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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Cetyl Triethylmonium Dimethicone PEG-8 Succinate

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Cetyl Triethylmonium Dimethicone PEG-8 Succinate

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Johnson & Johnson Pacific Pty Limited (ABN 73 001 121 446)
Level 3, 1 Bay Street Broadway NSW 2007

NOTIFICATION CATEGORY
Limited-small volume: Polymer with NAMW ≥ 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Not applicable

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Cetyl triethylmonium dimethicone PEG-8 Succinate

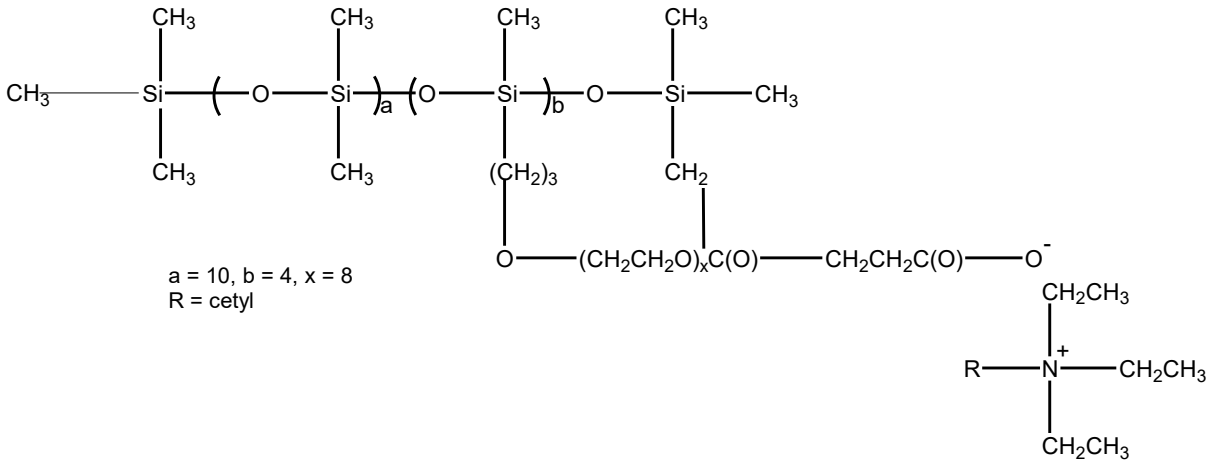
OTHER NAME(S)
Cetyl triethonium dimethicone copolyol succinate

MARKETING NAME(S)
Biosil Basics Cetylsil S

CAS NUMBER
229327-93-9

MOLECULAR FORMULA
Not provided.

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	9860
Weight Average Molecular Weight (Mw)	14500
Polydispersity Index (Mw/Mn)	1.47
% of Low MW Species < 1000	0
% of Low MW Species < 500	0

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared (IR) spectroscopy, Gel permeation chromatography (GPC) and Electrospray Mass Spectrometry (EMS)
Remarks	GPC: At MW <3000, there are salt peaks which interfere in the chromatogram and may mask the presence of low MW species. However, from the concentration work performed there appears to be no detectable MW species <3000. EMS: None of the low MW species found corresponded to monomeric species expected form the fragmentation of the polymer.
TEST FACILITY	UNSW (2002)

3. COMPOSITION

DEGREE OF PURITY
100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Succinic anhydride		
CAS No.	108-30-5	*Weight %*	<0.1
Hazardous Properties	At Concentrations equal to or more than 1%: Harmful (Xi): R36/37 - Irritating to eyes and respiratory system.		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS

Chemical Name	water		
CAS No.	7732-18-5	*Weight %*	60
Chemical Name	phenonip		
CAS No.	8066-38-4	*Weight %*	1

POLYMER CONSTITUENTS

Chemical Name	*Synonyms*	*CAS No.*	*Weight % starting*	*Weight % residual*
Siloxanes and silicones, dimethyl, hydroxy terminated, ethoxylated propoxylated	Dimethicone copolyol	64365-23-7	75	<1
1-Hexadecanaminium, N,N,N-triethyl-, chloride	Cetyltriethylammonium chloride	13287-79-1	15	<1
2,5-Furandione, dihydro-	Succinic anhydride	108-30-5	10	<0.1

DEGRADATION PRODUCTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.09	0.36*	0.36*	0.36*	0.36*

* Of the imported volume, 60 kg is to be trans-shipped to New Zealand.

