % and 95 % of the notified polymer will be absorbed by the fabric. After absorption of the notified polymer to fabric, it is not expected to be separately available for exposure.

Application of the fabric softener is likely to be done either by padding or exhaust dyeing or finishing. In either method, a bath is prepared containing the notified polymer emulsion in water, with other fabric treatment additives. Padding is a continuous operation, with the mixture being applied by padding, foaming, kissing or padding with vacuum slot, and excess

being removed by rollers and directed back to the padding bath. Exhaust dyeing or finishing is a batch process involving immersion of the textile in a dye bath and adding the emulsion to the solution at the completion of the dyeing process.

The notifier expects that 8 quality assurance staff will handle the notified polymer during sampling and testing of treated fabric for 1 hour per day, 20 days per year. Approximately 12 manufacturing operators will handle the notified polymer, dispensing emulsion and processing treated fabric for 4 hours per day, 20 days per year. It is likely that dermal exposure to the emulsion, containing 15 % notified polymer, may occur during dosing, and dermal exposure to the bath, containing < 0.075 % notified polymer, and spent water, containing < 0.0075 % notified polymer, may occur during treatment of fabric and handling of wet fabric.

7. PUBLIC EXPOSURE

The imported notified polymer and the reformulated textile softener containing the notified polymer will not be sold to the public, and only used by industry customers. The notified polymer will be applied to fabric at an end use concentration of < 0.075 % notified polymer. It is expected that 90 – 95 % of the notified polymer will be absorbed by the fabric. There is potential for public exposure to the treated fabrics. However, after being dried and cured, the notified polymer in finished fabric products is not expected to be available for exposure.

8. ENVIRONMENTAL EXPOSURE

8.1. Release

Some of the imported polymer will remain in the drums after production of the emulsion, and the notifier has estimated this to be < 1 % or 2 kg in a 200 L drum. These residues will be washed out at drum recycling facilities, and would most probably become incorporated into waste sludge which would in turn be either incinerated or be placed into landfill. At annual imports of 5.5 tonne, a maximum 55 kg of notified material could be disposed of via this route.

Some polymer is also likely to be released through discharge of spent bath solution containing the notified polymer. Reportedly between 90 % and 95 % of the notified polymer will be absorbed from the bath solution by the fabric prior to drying, and as these solutions are likely to be continually replenished in a closed system, releases will be small. Spent solution would also be passed to the sewer system and the notifier estimates a maximum of 10 % (550 kg per annum) of the imported polymer would be released via this route.

Most of the polymer will become strongly bonded to textiles. However some small release may be incurred as a result of washing clothes and domestic furnishings. This release will be diffuse and at low levels.

8.2. Fate

The majority of the notified polymer will become 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 and fabric off-cuts are likely to be placed into landfill or incinerated.

Waste sludge from drum recycling or sewage treatment plants may contain some of the notified polymer. Waste sludge would either be placed into landfill or incinerated. Incineration would destroy the polymer with production of silica, water vapour and oxides of carbon and nitrogen.

Polymer and degradation products which enter sewer systems may be adsorbed onto the organic component of sediments, but may be mobile in these media due to the expected moderate affinity for soils and sediments. Consequently it must be assumed that some notified polymer released to the water compartment (eg. in sewage) would remain in the water column.

Polymer associated with soils in landfill may be degraded due to the apparent instability of silicones in contact with dry clay minerals (Hamelink, 1992; Lehmann et al., 1994a; Lehmann et al., 1994b). In dry soils clay minerals catalyse the hydrolytic decomposition of siloxane polymers 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).

No biodegradation data was included in the notification dossier, but siloxane polymers are not expected to be degraded through biological action.

Due to its moderate water solubility and high molecular weight the polymer is not expected to have high potential for bioaccumulation (Connell, 1990).

In conclusion, some of the notified polymer is expected to enter the water compartment where it is unlikely to become fully associated with soils and sediments due to moderate water solubility and moderate Log P_{ow} . Since biodegradation is also unlikely the polymer is expected to persist in the environment although potential for bioaccumulation is low.

