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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Silicone Quaternium-8

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Lever Rexona of 219 North Rocks Road, North Rocks, NSW 2151 has submitted a limited notification statement in support of their application for an assessment certificate for Silicone Quaternium-8.

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 and the Summary Report.

Marketing Name:	Silicone Quaternium-8. Lambent Quat AD (30-60% aqueous solution of Silicone Quaternium-8).

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data are for the Lambent Quat AD product, unless otherwise stated.

Appearance at 20°C and 101.3 kPa:	Clear light brown liquid
Boiling Point:	> 100 °C (water)
Specific Gravity:	1.05 g/cm^3
Vapour Pressure:	2.4 kPa at 25°C (water)
Water Solubility:	Soluble to between 30-60 %
Partition Co-efficient (n-octanol/water):	Not determined. The polymer is expected to be surface active given its polar and non polar regions.
Hydrolysis as a Function of pH:	Not determined. Contains ester and amide groups that may undergo hydrolysis under extreme environmental conditions.
Adsorption/Desorption:	Not determined. Expected to be immobile in soil as a result of its high molecular weight and charged nature.
Dissociation Constant:	Not determined. Contains a quaternary ammonium

	group that will be fully dissociated in an aqueous environment.
Flash Point:	Not flammable. Imported in an aqueous solution.
Flammability Limits:	Not flammable.
Autoignition Temperature:	Does not undergo auto-ignition.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable and not reactive

Comments on Physico-Chemical Properties

The polymer is never isolated as a defined entity and the data provided was for Lambent Quat AD, as a 30-60% solution of the polymer in water. The vapour pressure of the polymer salt would be expected to be very low.

The notifier states the water solubility of the notified polymer is between 30-60% by weight, which is the amount contained in Lambent Quat AD. Even though the notified polymer has a large component of hydrophobic siloxane, it also contains polyethylene oxide and amino functional cationic groups as well as a carboxylic acid group, which would have some affinity for water.

The notifier did not determine the stability of the notified polymer in water. The polymer contains ester and amide linkages that could be expected to undergo hydrolysis under extreme pH conditions. This is unlikely in the environmental pH range of between 4 and 9 even though the notified polymer is soluble in water.

The notifier did not determine the partition coefficient and adsorption/desorption of the notified polymer. The notified polymer is soluble in water and will largely partition into water rather than *n*-octanol. The polymer is expected to be mobile due to its high water solubility and is, therefore, not expected to become associated with the organic component of soils and sediments. However, due to the large component of hydrophobic siloxane and fatty acid moieties in the polymer, it is likely that it would have some affinity for either the organic component of soils, sediments or activated sludge in sewage treatment plants. Furthermore, quaternary nitrogen groups also have some affinity for the organic component of soils and sediments (Nabholz et al., 1993).

The notifier did not determine the dissociation constant of the notified polymer. The notified polymer contains a quaternary ammonium group that is expected to be fully dissociated in an aqueous environment. The remaining carboxylic acid group would be expected to have typical acidity.

4. PURITY OF THE CHEMICAL

The degree of purity and maximum content of residual monomers and additives/adjuvants have been exempted from publication in the Full Public Report and the Summary Report.

Hazardous Impurities: None known

Non-hazardous Impurities (> 1% by weight): None known

5. USE, VOLUME AND FORMULATION

The notified chemical, Silicone Quaternium-8, is a skin conditioning agent and will be used as an ingredient in the facial skin cleanser product, Pond's Clear Solutions Deep Pore Foaming Cleanser.

The skin cleanser product, Pond's Clear Solutions Deep Pore Foaming Cleanser will be imported in a ready-to-use air foam pump form in 177 mL plastic bottles (12/carton). The product will be transported by for relabelling and repackaging, where a sticker label containing Australian contact details will be applied and the product repackaged into cartons of 36. The relabeled and repackaged product will then be transported back Lever Rexona for storage prior to being distributed by road to supermarkets Australia wide for sale to the general public.

