File No: LTD/1637

January 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]- (INCI Name: Methyl Trimethicone)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1637	Chanel (Australia) Pty Ltd	Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]- (INCI Name: Methyl Trimethicone)	ND*	≤ 1 tonne per annum	Component of cosmetic products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Flammable Liquids (category 4)	H227 - Combustible liquid

Based on the available data the notified chemical is not recommended for classification according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, provided that formulation control measures are being adhered to, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used at ≤34% concentration in cosmetics, excluding body lotions and aerosols, and at ≤20% concentration in lip products, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assessed use pattern, limited exposure to the aquatic compartment and absence of predicted toxic effects to aquatic organisms up to its limit of water solubility, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP.

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible
  - Ventilation system including local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure while handling the notified chemical during reformulation processes:
  - Avoid contact with skin and eyes
  - Avoid inhalation

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation processes:
  - Coveralls, impervious gloves, goggles
  - Respiratory protection, if ventilation is inadequate

- Guidance in the selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards. .A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - The notified chemical should only be used at ≤ 34% concentration in cosmetics, excluding body lotions and aerosols, and at ≤ 20% in lip products.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 importation volume exceeds one tonne per annum notified chemical;
  - information associated with the reproductive toxicity, and/or carcinogenicity of the notified chemical becomes available;
  - the chemical is intended for use in body lotions;
  - the chemical is intended to use in aerosol spray cosmetics;
  - the concentration of the notified chemical exceeds or is intended to exceed 34% concentration in cosmetics (excluding body lotions and aerosols), and 20% in lip products.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a component of cosmetic products, or is likely to change significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified chemical and a product containing the notified chemical were provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chanel (Australia) Pty Ltd (ABN: 83 000 012 153)
Level 12, 121 Walker street,
NORTH SYDNEY NSW 2060

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: other names, spectral data, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints except for water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Methyl Trimethicone (INCI name)

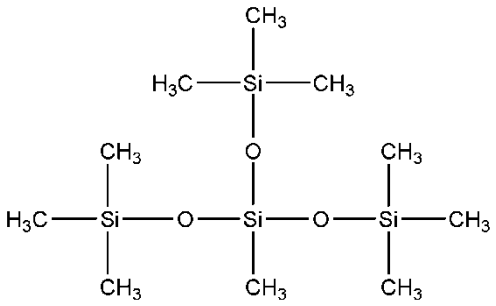
CAS NUMBER
17928-28-8

CHEMICAL NAME
Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]-

OTHER NAME(S)
Methyltris(trimethylsiloxy)silane
1,1,1,3,5,5,5-Heptamethyl-3-(trimethylsiloxy)trisiloxane

MOLECULAR FORMULA
$C_{10}H_{30}O_3Si_4$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
310 Da

ANALYTICAL DATA
Reference IR and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-83 °C	(M)SDS
Boiling Point	191°C at 101.3 kPa	(M)SDS
Density	850 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	1.02 kPa at 25 °C	Calculated
Water Solubility	≤ 3.64x10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical has low water solubility.
Partition Coefficient (n-octanol/water)	log Pow = 8.16	Estimated. A high log K_{OW} is predicted (KOWWIN v1.68, US EPA, 2012) which is consistent with the hydrophobic structure of the notified chemical and its low water solubility.
Adsorption/Desorption	Log K_{OC} = 4.31	Estimated. A high log K_{OC} is predicted (KOCWIN v2.00, MCI method, US EPA, 2012) indicating strong partitioning from water to soil.
Dissociation Constant	Not determined	The notified chemical is only slightly soluble in water and lacks readily dissociable groups.
Flash Point	61°C at 101 kPa (closed cup)	(M)SDS.
Flammability	Not determined	Based on the flash point not classified as flammable
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Flammable Liquids (Category 4)	H227 - Combustible liquid

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of finished cosmetic products at up to 34% concentration. The notified chemical may at some point in the future be imported in neat form (> 99% purity).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 1	≤ 1	≤ 1	≤ 1	≤ 1

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The finished cosmetic products containing the notified chemical (at ≤34% concentration) will be imported by sea in containers suitable for retail sale (typically ≤ 500 mL). These will be packed in pallets and distributed within Australia by road.

USE
The notified chemical will be used at ≤34% concentration in a range of cosmetics, including facial cleansers, shampoos, conditioners, shower gels, makeup removers and lip products.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of finished cosmetic products at up to 34% concentration. The notified chemical may at some point in the future be imported in neat form (i.e. at > 99% purity) for formulation of cosmetic products within Australia.

Formulation of cosmetic products
If imported in neat form (i.e. at > 99% purity), at the formulation site the notified chemical will be weighed and added to the mixing tank. Mixing will be highly automated and occur in a fully enclosed environment, followed by automated filling of the finished cosmetic products into containers of various sizes. During the formulation process, samples of the notified chemical and the finished cosmetic products will be taken for quality control testing.