9. EVALUATION OF TOXICOLOGICAL DATA

No studies on the repeat dose toxicity or genotoxicity of the notified polymer were provided by the notifier.

9.1 Acute Toxicity

Summary of the acute toxicity of Rhodorsil 21645

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 2000 mg/kg	(de Jouffrey, 1995d)
acute dermal toxicity	rat	LD ₅₀ > 2000 mg/kg	(de Jouffrey, 1995b)
acute inhalation toxicity	rat	LD ₅₀ (4 hr) > 5.1 mg/L (25 % emulsion)	(Muijsers, 1998)
skin irritation	rabbit	minimally irritating	(de Jouffrey, 1995a)
eye irritation	rabbit	minimally irritating	(de Jouffrey, 1995c)
skin sensitisation	guinea pig	slightly sensitising	(de Jouffrey, 1995e)

9.1.1 Oral Toxicity (de Jouffrey, 1995d)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage, dose level 2000 mg/kg of pure notified polymer
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	there were no premature decedents during the study
<i>Body weight:</i>	body weight gain was unaffected by treatment
<i>Clinical observations:</i>	no clinical signs of toxicity were observed
<i>Morphological findings:</i>	no gross pathological abnormalities were observed at necropsy
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the notified polymer was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (de Jouffrey, 1995b)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	semi occlusive patch, 24 hr treatment, dose level 2000

	mg/kg of pure notified polymer
<i>Test method:</i>	OECD TG 402
<i>Mortality:</i>	there were no premature decedents during the study
<i>Dermal observations:</i>	no cutaneous reactions were observed
<i>Body weight:</i>	body weight gain was unaffected by treatment
<i>Clinical observations:</i>	no clinical signs of toxicity were observed
<i>Morphological findings:</i>	no gross pathological abnormalities were observed at necropsy
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the notified polymer was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

(a) Rhodorsil 21645 in silicone oil (Jackson, 1997)

<i>Species/strain:</i>	rat/Sprague-Dawley										
<i>Number/sex of animals:</i>	5/sex/group										
<i>Observation period:</i>	14 days										
<i>Method of administration:</i>	aerosol (snout only exposure), mass median aerodynamic diameter $\leq 3.1 \mu\text{m}$; notified polymer concentrations 0.73, 0.176, 0.046 mg/L (total aerosol loading 1.82, 0.44, 0.12 mg/L); 40 % in diluent silicone oil; control groups treated with vehicle (total aerosol loading 1.20 mg/L) and air only were also used; 4 hr treatment										
<i>Test method:</i>	OECD TG 403										
<i>Mortality:</i>	<table> <tr> <td>0.73 mg/L</td><td>9/10</td></tr> <tr> <td>0.176 mg/L</td><td>4/10</td></tr> <tr> <td>0.046 mg/L</td><td>3/10</td></tr> <tr> <td>vehicle control</td><td>3/10</td></tr> <tr> <td>air control</td><td>0/10</td></tr> </table> <p>all deaths occurred within 3 days of exposure</p>	0.73 mg/L	9/10	0.176 mg/L	4/10	0.046 mg/L	3/10	vehicle control	3/10	air control	0/10
0.73 mg/L	9/10										
0.176 mg/L	4/10										
0.046 mg/L	3/10										
vehicle control	3/10										
air control	0/10										
<i>Clinical observations:</i>	<p>no treatment related signs were observed during exposure</p> <p>all test and vehicle control groups showed exaggerated respiratory movements; hypothermia (whole body) was</p>										

observed in the 0.73 and 0.176 mg/L groups immediately post exposure, and rapid or irregular respiration was observed in the 0.73 mg/L group on the day after exposure; all animals treated with the notified polymer showed oily fur

all except one male of the surviving members of the 0.046 mg/L group had recovered by day 12; complete recovery was not observed for the 0.73 and 0.176 mg/L groups; vehicle control animals had recovered by day 5