The notified chemical will not be manufactured in Australia. The expected import volume will be 400 kg/annum for 5 years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The product, Pond's Clear Solutions Deep Pore Foaming Cleanser, containing the notified chemical will be imported in 177 mL plastic bottles packed in cartons (12 per carton). The product will be transported from the dockside to the Lever Rexona prior to being sent for labeling and repacking. The notifier estimates that 4-6 waterside transport workers and 2-3 warehouse workers will be involved in its transportation and warehousing. The total time for handling the substance has been estimated to be 1-2 hours per day on 2-4 days per year. It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of an accident.

Labeling and Repacking
The imported product will be unpacked at the repackaging site. Workers will stick an overlabel to the product containers giving Australian contact details for Lever Rexona. The product will then be repacked into cartons (36 per carton) and then transported back to the Lever Rexona warehouse for storage prior to distribution to supermarkets. The notifier estimates that 4-5 workers will be involved in the labeling and repacking of the imported product. The total time for handling the substance has been estimated to be 2-4 hours per day on 5-10 days per year. It is anticipated that labeling and repacking workers would only be exposed to the notified chemical in the event of an accident.

Supermarket

Supermarket personnel will unload the facial cleanser product containers from the cardboard boxes and stack them on the shelves. The notifier estimates that approximately 1000 workers will be involved in the unloading and stacking of the imported product. The total time for handling the substance has been estimated to be 1-2 hours per day on 100-150 days per year. It is anticipated that they would only be exposed to the notified chemical in the event of an accident.

Prevention of worker exposure
As the facial cleaner product will be imported in a ready-to-use form for sale to the general public, no safety precautions, other than those listed on the product label, have been recommended by the notifier.

Education and training
No special education or training is proposed.

7. PUBLIC EXPOSURE

Public exposure to the notified chemical is expected to be widespread and repeated, as the facial cleanser containing the notified chemical will be sold to the public and be applied daily directly to the skin. The most likely route of exposure will be dermal, but ocular exposure will also be possible. According to the notifier, consumers will be exposed to 2 mL of the facial cleaner twice a day. Daily use of the facial cleaner would result in an exposure to the notified chemical of less than 40 mg/person/day. It is anticipated that all of the notified chemical will be washed off during each use.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The new polymer will comprise less than 5% of the cosmetic product, and the notifier has indicated that 400 kg of the new polymer will be imported per year. This equates to the distribution and sale through supermarket outlets throughout Australia of approximately 300000 (177 mL) bottles of facial cleanser. The notifier indicated that the majority, equivalent to 397 kg of the notified polymer contained in the product, would be released directly to the sewage system when washed off the skin each year.

Some residue will remain in the 'empty' bottles after application. The notifier estimates that 0.56% of the bottle contents containing up to 5 kg per annum of the notified polymer, will remain as residue in the containers.

Release of the notified polymer to the environment would occur in cases of accidental spills. However, this would be minimised since the facial cleanser product is contained in small bottles of 177 mL volume. The MSDS and material handling instructions provide directions for the proper containment, collection and disposal of wastes in accordance with local regulations and disposal would be to landfill.

8.2 Fate

Almost all of the skin cleanser product would be released to the sewage system when washed off the skin each year. Assuming that approximately 2 mL of the product may be applied twice daily by a typical consumer, and that a person uses 60 L of water per day, the expected concentration of the notified chemical released to sewer for each daily use of the chemical would be less than 1 ppm.

Most of the polymer is expected to become associated with the water compartment due to its high water solubility. However, at least some adsorption may occur due to the large component of hydrophobic moieties in the polymer as well as quaternary nitrogen groups which all have at least some affinity for the organic component of soils and sediments.

Residues that persist after sewage treatment will enter marine and freshwater environments in solution from city and country wastewater treatment systems. The concentrations are expected to be very low because of the very high dilution rates in the release processes.

The notifier has indicated that a small amount, up to 5 kg per annum of the notified polymer, would be released to landfill with residuals in empty.