End-use
The finished cosmetic products containing the notified chemical at up to 34% concentration will be used by consumers and professionals (such as workers in beauty salons). Application of products could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing and capping)	8	12
Store persons	4	12
End users	8	365

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical in the neat form (> 99% purity) or as a component of cosmetic products (≤ 34%) only in the event of accidental rapture of containers.

Formulation of cosmetic products

During formulation of cosmetic products from the neat notified chemical, dermal, ocular and inhalation exposure of workers to the notified chemical (at > 99% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment such as coveralls, safety glasses and impervious gloves. The use of respirators should also be considered, if appropriate.

End-use

Exposure to the notified chemical (at ≤ 34%) in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. workers in beauty salons). Such professionals may use some personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (at ≤ 34% concentration) through the use of the cosmetic and personal care products. The principal routes of exposure will be dermal and oral (through the use of lip products), while ocular and inhalation exposure is also possible.

Data on typical use patterns of product categories in which the notified chemical may be used are shown in the following table (SCCS, 2010). For the purposes of the exposure assessment, dermal, inhalation and oral exposure have been considered, with the daily systemic exposure from all three routes combined calculated using ConsExpo (ConsExpo, 2006). Australian use patterns for the various product categories are assumed to be similar to those in Europe and an adult bodyweight of 60 kg has been used for calculation purposes. In addition, the following absorption values have been assumed: dermal (0.5%), inhalation (12%) and oral (52%) (see Section 6.2). The table below shows factors relevant for the dermal route, which is the main contributor to exposure for all product types except lipstick. Exposure to lipstick products is mainly through ingestion. The Daily systemic exposure values in the table account for contributions from all exposure routes considered by ConsExpo.

Product type	Amount (mg/day)	Skin Surface area (cm^2)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Body lotion	7,820	15670	34	1	0.27
Face cream	1,540	565	34	1	0.044
Foundation	510	565	34	1	0.014
Eyeliner	5	3.2	34	1	0.00014
Lipstick	57	4.8	34	1	0.17
Makeup remover	5,000	4.8	34	0.1	0.0143
Facial cleanser	800	565	34	0.01	0.000227
Shampoo	10,460	565	34	0.01	0.00296
Conditioner	3,920	565	34	0.01	0.00111
Shower gel	10,000	3.2	34	0.01	0.00354
Total					**0.52**

C = concentration; RF = retention factor

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table that contain the notified chemical. This would result in a combined internal dose (*via* dermal, oral and inhalation routes) of 0.52 mg/kg bw/day.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation –adjuvant test.	no evidence of sensitisation (50% and 90% induction concentration)
Rat, repeat dose oral (gavage) toxicity – 28 days.	NOEL 1500 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

Additional information on the expected health effects of the notified chemical is based on the recent opinion on analogues of the notified chemical (SCCS, 2010a and references there-in). The analogues are cyclic siloxanes, including cyclotetrasiloxane (D4; CAS no. 556-67-2) and cyclopentasiloxane (D5; CAS no. 541-02-6), with similar physicochemical properties to the notified chemical (see below). Only a brief indication of the relevant toxicological effects is provided below. Thus, for further details the associated references should be consulted.

	Notified chemical	*D4*	*D5*
Molecular weight (Da)	310	296	371
Water solubility	$\leq 3.64 \times 10^{-4}$ g/L at 20 °C	2×10^{-5} g/L at 25 °C	$1.7\text{-}2 \times 10^{-5}$ g/L
Partition co-efficient (log K_{ow})	8.16 (calculated)	5.1	5.2
Vapour pressure	1.02 kPa at 25 °C (calculated)	0.091 kPa at 20 °C	0.020 kPa at 23 °C

Toxicokinetics, metabolism and distribution.
Given the relatively low molecular weight of the notified chemical, absorption across biological membranes is possible. However, it may be limited by the low water solubility and expected high partition co-efficient of the notified chemical.

Dermal absorption studies conducted on D4 and D5 indicated that the majority of the chemical volatilised from the skin and, in general, <1% was absorbed. It was determined that 0.5% was a conservative estimate of the

amount absorbed via the dermal route. In addition, studies indicated that 12% D4 was absorbed via inhalation in humans and 5% was absorbed in rats, with the former being used for the purposes of risk assessment (SCCS, 2010a). It was determined that D4 was absorbed orally, with absorption influenced by the vehicle. Note that 52% oral absorption was used for the purposes of risk assessment based on the maximum absorption observed experimentally (SCCS, 2010a).
The calculated vapour pressure of the notified chemical is greater than that of the D4 and D5 analogues. This suggests that the notified chemical is more volatile than the analogues; therefore, the dermal and oral absorption factors used in the risk assessment, which are the routes most relevant to human exposure, are conservative.