Body weight:

body weight losses were observed for up to 3 days following exposure to the notified polymer; lower body weight losses were also observed for the vehicle control group; all animals gained weight normally after day 4

Morphological findings:

severe congestion of the lungs was observed for all premature decedents, along with red/brown staining around the snout and opacities in both eyes

Comment:

separate tests were performed to show that the pure notified polymer could not be sprayed as an aerosol, forming strands instead

the notifier postulated that the results may be due to lipoid pneumonia, resulting from the physical effect of spreading of an oil mist across the lung surfaces, and that this is at least responsible for the observed mortalities in the vehicle control group; it was not possible to separately determine the inhalation toxicity of the notified polymer

LC₅₀:

0.34 mg/L

Result:

the test material was of moderate acute inhalational toxicity in rats

(b) 25 % Aqueous Emulsion (Rhodorsil Emulsion F4/49A) (Muijsers, 1998)

Species/strain:

rat/Crl:[WI]WU BR

Number/sex of animals:

5/sex

Observation period:

14 days

Test substance:

Rhodorsil Emulsion F4/49A (25 % aqueous emulsion of notified polymer)

<i>Method of administration:</i>	aerosol (nose only exposure), mass median aerodynamic diameter 2.5 µm; total emulsion concentration 5.1 mg/L (the maximum achievable concentration); 4 hr treatment
<i>Test method:</i>	OECD TG 403
<i>Mortality:</i>	there were no premature decedents during the study
<i>Clinical observations:</i>	<p>slightly decreased breathing rate in all animals and slight to moderate laboured breathing in all males and two females during exposure</p> <p>approximately 20 minutes after exposure, all animals were wet and sluggish with piloerection; on day 1, all animals showed encrustations at the nose and eyes, soiled fur and hunched appearance; food and water consumption was non-existent to minimal</p> <p>soiled fur was observed in males on days 2 – 4 and in females on days 2 and 3; on day 3, sluggishness was observed in the males and piloerection in the females; after day 3 for females and day 4 for males, all signs had resolved</p>
<i>Body weight:</i>	body weight losses were observed in 4 males in the first week, and minimal weight gain in the fifth male; females showed a reduced rate of weight gain in the first week; weight gains for all animals in the second week were normal
<i>Morphological findings:</i>	all morphological findings were restricted to the lungs; these consisted of atelectasis (incomplete expansion of a lung or portion of a lung) in 2 males and 1 female, discoloured lobes in 3 females, and white and/or hyalin spots in all males and 3 females
<i>Comment:</i>	white and/or hyalin spots in the lungs are occasionally observed in unexposed animals, however not at the frequency observed in this study
<i>LC₅₀:</i>	> 5.1 mg/L test substance, equivalent to > 1.3 mg/L notified polymer
<i>Result:</i>	the test material was of moderate or low acute inhalational toxicity in rats

9.1.4 Skin Irritation (de Jouffrey, 1995a)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	3 male

Observation period: 4 days

Method of administration: semi-occlusive patch; 0.5 mL notified polymer applied to the clipped right flank for 4 hr

Test method: OECD TG 404

Draize scores:

<i>Time after treatment</i>	<i>Animal #</i>		
	<i>1</i>	<i>2</i>	<i>3</i>
<i>Erythema</i>			
1 hour	^a 0	0	0
1 day	0	0	1
2 days	0	0	1
3 days	0	0	1
4 days	0	0	0
<i>Oedema</i> all Draize scores were zero			

^a see Attachment 1 for Draize scales

Result: the notified polymer was minimally irritating to the skin of rabbits

9.1.5 Eye Irritation (de Jouffrey, 1995c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 male

Observation period: 3 days

Method of administration: 0.1 mL of notified polymer was instilled in the conjunctival sac of the left eye; the untreated eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

