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4 March 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

E-1275

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Original Holder of Assessment Certificate (First Applicant)
An Assessment Certificate for the notified polymer known by the name E-1275 was granted to Salkat Australia Pty Ltd of 55 Halstead Street, South Hurstville NSW 2221.

The Assessment Report for E-1275 is identified by the sequence number PLC/245 (Synthetic Polymer of Low Concern Notification).

Second Applicant
Procter & Gamble Australia Pty Ltd (ABN 36 008 444 166) of 320 Victoria, Rydalmere NSW 2116 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for E-1275. Salkat Australia Pty Ltd. has agreed to this extension.

Information submitted by Procter & Gamble Australia Pty Ltd pertains to the introduction of the notified polymer for use in as an emulsifier in personal care products. Introduction volumes will be up to 40 kg per year, imported as the finished product.

2. IDENTITY OF THE CHEMICAL

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

Other names: Polyether-modified polysiloxane
Component in ABIL EM 97, ABIL Care 85 and Tego Glide 440

Marketing names: E-1275

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Yellowish liquid	
Melting point	Not determined	
Density	0.97 g/cm^3 at 25^{o}C	
Water solubility	145 mg/L	The notified polymer is dispersible in water at concentrations above its water solubility.
Particle size	Not relevant	
Flash point	80^{o}C	
Autoignition temperature	Not applicable	
Explosive properties	Not explosive	
Stability/reactivity	Not determined	Polysiloxanes are an inert group of substances.
Hydrolysis as function of pH	Not determined	There is no hydrolysis expected in the pH range of 4-9. Polysiloxanes are known to be stable in normal environmental pH range of 4-9.
Partition coefficient	Not determined	The polymer is expected to be partially soluble in n-octanol given the partial solubility of dimethicones in butanol, ethanol, heptadecanol and isopropanol. Dimethicones are soluble in kerosene and gasoline (Anon, 1982).
Adsorption/desorption	Not determined	The polymer is expected to adsorb to soils and sediments due to its surface active nature.
Dissociation constant	Not applicable	The notified polymer is non-ionic

5.1 Comments on physical and chemical properties

Siloxanes are surface-active agents, and extremely hydrophobic, with the most common linear siloxanes insoluble in water (Kukkonen and Landrum, 1995). In a pre-test to determine its water solubility, the notified substance was added to water at a quantity above its solubility. At concentrations above its water solubility, the substance was observed to

form a stable emulsion in water. As such, it was not possible to physically separate the water-soluble phase for measurement. To prevent the formation of an emulsion during the definitive test, the water-soluble fraction was prepared by adding the test substance drop by drop and then shaking vigorously. The sample was then visually checked for turbidity, which would indicate the crossing of the limit of solubility. To determine the concentrations of test substance in solution, the clear water phase of the solution was taken for analysis using the Si content to represent the amount of test substance. After 72 hours, droplets of the notified polymer were still visible in the test water. The high water solubility value given by the test suggests that the presence of the polyether groups may keep the polymer solubilised to a greater degree than would be expected for a siloxane.

6. USE, VOLUME AND FORMULATION

Use:
The notified polymer will be used as an emulsifier for cosmetic and personal care products, such as antiperspirant gels and roll-on emulsions, clear gels, hair gels, make up emulsions, body lotions and anti-ageing creams.

Manufacture/Import volume:
Approximately 2 tonnes of the product containing 85% notified polymer will be imported during the first year and increasing to 5 - 10 tonnes/year in the next four years.

Formulation details:
The notified polymer will not be manufactured in Australia, but will be imported as a concentrate in 20 L plastic or 200 L lined steel or plastic drums. The imported product will be sold to cosmetic formulators for incorporation into cosmetic and personal care products for retail distribution.

At the formulation site, quality testing of the imported bulk product is carried out prior to cosmetic formulation. During formulation, the product is weighed and transferred into an enclosed blending vessel on a batch basis. Transfer and formulation processes are partially automated and enclosed.

Finished products are kept sealed in the mixing vessel to prevent microbial contamination and transferred to an automatic filling line for packaging into containers of less than 100 mL capacity. The end use products will contain 1.3 - 2.6% notified polymer, depending on the type and application of the end-use product.