Acute toxicity.
The notified chemical was found to be of low acute oral toxicity in rats (LD50 > 2,000 mg/kg bw). Based on studies conducted on D4 and D5, low acute dermal and inhalation toxicity is expected for the notified chemical.

Irritation and Sensitisation.
The notified chemical was not a skin irritant in rabbits (14-day repeated application study).

The notified chemical was not an eye irritant in rabbits and was not a skin sensitiser in guinea pigs at 50% induction concentration (Magnus-Kligman method).

Repeated Dose Toxicity.
A 28-day repeat dose oral toxicity study was conducted on the notified chemical in rats. No deaths or clinical effects were recorded for this study. While this study established a NOEL of 1500 mg/kg bw/day, only one dose of the test substance was administered and no haematological or clinical chemistry measurements were made. In this same study D5 was shown to cause an increase in liver weights at a dose of 1500 mg/kg bw/day. Several other studies on D4 and D5 have been conducted via the oral, dermal and inhalation routes. Notable effects included increased kidney and liver weights. However, these were considered to be adaptive and/or reversible.

No reproductive toxicity studies were provided on the notified chemical. Studies on D4 have been conducted and this chemical is classified under category 3 for reproductive toxicity (R62 Possible risk of impaired fertility; HSIS). Reproductive toxicity effects were noted in rats following inhalation. These included an increase in pre-implantation loss, increased post-implantation loss suppression of luteinising hormone surge, reductions in corpora lutea and in the number of pups born to exposed dams. While the relevance of these findings to humans and to the notified chemical is uncertain, the possibility of chronic effects following repeated, long term exposure to the notified chemical via inhalation cannot be ruled out

No carcinogenicity studies on the notified chemical were provided. In chronic/carcinogenicity studies conducted on D4 and D5 in rats via inhalation, endometrial adenomas were observed at the highest dose level and were concluded to be due to threshold effects on the rat endocrine system (which was also supported by the lack of genotoxic potential). However, the relevance of these effects to humans and to the notified chemical is uncertain.

In the SCCS opinion on D4 and D5, a NOAEL of 150 ppm (equivalent to 17.8 mg/kg bw/day) was chosen for risk assessment purposes following consideration of the most critical effects observed in the available chronic studies, carcinogenicity studies and reproductive toxicity studies. As such, in light of the limited information on the notified chemical, the use of this value is considered to adequately cover the most relevant effects that may be associated with the notified chemical, particularly those related to carcinogenicity and reproductive toxicity.

Mutagenicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an *in vitro* mammalian chromosome aberration test.

Health hazard classification
Based on the available information, the notified chemical is not recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Beauty care professionals will handle the notified chemical at ≤ 34% concentration in cosmetic products, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment, see Section 6.3.2.

Compounders and laboratory staff involved in the formulation of cosmetic products may come in contact with the neat notified chemical. Exposure is expected to be limited during product formulation by the engineering controls and PPE used, and the enclosed and automated processes. Under the proposed occupational settings and provided that formulation control measures are being adhered to, the notified chemical is not considered to pose an unreasonable risk to workers.

Based on the information available, the risk to workers associated with use of the notified chemical at ≤ 34% concentration in cosmetic products is not considered to be unreasonable.

6.3.2. Public Health

At the proposed use concentration of ≤ 34% notified chemical in cosmetic products, acute toxicity effects are not expected. The repeated dose toxicity effects of the notified chemical have not been determined. However, based on the observation of adverse effects in analogue chemicals, D4 and D5, particularly with respect to reproductive toxicity and carcinogenicity, similar effects in the notified chemical cannot be ruled out.

Repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the worst case exposure scenario of 0.52 mg/kg bw/day (see Section 6.1.2) and the NOAEL of 17.8 mg/kg bw/day, which was established in toxicity studies involving the analogues D4 and/or D5. A MoE value greater ≥ 100 is considered acceptable to account for intra- and inter-species differences. Using the abovementioned NOAEL, a MoE of 34 was estimated. Thus, the risk to the public from use of the notified chemical at 34% concentration in cosmetic products, including facial cleansers, shampoos, conditioners, shower gels, makeup removers and lip products is considered to be unreasonable.

In the exposure estimate, the greatest contributors were body lotion (based on the large daily exposure amount and large skin surface area) and lipstick (based on ingestion of the notified chemical). Exclusion of body lotion from the possible product types and reduction of the concentration of the notified chemical in lipstick products from 34% to 20%, allows recalculation of the combined internal dose to 0.182 mg/kg bw/day. A MoE of 98 is then estimated.