<i>Time after instillation</i>												
<i>Animal</i>	<i>1 hour</i>			<i>1 day</i>			<i>2 days</i>			<i>3 days</i>		
<i>Cornea</i>	all Draize scores were zero											
<i>Iris</i>	all Draize scores were zero											
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>

1	1	1	-	1	1	0	0	0	0	0	0	0
2	0	0	-	1	0	0	0	0	0	0	0	0
3	1	0	-	1	0	0	0	0	0	0	0	0

¹ see Attachment 1 for Draize scales

r = redness c = chemosis d = discharge

Comment: observation of discharge at 1 hour was not possible due to residual test substance

Result: the notified polymer was minimally irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (de Jouffrey, 1995e)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 10/sex (test group)
5/sex (control group)

Induction procedure:

test group:
day 1, 8, 15 0.5 mL notified polymer was applied by occlusive patch for 6 hr to a clipped area of the anterior left flank; residual test substance was then removed with a dry gauze pad

control group:
day 1, 8, 15 treatment was as for test group, with distilled water used in place of notified polymer

Challenge procedure:

day 29 0.5 mL notified polymer was applied by occlusive patch for 6 hr to a clipped area of the posterior right flank; residual test substance was then removed with a dry gauze pad; 0.5 mL distilled water was applied to the posterior left flank under similar conditions

Test method: OECD TG 406 (Buehler method)

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 %	**4/20	2/20	0/9	0/9

* time after patch removal

** number of animals exhibiting positive response

Comment:

one control animal was found dead on day 7

the observation of 20 % response at 24 hr and 10 % response at 48 hr reaches the criterion of 15 % response in a non-adjuvant type test for a chemical to be classified as a skin sensitiser

Result:

the notified polymer was slightly sensitising to the skin of guinea pigs

9.2 Overall Assessment of Toxicological Data

The notified polymer was found to be of very low acute oral toxicity ($LD_{50} > 2000$ mg/kg) and low acute dermal toxicity ($LD_{50} > 2000$ mg/kg) in rats. It was a minimal skin and eye irritant in rabbits. The results of the sensitisation study indicated that the notified polymer may have some sensitising potential, particularly on long exposures and with sensitive members of the population. The criterion of 15 % response in a non-adjuvant type test is met, and the notified polymer should therefore be classified as a hazardous substance, with the risk phrase R43, 'May cause sensitisation by skin contact', in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (Approved Criteria) (NOHSC, 1999).

The results of the acute inhalation toxicity studies indicate that the notified polymer is moderately toxic by inhalation ($LD_{50} = 0.34$ mg/L) if prepared in a form where a pure oil phase containing the notified polymer can be produced as an aerosol. The pure notified polymer, as imported to Australia, cannot produce an aerosol (Bergeron, 1999). The results for the aqueous emulsion of the notified polymer indicate that in this form, where the physical spreading within the lungs is reduced, the inhalation toxicity is reduced ($LD_{50} > 1.3$ mg/L). The test was limited by the low maximum achievable concentration of 1.3 mg/L notified polymer. The result of this test indicated that the notified polymer should be classified as a hazardous substance, with the risk phrase R20, 'Harmful by inhalation', in accordance with the Approved Criteria. The presence of oil diluents may have an influence on the toxicity and classification of mixtures containing the notified polymer will depend on measured data for the mixtures.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided no ecotoxicity data in support of their application. The notified polymer contains an amino group component and the presence of such groups (which are capable of becoming cationic in aquatic environments) in polymers is known to impart toxic properties against aquatic organisms (Boethling and Nabholz, 1997). However, the density of these groups in the polymer is relatively low with the information provided by the notifier indicating that the polymer contains only 0.2 % amino nitrogen (Functional Group Equivalent Weight of amino groups = 7000), and so the polymer is unlikely to exhibit extreme toxicity. The aquatic toxicity of the polymer to fish, daphnia and green algae may be estimated using Quantitative Structure Activity Relationships (QSARs) given by Boethling and Nabholz (1997) which relate the estimated toxicities to the percentage of amino nitrogen in the polymer.