In addition, Procter & Gamble Australia Pty Ltd will import the notified polymer at up to 40 kg per year. It will be imported as a component of Olay Regenerist moisturisers, cream and serum, at concentrations of 0.3% and 0.45% respectively.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier

Formulation

Chemical testing of imported product prior to blending (0.5 hours/day, 12 days/year)

Dermal	Possible skin contamination when testing small samples	• Laboratory testing performed in a fume hood • Personal protective equipment (PPE) – Protective clothing, safety glasses and impervious gloves

Weighing and transferring of notified polymer into blending vessel and mixing to form the end use product (2 hours/day, 24 days/year)

Dermal and limited ocular	Dermal and limited ocular exposure to spills and splashes when weighing and transferring to mixing vessel and cleaning of equipment (including mixing vessel)	• Enclosed and automated transfer and mixing processes • Enclosed blending vessel • PPE – Protective clothing, safety boots, impervious gloves and safety glasses

Filling and packing of end use products (0.5 hours/day; 24 days/year)

Dermal	Dermal exposure to spills when connecting and disconnecting mixing vessel to filling lines and cleaning of equipment	• Process largely enclosed and automated • General ventilation employed • PPE – as above

Transport and storage

Transport and storage of imported product containing the notified polymer (0.5 hours/day; 12 days/year)

Dermal	Possible skin contamination if accidental spillage occurs	• PPE – as above

Procter and Gamble will be importing the notified chemical as a component in finished goods only at a concentration of 0.3% and 0.45%. No exposure to the notified chemical is expected during transport and storage except in the event of an accident where the packaging may be breached.

8. PUBLIC EXPOSURE

Personal care products containing the notified polymer at 0.3%-2.6% will be sold to the public. The end use products are topically applied to the skin or hair, and the main route of exposure will be dermal, with the possibility of accidental ocular and oral exposure. Exposure during the use of moisturising products is expected to be confined to the dermal route although inadvertent exposure via the ocular and oral route may occasionally occur. Typical daily use for these products are 0.5 g/day for antiperspirant, 0.8 g/day for face creams, 5 g/day for hair styling products and 7.5 g/day for body lotions. This is equivalent to 2.5 – 195 mg/day of notified polymer for using a single product.

Public exposure may occur during transport accident.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Cosmetic and personal care product are applied directly to the body, as hence, the majority of the notified polymer will enter the environment mainly through sewage systems when the products are washed off the body during bathing.

A small amount of the notified polymer may enter the environment directly during manufacturing when the vessels are steam cleaned after use. The notifier provided an example of such release from one potential customer site. At this site, it is anticipated that, 2000 kg of the new chemical will be used during the manufacturing process. Of this volume approximately 400 g of the bulk manufactured product may be released in a diluted form to the effluent treatment plant as a result of vessel cleaning. Following treatment at their effluent treatment facilities, the effluent water is released to the Southeast Melbourne Waste Water Treatment Plant.

Direct release of the notified polymer to the environment could also occur in cases of accidental spills during formulation of the products. However, release via this route will be minimised by the use of chemical spill kits comprising containment barriers, drain covers, booms, pillows, pads and particulate, which are used to contain the spills. Disposal of spills is contracted to an EPA registered authority for incineration.

Some polymer may enter the environment directly as residues after the containers are emptied and disposed of through normal household garbage. The notifier estimates about 3% or up to 300 kg per year could remain as residues in containers. It is expected that these residues will be disposed of with the containers in landfill.

9.2. Fate

The majority of the notified polymer in the cosmetic and personal care products will enter the environment through sewage treatment systems when the products are washed off the body during bathing. The products will be sold through supermarket outlets throughout Australia, and hence, usage and release to the sewer is expected to occur nationwide.

Siloxanes are surface-active agents, and 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). Hence in aquatic and terrestrial environments, the polymer is expected to partition mainly to soils and sediments, whereas in sewage treatment facilities, it is expected to become associated with the sludge.

No degradation studies were provided in the notification dossier. However, dimethicone is not broken down by sewage microorganisms (Anon, 1982). Residues that persist after sewage treatment, either sorbed onto particles or associated with the aquatic compartment, are expected to enter marine and freshwater environments in effluent released from city and country wastewater treatment systems. The concentrations of the notified polymer in the water compartment are expected to be very low, however, because of the high adsorption potential and the significant dilution rates once released into the receiving waters.