USE
A hair conditioning agent (0.5% w/w) in a baby shampoo product.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

IDENTITY OF MANUFACTURER/RECIPIENTS
Johnson & Johnson Pacific Pty Limited

TRANSPORTATION AND PACKAGING
The notified polymer will be transported as a constituent of a shampoo product in plastic containers of 500 mL or less with suitable closures which are packed inside sealed cartons of corrugated cardboard.

5.2. Operation Description

The shampoo product containing 0.5% notified polymer will be imported as a finished formulation ready for distribution through grocery wholesalers and retail outlets for sale to consumers. No reformulation or repackaging will occur in Australia.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Warehouse staff	4	Expected to be short	Not stated.

Exposure Details
The notified polymer is imported in final consumer use packages. Therefore, occupational exposure to

the notified polymer will be limited to handling of the closed packages during transport, distribution and retail sale. A large number of workers in these sectors will handle the product containing the notified polymer for brief periods, with no exposure expected except in the case of an accident.

The notifier indicates that during normal shipment and handling precautions are taken to avoid accidental spillage. Warehouse staff are trained in the safe handling, transport, and storage of cosmetic products, good housekeeping practices, control of spillage and the correct use of equipment.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release is anticipated during storage, transport and distribution to customer sites, except in the event of an accident. In the event of a transport accident, the type (plastic) and size of the containers would limit any release of the chemical.

RELEASE OF CHEMICAL FROM USE

All of the notified chemical (except for residues in containers) is expected to enter the sewer during use of the shampoo when it is washed from the hair. The notifier estimates a daily release of about 1 kg from a maximum yearly imported volume of 360 kg of the chemical contained in the shampoo.

The notifier estimates that 10 mL (~0.01 kg) of the product will remain as residues in containers, amounting to about 7.2 kg per year of notified chemical being disposed of in landfill.

5.5. Disposal

Used containers are expected to be disposed of through domestic garbage disposal from where they will enter landfill or a recycling program.

5.6. Public exposure

Public exposure to the notified polymer is possible but unlikely following the rupture of the shampoo containers as a result of a transport accident.

All of the imported polymer will eventually pass to the environment, either from residues in discarded containers sent to landfill or as a component of used shampoo entering sewage. In the environment the notified polymer is expected to be highly diluted and immobile in sediment or soil. Public contact with the notified polymer as an environmental contaminant is therefore also unlikely.

The notified polymer is an ingredient of a children's shampoo product, public exposure during end use therefore will be widespread. The main route of exposure will be via dermal and ocular contact during hair washing. It is estimated that approximately 3-5 mL product, containing 0.5% notified polymer, will be used 2 – 7 times per week.

6. PHYSICAL AND CHEMICAL PROPERTIES

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

Melting Point/Boiling Point 0 °C / >100 °C

Remarks Test report not provided.

Density 1000 kg/m^3

Remarks Test report not provided.

Vapour Pressure 3.2 kPa at 25 °C

Remarks Test report not provided. The low vapour pressure is attributed to the high MW of the polymer.

Water Solubility >1000 g/L

METHOD OECD TG 105 Water Solubility.
Remarks Full test report not provided. The high solubility is due to the presence of the dimethicone copolyol.
TEST FACILITY UNSW (2002)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*% hydrolysed at 50 ºC*	*$t_{½}$ 25 ºC*
4	0.13	>1 year
7	0.11	>1 year
9	0.06	>1 year

Remarks The notified polymer is hydrolytically stable. The content of succinic acid was analysed by HPLC using an ion exchange column and a UV detector set at 210 nm. The notifier indicated that the hydrolysis of the polymer is a retrograde reaction giving the starting materials dimethicone copolyol and monosodium succinate, which are both water soluble. Hydrolysis of the demethicone copolyol occurs at the ester linkages.
TEST FACILITY UNSW (2002)

Partition Coefficient (n-octanol/water) Not determined.

Remarks The notified polymer dissociates in water and is surface active. Dimethicones are partially soluble in butanol, ethanol, heptadecanol and isopropanol, and are also soluble in kerosene and gasoline (Anonymous, 1982). However the notified polymer is a salt, based on the dimethicone copolyol, rather than dimethicone, hence it is expected to largely partition into water rather than n-octanol.

Adsorption/Desorption Not determined.

Remarks Surface active substances prefer to reside at or on the interfaces between polar and apolar media; the polar media being water, and the apolar media being sewage sludge or sediment (Kukkonen and Landrum, 1995). Consequently, the notified polymer may partition to soils, sediments, and sewage sludge.

