File No: NA/470

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SF1642

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

SF1642

1. APPLICANT

Lever Rexona of 219 North Rocks Road has submitted a limited notification statement in support of their application for an assessment certificate for SF1642.

2. IDENTITY OF THE CHEMICAL

SF1642 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore 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.

Other Name: SF1642

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	solid grey, tan or white, opaque pastilles with a waxy texture
Melting Point:	60°C
Density:	880 kg/m^3
Vapour Pressure:	not determined
Water Solubility:	not determined
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined

Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	> 100°C
Flammability Limits:	not flammable
Autoignition Temperature:	not determined; the notified chemical is inert
Explosive Properties:	not explosive
Reactivity/Stability:	stable under room conditions
Particle Size:	the notified chemical is a solid wax material which is formed into approximately 5 mm pastilles

Comments on Physico-Chemical Properties

The vapour pressure of the notified polymer is expected to be low given its relatively large molecular weight.

Data such as solubility and partition coefficient are not particularly relevant to surface active compounds, which prefer to reside at or on the interface between polar and apolar media, rather than partitioning between them. Polydimethylsiloxanes are generally extremely hydrophobic. The long aliphatic substituents on the polydimethylsiloxane backbone of the notified polymer would increase this hydrophobicity.

The notifier claims that the notified polymer is insoluble based on the known solubility of analogous compounds. This is supported by the literature (1).

The extent to which hydrolysis would occur in the environment is unclear, given that silicones adsorb strongly to surfaces.

The notified chemical contains no dissociable hydrogens or basic functionalities.

4. USE, VOLUME AND FORMULATION

The polymer will be used as a component of an antiperspirant deodorant product.

The notified chemical will not be manufactured in Australia, but will be imported at a rate of 3.4 tonnes per annum for the next 5 years. The notified chemical will be imported as a 6% component of an antiperspirant deodorant finished product.

5. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in ready-to-use 50 mL containers, packed in cartons. The cartons will be transported from the dockside to a warehouse, where they will be stored prior to distribution to retail customers. Occupational exposure to waterside workers, transport drivers and warehouse workers is anticipated only in the event of an accident.

The chemical has been used overseas and no adverse effects following human exposure to the chemical have been reported.

6. PUBLIC EXPOSURE

The potential for public exposure to the notified polymer is considered to be high given that the primary route of exposure will be by dermal contact.

7. ENVIRONMENTAL EXPOSURE

Release

The use of the product containing the polymer would be widespread but diffuse as it is applied in small quantities to the skin. Removal of the deodorant product through washing will result in its release to the sewer. This would result in the release approx 3 400 kg of SF1642 to effluent Australia wide (Assuming 1% remains in containers) through washing and 34 kg to landfill in used containers.

Fate

The environmental properties of polydimethylsiloxane fluids have been well reviewed by Hamelink (2).

Silicone fluids are very surface active because the flexible siloxane linkages permit alignment of the hydrophobic methyl substituents towards the non-polar phase, and of the polysiloxane backbone towards the polar phase.

The polar medium is generally water, and apolar media to which polydimethylsiloxanes become attached may be textiles, sewage sludge, algae, sediment etc. In aqueous environments, strong, complete and permanent adsorption of high molecular weight silicone fluids to sediment may be assumed. Hence, this modified silicone will be removed from solution by adsorption onto sludge with little, if any, likely to be contained in treated waste waters. Sludge containing the notified substance may then be incinerated or landfilled. Incineration would destroy the substance and liberate water and oxides of carbon and silicon, while disposal to landfill would immobilise it.

Polydimethylsiloxanes are thought to be unstable in terrestrial environments where clays can catalyse cleavage of the siloxane linkage. They are probably more permanent in aquatic sediment as the catalytic action of clays is inversely related to

their degree of hydration (2).

8. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data are not required for polymers with a number-average molecular weight (NAMW) greater than 1 000, although the data summarised below were submitted

8.1 Acute Toxicity

Summary of the acute toxicity of

Test	*Species*	*Outcome*	*Reference*
skin irritation	rabbit	non-irritant	(3)

8.1.1 Skin Irritation (3)

Species/strain:	adult New Zealand White albino rabbits
Number/sex of animals:	3/sex
Observation period:	24, 48 and 72 hours
Method of administration:	a gauze patch bearing 0.5g of the test article was applied to the right shaved flank of each animal for four hours. A control gauze patch was applied to the contralateral flank.
Test method:	OECD guidelines for testing of chemicals (4)
Result:	non-irritant to rabbit skin

8.2 Overall Assessment of Toxicological Data

The notified polymer is a non-irritant to rabbit skin.

On the basis of toxicological data provided for the notified polymer it would not be classified as hazardous according to *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (5) based on the skin irritation study in rabbits skin.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW greater than 1 000 according to the Act. The high molecular weight of the substance suggests that it will not cross biological membranes, and will therefore be of low toxicity and not bioaccumulate. It is well accepted that polydimethylsiloxane fluids become permanently adsorbed to sediment and should not exert adverse environmental effects. Physical effects such as surface entrapment has been observed when testing aquatic invertebrates in clean laboratory water. Similar effects are not expected in natural environments where a large variety of other surfaces provide opportunities for deposition (2).

10. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer is a minor component of an antiperspirant deodorant and as such will be released to the environment in small amounts through washing. As a worst case, an environmental concentration of 3.4 ppb is predicted if all the imported polymer remains suspended in sewage waters (assuming: 3 400 kg are discharged annually to the sewer, by an Australian population of 18 million with a daily per capita waste water discharge of 150 L). However, most is expected to adsorb to sewerage sludge which will be landfilled or incinerated. In landfill, the substance is not expected to be mobile or degrade due to its low water solubility. Little exposure to natural waterways and low aquatic toxicity is also expected. Hence, the overall environmental hazard of the chemical can be rated as low.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will not be manufactured in Australia. Occupational exposure to the notified polymer can occur during transport and warehousing although this will only occur during accidental release.

The risk of adverse occupational health effects resulting from transport, storage, use and disposal of SF1642 is expected to be low given the low hazard and likely low exposure.

The potential for public exposure to the notified polymer in the form of the antiperspirant deodorant product is considered to be high. On the basis of a concentration of the notified polymer in the antiperspirant deodorant product of 6% and an application rate of approximately 1 mL per use per day, the notifier estimates a release of approximately 0.05 g of the notified polymer per use per day. The notified polymer is likely to be insoluble in water, and is removed from the body surface through washing.

In the case of accidental spillage during transport, public may be exposed to the notified polymer. Compared to the skin exposure from using the antiperspirant deodorant product containing the notified polymer, public exposure resulting from transport and disposal is expected to be negligible.

12. RECOMMENDATIONS

To minimise occupational exposure to SF 1642 the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (6).

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.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

15. REFERENCES

1. Varaprath S, Freye C L and Hamelink J., "Aqueous Solubility of Permethylsiloxanes (Silicones)". *Enviromental Toxicology and Chemistry*, Vol 15 No 8, 1263-1265, 1996.

2. Hamelink J L., Silicones. "In: N T de Oude (ed)", *The Handbook of Environmental Chemistry, Volume 3 Part F, Anthropogenic Compounds:* Detergents. Springer-Verlag, pp 383-394, 1992.

3. Fitzgerald G.B., 1995, *Primary skin irritation study with SF 1642 in rabbits*. Study No: 95G-1593, project on file, Toxikon Corporation, Bedford, MA, USA.

4. Organisation for Economic Co-operation and Development, OECD *Guidelines for Testing of Chemicals*, OECD, Paris, France.

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

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

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
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 for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
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

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
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

Values	*Rating*
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