Taking the percentage of amine nitrogen as 0.2 % these relationships provide estimates of the toxicity against rainbow trout, daphnia and green algae, with estimated EC₅₀ values of 100, 398, and 23.7 mg/L respectively.

The QSAR estimated toxicities are for the polymer in clean water, and it is known that toxicity of cationic polymers is mitigated when the water contains colloidal organic material (Nabholz et al, 1993 and Boethling and Nabholz, 1997), as do most natural water bodies. Consequently, the QSAR estimated toxicities could be regarded as worst case values.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Notified polymer released into the sewage system as a result of disposal of drum residues or spent process solution from textile mills may become adsorbed into sediments within the sewer mains and eventually be incorporated into waste sludge from sewage treatment operations. It is probable that the notified polymer would be mobile in these media and re-released to the water column. Any material remaining in association with waste sludges would be incinerated or be placed into landfill.

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.

While no ecotoxicity data was provided, the polymer structure indicates that it may have some toxicity to aquatic organisms.

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 a maximum of 10 % is discharged, 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) the calculated PEC (predicted environmental concentration) is 0.5 mg/L for the sewage treatment plant effluent assuming no assimilation of the polymer into sediments or sludge. Release of sewage effluent to receiving waters would further lower the PEC in these waters, and assuming a dilution factor of 1:3 for country sewage plants, the PEC becomes 0.16 mg/L. This PEC is at least 2 orders of magnitude less than the estimated EC₅₀ of 23.7 mg/L for green algae (the most sensitive aquatic species). Nabholz *et al* (1993) indicates that the interaction between cationic polymers and the dissolved and suspended organic matter in natural waters can significantly mitigate toxicity of the compounds through reducing effective exposure to sensitive organisms, and so the safety margin is likely to be greater than two orders of magnitude.

In conclusion, based on the available information the environmental hazard from the notified polymer is expected to be small when the material is used in the indicated 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

The notified chemical is of very low oral toxicity ($LD_{50} > 2000$ mg/kg) and low dermal toxicity ($LD_{50} > 2000$ mg/kg) in rats. It was a slight irritant to skin, and a slight eye irritant in rabbits. The results of the sensitisation study indicated that the notified polymer may have some sensitising potential, particularly on long exposures and with sensitive members of the population. The notified polymer should therefore be classified as a hazardous substance, with the risk phrase R43, 'May cause sensitisation by skin contact'.

The results of the acute inhalation toxicity studies indicate that the notified polymer is moderately toxic by inhalation ($LD_{50} = 0.34$ mg/L) if prepared in a form where a pure oil phase containing the notified polymer can be produced as an aerosol. Lower inhalation toxicity was observed where the notified polymer was sprayed as an aerosol of a 25 % aqueous emulsion ($LD_{50} > 1.3$ mg/L). The result of this test indicated that the notified polymer should be classified as a hazardous substance, with the risk phrase R20, 'Harmful by inhalation'. Test results were provided to indicate that it is not possible to produce an aerosol of the pure notified polymer, due to its high viscosity.

The notified chemical cannot be assessed against the Approved Criteria for other toxicity endpoints, as no test reports were provided.

The MSDS for the notified polymer indicates that formaldehyde may be produced on thermal decomposition above 150°C.

Occupational Health and Safety

There is little potential for significant occupational exposure to the notified chemical in the transport and storage of the notified polymer or the textile softener containing the notified polymer. There may be exposure during the reformulation of the notified polymer and during use of the textile softener.

During reformulation and end use, the main exposure route for the notified polymer will be dermal. Exposure to drips and spills of the notified polymer and the formulated textile softener (15 % notified polymer) is possible at a number of points where these products are transferred. Once the reformulated product has been dosed into fabric treatment baths, the final concentration will be very low (maximum 0.075 %) and little exposure to the notified polymer is therefore likely.