Dissociation Constant pKa = 4.51

Remarks Test report not provided. The polymer dissociates at the carboxyl group as a function of pH.

Particle Size Not applicable.

Remarks The polymer is a 40% aqueous solution.

Flash Point >200 ºC (Pensky-Martens closed cup)

METHOD Flash Point Method ASTM D-93
Remarks Test report not provided.

Flammability Limits Non-flammable

Remarks Test report not provided.

Autoignition Temperature >300 ºC

Remarks Test report not provided.

Explosive Properties Not explosive

Remarks Test not conducted.

Reactivity Non-oxidising

Remarks The polymer is expected to be compatible with common substances.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result (concentration of notified polymer)	*Assessment Conclusion*
Skin irritation – in vitro (10%)	slightly to moderately irritating
Eye irritation – in vitro (10%)	slightly irritating
Eye irritation – human (0.05%)	slightly irritating
Skin sensitisation – human (0.005%)	no evidence of sensitisation
Phototoxicity – human (0.005%)	no evidence of phototoxicity
Photoallergy – human (0.005%)	no evidence of photoallergy

7.1. Skin irritation – in vitro

TEST SUBSTANCE	Notified polymer at 10% aqueous solution
METHOD	MTT Viability Assay
Cell Type/Cell Line	MatTek EpiDerm
Vehicle	Culture medium
Exposure Times	1, 4, 24 h
Remarks - Method	The mean percent viability of the tissues for each time point was determined using the absorbance values of MTT uptake and conversion at 540 nm, referenced to 690 nm.
RESULTS	ET50 = 10.1 h. (ET50 = the time at which the EpiDerm tissue viability was reduced by 50% compared to control)
Remarks - Results	
CONCLUSION	The notified polymer was slightly to moderately irritating to skin under the conditions and criteria of the test.
TEST FACILITY	MB Research Laboratories (2001a)

7.2. Eye irritation – in vitro

TEST SUBSTANCE	Notified polymer at 10% aqueous solution
METHOD	MTT Viability Assay
Cell Type/Cell Line	MatTek EpiOcular
Vehicle	Culture medium
Exposure Times	4, 16, 64 min
Remarks - Method	The mean percent viability of the tissues for each time point was determined using the absorbance values of MTT uptake and conversion at 540 nm, referenced to 690 nm.
RESULTS	ET50 = 24.4 min. (ET50 = the time at which the EpiOcular tissue viability was reduced by 50% compared to control)
Remarks - Results	
CONCLUSION	The notified polymer was slightly irritating to the eye under the criteria and conditions and criteria of the test.
TEST FACILITY	MB Research Laboratories (2001b)

7.3. Eye irritation – human

TEST SUBSTANCE	Johnson's Baby Shampoo Formula 109.87 at 10% dilution (0.05% w/w notified polymer)
METHOD	In-house protocol: One drop from an eye dropper
Number of Volunteers	6 females, 4 males
Vehicle	Sterile distilled water
Observation Times	30 sec, 15 min, 60 min, and >60 min
Remarks - Method	
RESULTS	At the 15-min observation, mild responses noted in treated eyes include 2 mild stinging responses (7% of max), 4 mild bulbar redness (13% of max), 3 mild palpebral redness (10% of max). These were not statistically significant difference from vehicle control. Lacrimation was not observed in both treatment and control groups.
Remarks - Results	At 60 min, one subject exhibited mild bulbar and palpebral redness in her shampoo-treated eye. After rinsing with EyeAid, this residual redness disappeared within 10 min.
CONCLUSION	Instillation of the test substance produced mild ocular stinging, at levels which did not differ significantly from sterile water.
TEST FACILITY	HRL (2000a)

7.4. Skin sensitisation – human

TEST SUBSTANCE	Johnson's Shampoo Formula 109.87 at 1% dilution (0.005% w/w notified polymer)
METHOD	Human Repeated Insult Patch Test (In-house protocol)
Number of Subjects	154 females, 52 males, age range 19-70
Vehicle	Tap water
Type of Dressing	Occlusive
INDUCTION PHASE	Nine repeat, 24-h applications (three per week) of 0.2 mL of the test substance to the same skin area of the left side of the back. Each subject was instructed to keep the patch in place and dry.
REST PERIOD	14 days
CHALLENGE PHASE	Same as the induction phase but applied to the right side of the back. Challenge sites were examined for dermal reactions 48, 72, and 96 h post-patching.
Remarks - Method	
RESULTS	Low level, transient reactions were exhibited during both induction and challenge phase.
Remarks - Results	Seven subjects missing the 96 h challenge visit reported 'no reaction at 96 hour' verbally.
CONCLUSION	The test substance did not induce dermal sensitisation in human subjects under the conditions and criteria of the test.
TEST FACILITY	HRL (2000b)