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

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicology data has been submitted in support of the notified chemical. The supplied MSDS provides very brief hazard information on Lambent Quat AD, which contains the notified chemical in water. Lambent Quat AD is Scheduled Poison S6 based on the concentration of the notified chemical (a quaternary ammonium salt). Mild irritation of the gastrointestinal tract may occur following ingestion. It may cause moderate irritation to the eyes. Repeated or prolonged exposure to the skin may cause mild irritation.

Given the absence of toxicological data and that Silicone Quaternium-8 is a quaternary ammonium compound, the notified chemical is classified as hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999), with the risk phrase 'R36 – Irritating to eyes' assigned.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were available.

It is known that many silicone-based backbone polymers with quaternary amine groups have LC_{50}/EC_{50} ecotoxicity values towards fish and *Daphnia magna* of approximately 1 mg/L (Nabholz and Boethling, 1997).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Due to the anticipated nationwide use of the product and the low levels of release the final Predicted Environmental Concentration (PEC) of the notified polymer maybe estimated over the entire population of Australia of approximately 18 M people. If we assume that 150 L of

sewerage are generated each day by each person, then the total volume of sewerage generated in one year would be 9.86×10^{11} L. If all of the 400 kg of the notified chemical are liberated to sewer then a mean concentration in sewerage would be 0.4 μg/L. On release to receiving waters after treatment at the sewage treatment plant, it is usually assumed that the effluent is diluted by a factor of 10. This gives a final PEC in receiving waters of the notified chemical of 0.04 μg/L. The PEC is several orders of magnitude higher than the lower than expected toxicity levels (see section 10).

The potential environmental concentration calculated above is a conservative estimate. No biodegradation and adsorption to solids at sewage treatment plants, for example, has been assumed. Biodegradation of the notified polymer is not expected, however, some adsorption to solids may occur and if this is taken into account then safety margins towards aquatic organisms are expected to be even higher.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The MSDS is adequate to limit the environmental exposure and, therefore, limit the environmental effects.

Given the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
No toxicology data has been submitted in support of the notified chemical.

Based on information on the MSDS and known data for quaternary ammonium salts, the notified chemical is classified as hazardous according to NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999), with the risk phrase R36 – Irritating to eyes.

Due to the listing of quaternary ammonium compounds on the Drugs and Poisons Schedule (SUSDP) in Australia, Lambent Quat AD is a Schedule 6 poison (Australian Health Ministers' Advisory Council, 1999).

Occupational Health and Safety
Occupational exposure to the notified polymer during transport, storage, relabelling, repackaging and stacking of supermarket shelves with the ready-to-use product Pond's Clear Solutions Deep Pore Foaming Cleanser, should not occur except in the event of accidental spillage.

Given the low concentration of the notified polymer in Pond's Clear Solutions Deep Pore Foaming Cleanser and that it is imported as a ready-to-use product, the risks to human health through occupational exposure to the notified polymer are considered as low.

Public Health
Based on the expected low level and transient exposure, it is considered that Silicone

Quaternium-8 will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Silicone Quaternium-8, the following guidelines and precautions should be observed:

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical;
  -eye protection

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

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- If products and mixtures containing the notified chemical 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;

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* ([NOHSC, 1994 #48]).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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 import or manufacture volume exceeds one tonne per year.

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

16. REFERENCES

Australian Health Ministers' Advisory Council (1999) Standard for the uniform scheduling of drugs and poisons No. 14. Canberra, ACT, Commonwealth Department of Health and Family Services.

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW, ed. Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA, pp 56-57.

Nabholz JV, Miller P & Zeeman M (1993) Environmental risk assessment of new chemicals under the toxic substances control act (TSCA) section five, In: Landis WG, Hughes JS, & Lewis MA, eds. Environmental Toxicology and Risk Assessment, American Society for Testing and Materials, ASTM STP 1179. Philadelphia, pp 40-55.

Nabholz JV & Boethling RS (1997) Environmental assessment of polymers under the US toxic substances control act, In: Hamilton JD & Sutcliffe R, eds. Ecological Assessment of Polymers, Van Nostrand Reinhold, pp 187-234.

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

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.