Precautions should be taken to avoid dermal contact with the notified polymer, because of the potential for skin sensitisation. Workers who become sensitised to the notified polymer should not continue to handle it in the workplace. The notified polymer should not be used in any form in which an aerosol may be generated without the use of a high level of respiratory protection. The MSDS indicates that protective clothing, protective gloves and safety glasses should be worn while handling the notified polymer. Precautions should also be taken to avoid overheating of the notified polymer, particularly during drying of treated fabrics, to avoid formaldehyde production. The NOHSC exposure standard for formaldehyde should apply in the workplace.

Public Health

The imported notified polymer and the reformulated textile softener containing the notified polymer will not be sold to the public, and only used by industry customers. The public will come into contact with fabric products treated with a very low level of the notified polymer in the textile softener dilution. Given the low toxicity of the notified polymer, and its low

concentration and inert nature in finished textile products, the notified polymer will not pose a significant risk to public health.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
 - R43, ‘May cause sensitisation by skin contact’.

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - The notified polymer should not be applied as a spray or used in a manner which will generate aerosols in the workplace;
 - Individuals who become sensitised should not continue to handle the notified polymer.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Safety goggles, chemical resistant industrial clothing and footwear and impermeable gloves should be used while handling the product containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed respirator should also be used.

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

- 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(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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* (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

Bergeron V (1999) Toxic Inhalation Evaluations, Project No. Centre de Recherche d'Ingeniere de Technologie, Carrieres, France.

Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers Under the US Toxic Substances Control Act. In: J. D. Hamilton and R. Sutcliffe ed. Ecological Assessment of Polymers. van Nostrand Reinhold,,: 187-234.

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

CRC Press, 1977; Handbook of Chemistry and Physics, 57th edition. Boca Raton, FLA, USA.

de Jouffrey S (1995a) Acute Dermal Irritation in Rabbits: Huile Pex 21645, Project No. 12630 TAL, Centre International de Toxicologie (CIT), Evreux, France.

de Jouffrey S (1995b) Acute Dermal Toxicity in Rats: Huile Pex 21645, Project No. 12634 TAR, Centre International de Toxicologie (CIT), Evreux, France.

de Jouffrey S (1995c) Acute Eye Irritation in Rabbits: Huile Pex 21645, Project No. 12631 TAL, Centre International de Toxicologie (CIT), Evreux, France.

de Jouffrey S (1995d) Acute Oral Toxicity in Rats: Huile Pex 21645, Project No. 12629 TAR, Centre International de Toxicologie (CIT), Evreux, France.

de Jouffrey S (1995e) Skin Sensitisation Test in Guinea Pigs (Buehler Test: 3 Applications): Huile Pex 21645, Project No. 12632 TSG, Centre International de Toxicologie (CIT), Evreux, France.

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

Jackson GC (1997) Huile Pex 21.645: Acute Inhalation Toxicity in Rats 4-hour Exposure, Project No. RNP 490/961490, Huntingdon Life Sciences Ltd, Huntingdon, UK.

Lehmann RG, Varaprath S & Frye CL (1994a) Degradation of Silicone Polymers in Soil. Environ. Toxicol. Chem., 13 (7): 1061-1064.

Lehmann RG, Varaprath S & Frye CL (1994b) Fate of Silicone Degradation Products (Silanols) in Soil. Environ. Toxicol. Chem., 13 (11): 1753-1759.

Muijser H (1998) Acute (4-hour) Inhalation Study with an Aerosol of Rhodorsil Emulsion F4/49A in Rats, Project No. V98.879, TNO Nutrition and Food Research Institute, Zeist, The Netherlands.

Nabholz JV, Miller P & Zeeman M (1993) Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five. In: W. G. Landis, J. S. Hughes and M. A. Lewis ed. Environmental Toxicology and Risk Assessment, American Society for Testing and Materials. ASTM STP 1179, Philadelphia,: 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 (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

Roth F (1997) Solubility of Rhodorsil Oil 21650 in Water and n-Octanol, Project No. Beak Study 3406.1, Novamann International, Mississauga, ON, Canada.

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.