7.5. Phototoxicity – human

TEST SUBSTANCE	Johnson's Shampoo Formula 109.87 at 1% dilution (0.005% w/w notified polymer)
METHOD	In-house protocol

Number of Subjects	10 subjects, age range 36-66
Vehicle	Tap water
Type of Dressing	Occlusive
Remarks - Method	A 0.2 mL of the test substance was patched to the volar forearm starting proximal (closest to elbow) to distal (closest to wrist) for 24 h. The right forearm was the irradiated arm for the odd-numbered subjects; and the left forearm was the irradiated arm for the even-numbered subjects. Each subject was instructed to keep the patch in place and dry. Irradiation with UV-A took place approximately 24 h after patching. Non-irradiated site was either on the "opposite" arm or on the back. Patched sites were examined for dermal reactions after 48, 72, and 96 h.
RESULTS	No reactions were exhibited on either the irradiated or non-irradiated test contact sites. No reactions were observed on the irradiated control (without test substance) site.
Remarks - Results	
CONCLUSION	The test substance did not induce a dermal phototoxic response in human subjects under the conditions and criteria of the test.
TEST FACILITY	HRL (2000c)

7.6. Photoallergy test – human

TEST SUBSTANCE	Johnson's Shampoo Formula 109.87 at 1% dilution (0.005% w/w notified polymer)
METHOD	In-house protocol
Number of Subjects	22 females, 4 males, age range 23-70
Vehicle	Tap water
Type of Dressing	Occlusive
INDUCTION PHASE	Six repeat, 24-h applications (twice a week) of 0.2 mL of the test substance to the same skin area of the right volar forearm starting proximal to distal. On the same arm, an additional site served as the control (no test substance) site. The sites were irradiated with both UV-B and UV-A approximately 24 h after each patching. Non-irradiated site was on the left scapular area of the subject's back.
REST PERIOD	14 days
CHALLENGE PHASE	Same as the induction phase but irradiation was with UV-A only and the non-irradiated patch was the right side of the scapular area. Challenge sites were examined for dermal reactions 48, 72, and 96 h post-patching.
Remarks - Method	
RESULTS	During the induction phase, low level, transient reactions were exhibited on the irradiated sites (with/without test substance) and slight tanning responses were observed. No reactions were exhibited on the non-irradiated test substance contact sites. During the challenge, one subject exhibited a low level, transient reaction on the irradiated test substance contact site. No reactions were exhibited on the non-irradiated test substance contact sites and the irradiated control (no test substance) site.
Remarks - Results	For one subject, the irradiated test sites were not patched, the non-irradiated sites were patched and the data included in the results.
CONCLUSION	The test substance did not induce dermal photoallergy or dermal sensitisation in human subjects under the conditions and criteria of the test.
TEST FACILITY	HRL (2000d)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported as a component of shampoo preparations at an estimated yearly imported volume of 360 kg per year. During use of the products, all of the polymer will enter the sewer when the shampoo is washed from the hair. The products will be sold through retail outlets throughout Australia, and hence, usage and release to the sewer is expected to occur nationwide. A small amount of 7.2 kg will be released to landfill during disposal of residuals in empty containers.

The worst case scenario Predicted Environmental Concentration (PEC) of the notified polymer in the sewer is 3.7×10^{-4} µg/L per day. This value assumes all 360 kg of the polymer imported in one year is released into the sewer over a 365 day period, with no removal of the polymer by adsorption or degradation, giving an average daily release of about 0.99 kg. The PEC also assumes release occurs throughout the country, with a sewer output based on 18 million people using water at an average volume of 150 L per day per person, giving a daily sewer out put of 2700 ML.

During sewage treatment processes, some adsorption to solids and settling may occur, resulting in a further reduction in the final PEC being released into to receiving waters. In the receiving waters, it is commonly assumed that the effluent is diluted by a factor of 10 in metropolitan areas and by a factor of 3 in rural areas. This gives a final PEC in natural receiving waters of 3.7×10^{-5} µg/L and 1.3×10^{-4} µg/L per day, respectively.