Most of the notified polymer is expected to enter the soil environments indirectly through disposal of sludge from wastewater treatment plants or directly through leakages of residues from containers. In soil environments, the polymer is expected to eventually degrade through abiotic and biotic processes. Studies have shown that silicone polymers such as polydimethylsiloxane are hydrolysed in soils to low molecular weight water soluble products such as dimethylsilanediol which are in turn mineralised by microorganims to inorganic silicate (Lehmann *et al*. 1995; Sabourin *et al* 1999).

The notified chemical is not expected to cross biological membranes due to its high molecular weight and as such it should not bioaccumulate (Connell, 1989).

10. EVALUATION OF HEALTH EFFECTS DATA

The notifier submitted reports of a limited number of toxicological tests, which are summarised below. Toxicological tests were carried out on the imported product containing 85% notified polymer, ABIL EM 96:

10.1.1 Acute Dermal Toxicity

TEST SUBSTANCE	ABIL EM 96
METHOD	OECD 402 Acute Dermal Toxicity – Limit Test and EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	none
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviation
RESULTS	
LD50	>2000 mg/kg bw
Effects in Organs	None
Remarks - Results	No mortality and abnormal clinical signs were observed. Slight erythema observed in 4/10 animals up to 6 days.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Medcon Kontraktlabor GmbH

10.1.2 Eye Irritation

TEST SUBSTANCE	ABIL EM 96
METHOD	OECD 405 Acute Eye Irritation/Corrosion and EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (unspecified sex)
Observation Period	72 hours
Remarks - Method	One animal was used as a pilot study and subsequently, the 2 animals were treated on the same manner.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	1	1	1	2	48 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results: Slight swelling of the conjunctiva, which was associated with slight ocular secretion, was seen in one animal at 1 hour observation period.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Medcon Kontraktlabor GmbH

10.2 Toxicology of Dimethicone Polyols

The notifier also provided a Cosmetic Ingredient Review (CIR) on dimethicone copolyol group of compounds (Journal of the American College of Toxicology, 1982). Dimethicone copolyol, which belongs to a class of synthetic chemicals referred to as silicones, is structurally related to the notified polymer and has been widely used in cosmetic formulations (concentrations ranging from <0.1% to 10%). Silicone compounds do not easily cross biological membranes, are not absorbed through the skin and gut, and are not extensively deposited in body tissues.

Dimethicone copolyols had low acute oral toxicity (lowest LD_{50} 12 g/kg in rats) and acute dermal toxicity (lowest LD_{50} > 17 g/kg in rats or > 2 g/kg in rabbits). It showed slight irritation to rabbit skin and eyes. No evidence of skin irritation or sensitisation effects was seen in human subjects treated with dimethicone copolyol. Acute inhalation toxicity was evident in one chemical (Dimethicone copolyol A 7500), which caused death of 2/6 rats at 2347 mg/m^3 for 4h and higher mortality at longer exposure time (8 hours, but no concentration shown).

No death or overt toxicity was observed in a repeat oral study (89 days) in rats at up to approximately 3 g/kg bw/day. In a repeat dermal study (28 days) in rabbits at 200 mg/kg bw/day, a depression in spermatogenesis was noted in 1/10 animals. Slight to moderate skin irritation at the application sites were observed during this study. Based on the above toxicity endpoints, dimethicone copolyol was concluded by the Review Panel to be a safe cosmetic ingredient in the present practices of use and concentration.

10.3 Overall Assessment of Toxicological Data

ABIL EM 96 which contains 85% notified polymer was of low acute dermal toxicity in rats (LD50 > 2000 mg/kg bw). It caused slight eye irritation in rabbits.

The toxicity of dimethicone copolyols, which are of similar structure to the notified polymer was reviewed by the CIR Panel. Dimethicone copolyol was found to be of low acute toxicity, and slight skin and eye irritant. No evidence of skin sensitisation was found and no significant findings were observed from a 89-day feeding study in rats or a 28-day dermal study in rabbits.