9.1.2. Environment – effects assessment

No ecotoxicological studies were provided. However, published studies generally indicate that high molecular weight silicone polymers (ie polydimethylsiloxanes) are of a low order toxicity to aquatic organisms and do not significantly accumulate in fish either from aqueous or dietary exposure, mainly because the high molecular weight precludes it crossing biological membranes (Kukkonen and Landrum, 1995). Most of these studies were performed on relatively insoluble compounds, however, and it is not clear how the increased water solubility of the dimethicone copolyol will affect toxicity.

9.1.3. Environment – risk characterisation

Most of the notified polymer will be released into the aquatic environment via sewage treatment facilities when the shampoo products are washed from the hair. However, release is expected to occur in a diffuse manner owing to the low imported volumes and the nationwide use of the products. The PEC of the notified polymer in the sewer is 3.7×10^{-4} µg/L per day, and will be further reduced upon entering the receiving waters.

The notified polymer is a surface-active silicone salt. Hence in aquatic and terrestrial environments, some of the polymer may partition to soils and sediments, and in sewage treatment facilities, some may become associated with the sludge. Adsorption onto solids would further reduce the environmental concentration of the notified chemical in the aquatic environment.

The notifier has indicated that hydrolysis of the notified polymer is a retrograde reaction giving the starting materials dimethicone copolyol and monosodium succinate, which are both water soluble compounds. Hydrolysis of the dimethicone copolyol occurs at the ester linkages. Literature studies indicate that many silicone polymers (ie polydimethylsiloxanes) are hydrolysed in soils into low molecular weight water soluble compounds which are in turn mineralised by soil microorganisms to inorganic silicate (Lehmann *et al*. 1995; Sabourin *et al* 1999). These data suggest the notified polymer is expected to degrade in dry soil and sediment through biotic and abiotic processes.

Given the low imported volume and low environmental exposure, the overall environmental risk is determined to be low, and thus safety margins toward aquatic organisms are expected to be high.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified polymer will be introduced as a constituent of a ready-to-use shampoo, in consumer packages, occupational exposure would be limited to handling of spillages during an accident. The MSDS indicates collection and disposal of the spills will be in accordance with the local regulations. In addition, on the basis that only small amounts of shampoo involved and the low concentration (0.5%) of the notified polymer in the shampoo, the occupational exposure is assessed to be minimal.

9.2.2. Public health – exposure assessment

As the notified polymer is an ingredient of a shampoo product to be sold throughout Australia, public exposure is expected to be widespread. Dermal and ocular contact during hair washing is the main route of exposure. However, given the small amounts used per application, the pattern of use (ie rinsing off soon after application) and the low concentration of the polymer in the shampoo, the public exposure is determined to be low.

9.2.3. Human health - effects assessment

The notified polymer at 10% was a slight to moderate skin irritant in vitro. There was no evidence of sensitisation, photoallergy or phototoxicity in human test subjects exposed to 0.005% concentrations of the notified polymer. It is a slight eye irritant in both in vitro and human tests at 10% and 0.05% concentrations, respectively. With a high molecular weight, dermal absorption of the polymer is anticipated to be low. Therefore, the notified polymer would not pose a significant health hazard when used in the proposed manner.

9.2.4. Occupational health and safety – risk characterisation

Considering the low probability of exposure of workers to the polymer, the risk to occupational health and safety is negligible.

9.2.5. Public health – risk characterisation

Given the notified polymer will only be used in a shampoo product at a concentration of 0.5% and its high molecular weight will preclude it being absorbed systemically, the risk to public health is determined to be minimal.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the low imported volumes and the nationwide and diffuse use, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the baby shampoo product containing 0.5% notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). The notifier has also provided the MSDS for the notified polymer in a US format. The MSDS of the shampoo product is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the baby shampoo product containing 0.5% notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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.

Disposal

- The notified chemical should be disposed of in landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled in accord with the MSDS and government regulations.

12.1. 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 polymer is introduced in a form containing more than 5% of quaternary ammonium compounds, further skin and eye irritation studies for the form to be introduced will be required;
  - the importation volume has increased above 1 tonne, in which case further information on the likely aquatic toxicity will be required.

and

(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.

13. BIBLIOGRAPHY

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HRL (2000b) Repeated insult patch test (Ref no. 25805.03). Skillman, NJ, Harrison Research Laboratories, Inc (unpublished report submitted by the notifier).

HRL (2000c) Phototoxicity test (Ref no. 25805.06). Skillman, NJ, Harrison Research Laboratories, Inc (unpublished report submitted by the notifier).

HRL (2000d) Photoallergy test (Ref no. 25805.07). Skillman, NJ, Harrison Research Laboratories, Inc (unpublished report submitted by the notifier).

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