By analogy, the notified polymer is not expected to differ substantially from that of dimethicone copolyol. On the basis of the data supplied, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSSESSMENT

Due to the anticipated nationwide use of the product, release to the sewage system is expected to be continuous and occur in small pulses throughout the year, with most releases likely to occur in large metropolitan areas. As a worst-case scenario, the Predicted Environmental Concentration (PEC) of the notified chemical is 10 μg/L per year. In determining the PEC value, the following assumptions were made:

- All of the 10000 kg of chemical imported in one year is released into the sewer over a 365 day period, with no removal of the chemical by adsorption or degradation, giving a daily release of about 2.74 kg.

- Release occurs throughout the whole 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.

No biodegradation and adsorption to solids at sewage treatment plants has been assumed when calculating the PEC. While biodegradation of the notified polymer is not expected, some adsorption to solids is expected to occur, resulting in a significant reduction in the final PEC. Upon release to receiving waters after treatment at the sewage treatment plant the effluent will be further diluted. It is commonly assumed that the effluent is diluted by a factor of 10. This gives a final PEC in receiving waters of the notified chemical of 1 μg/L.

No toxicity data was provided in the notification dossier. Published studies generally indicate that polydimethylsiloxane is of low order of toxicity to aquatic organisms and does not significantly accumulate in fish either from aqueous or dietary exposure. The absence of toxicity and bioaccumulation is attributed to the inability of the substance to cross biological membrane due to its molecular size (Kukkonen and Landrum, 1995). As such the safety margins toward aquatic organisms are expected to be high.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

A limited number of toxicological tests carried out on the imported product containing 85% notified polymer showed low acute dermal toxicity and slight eye irritation effects. A Cosmetic Ingredient Review on dimethicone copolyols (Journal of the American College of Toxicology, 1982), which are structurally similar to the notified polymer, was also provided. Dimethicone copolyols have low acute toxicity, slight eye and skin irritation effects but no skin sensitisation effect. No death or overt toxicity was observed in a repeat oral study (89 days) and repeat dermal study (28 days). Slight to moderate skin irritation at the application sites were observed during the repeat dermal study.

The polymer meets the PLC criteria, has high molecular weight and is not expected to cross biological membranes. Based on the information provided, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

13.2. Occupational health and safety

The imported product containing 85% notified polymer will be formulated into cosmetic and personal care products. The formulation process is largely enclosed. Filling and packing of end-use products into <100 mL capacity containers also involves enclosed and automated processes. The most likely points at which exposure may occur are during weighing and transfer to the mixing vessel. Incidental exposure to the end use formulation may occur during transfer to the filling lines, and when cleaning equipment through skin and limited eye contact to spills and splashes. Local exhaust ventilation is employed in the formulation area and general ventilation in the packaging area. The end-use product contains 1.3 – 2.6% notified polymer.

QC testing provides the possibility of dermal exposure to small quantities of the notified polymer. Laboratory testing is performed in a fume hood.

The engineering controls in place and the low toxicity of the notified polymer render the health risk from the notified polymer for the plant operators and laboratory personnel as low. Possible skin and eye irritant effects will be further minimised by the wearing of PPE, including overall, safety boots, impervious gloves and safety glasses/goggles during the above activities.

Exposure of transport and storage workers is only possible in the event of accidental spillage. The health risk for transport and storage workers handling the notified polymer is expected to be negligible.

Conclusion
The notified polymer is of low hazard to human health and safety. The control measures in place during formulation, and protective measures during quality control, transfer and filling operations will ensure sufficient protection against exposure to the notified polymer. Therefore, the notified polymer is of low concern to human health and safety and no specific reduction measures are necessary.

13.3. Public health

The imported products containing a high level of the notified polymer will be used by industrial customers, and not be available to the general public. The public will be exposed to the notified polymer once it becomes a component in cosmetic formulations. Given that the notified polymer is of low toxicity, and presents at low concentrations in end-use cosmetic products and used in relatively small amounts, it is unlikely to cause significant public health concerns.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the 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). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the 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.

15. RECOMMENDATIONS

Control Measures

Occupational Health and Safety
No specific precautions are required to control exposure to the notified polymer. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed and automated formulation processes
  - Exhaust ventilation during transfer and filling processes

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - During transfer operations and cleaning of equipment, avoid spills and splashing

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Chemical resistant gloves
  - Protective clothing which protects the body, arms and legs
  - Eye protection

  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.

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 Subsection 64(1) of the Act; if
  - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Subsection 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.

16. REFERENCES

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