In light of the conservative parameters used, the risk to the public associated with the use of the notified chemical at ≤ 34% concentration in make-up, face care products and rinse off products and ≤ 20% in lip products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
No release to the environment is expected from sites as the notified chemical will not be manufactured in Australia. Reformulation may take place in the future and release to the environment may occur during this activity.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical will be applied to the skin of consumers as a component in skin care and cosmetic products. It is expected that most of the notified chemical will volatilise off the skin and be released to the air compartment. The notified chemical may also be released to sewer in domestic situations across Australia as a result of its use in products that will be washed off the skin.

RELEASE OF CHEMICAL FROM DISPOSAL
Residues in end-use containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate
No environmental fate data were submitted. Most of the notified chemical is expected to be released to the air compartment after application to the skin due to its volatility. According to SEHSC (2006), 80-90% of the structurally similar octamethylcyclotetrasiloxane (D_4) used in personal care products will evaporate after application. Volatile siloxanes photodegrade to dimethylsilanediol, and ultimately, inorganic silicate and carbon dioxide (Dow Corning, 1998). The half-life of the notified chemical in air is predicted to be 86 hours, based on reactions with hydroxyl radicals (AOPWIN v1.92, US EPA, 2012). The notified chemical has the potential for persistence in the atmospheric compartment as its half-life in air is greater than two days.

For the portion of notified chemical that is washed to sewer, it is likely to partition to the air compartment or partition to sludge during sewage treatment plant (STP) processes due to its predicted high K_{OC} (4.31, KOCWIN v2.00, US EPA, 2012). It is predicted that the notified chemical is not readily biodegradable and that its volatilisation half-life in rivers and lakes is 1.8 h and 167 h, respectively, based on a Henry Law Constant of 0.574 atm.m^3/mol (estimated by Bond SAR Method, US EPA, 2012). Therefore, any notified chemical released to surface waters from STPs is expected to partition to air or sediment.

A small proportion of notified chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation. In soil, D_4 degrades or volatilizes within a week, and ultimately degrades into inorganic silicate, water and carbon dioxide (SEHSC, 2006). Similarly, residues of the notified chemical in landfill, soil and sludge are expected to degrade, or volatilise and photodegrade, to inorganic silicates, water and oxides of carbon (Dow Corning, 1998).

While the reported use pattern and volatilisation of the notified chemical from water limit the potential for aquatic exposure, the notified chemical has potential for bioaccumulation with a predicted high K_{OW} (8.16, KOWWIN v1.68, US EPA, 2012) and a predicted BCF of 3600 (BCFBAF v3.01, regression-based model, US EPA, 2012).

Summary of environmental fate, referring to Appendix C for environmental fate results, e.g ‘For the details of the environmental fate studies please refer to Appendix C’.
If no environmental fate data were submitted for a limited notification, write “No environmental fate data were submitted” here. Otherwise, delete this row and fill out the appropriate sections in Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)
Since most the notified chemical is applied to the skin in cosmetic products, under a worst case scenario, the Predicted Environmental Concentration (PEC) is calculated assuming that the total import volume is washed off the skin to sewer. SimpleTreat (European Commission, 2003) predicts that ≥ 96% of the notified chemical will be removed during sewerage treatment plant (STP) processed through adsorption to sludge (69%) and volatilisation (27%).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day

Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	96%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.02	µg/L
PEC - Ocean:	0.002	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4.18 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.028 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 0.14 mg/kg and 0.28 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.024 µg/L may potentially result in a soil concentration of approximately 0.16 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.81 µg/kg and 1.6 µg/kg, respectively.

7.2. Environmental Effects Assessment

The notified chemical has long range transport potential as its atmospheric half-life in air is greater than two days. However, the notified chemical is not expected to significantly contribute to global warming due to its low import volume and it is not expected to contribute to ozone depletion as it does not contain chlorine or bromine atoms (Dow Corning, 1999).

No ecotoxicity data for the notified chemical were submitted. The notified chemical is not expected to be bioavailable to aquatic organisms at its limit of solubility in water due to its high partition coefficient. Therefore, no effects on aquatic biota are predicted for the notified chemical at its limit of water solubility (US EPA, 2012). Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A Predicted No Effect Concentration (PNEC) has not been calculated as the notified chemical is not expected to be readily bioavailable and is predicted to have no effect on aquatic biota at its limit of water solubility.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified chemical was not calculated as a PNEC was not derived.

The majority of notified chemical is expected to volatilise into air from the skin. The notified chemical is not considered to have potential for global warming or ozone depletion. The notified chemical is predicted to photodegrade in air by reaction with hydroxyl radicals although it has long range transport potential in the atmospheric compartment.

Notified chemical that is washed to sewer is expected to be efficiently removed from waste water by sorption to sludge and volatilisation to air. Therefore, there is limited exposure to the aquatic compartment arising from the reported use pattern. The notified chemical has the potential for bioaccumulation.

However, on the basis of the assessed use pattern, limited exposure to the aquatic compartment and absence of predicted toxic effects to aquatic organisms up to its limit of water solubility, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility $\leq 3.64 \times 10^{-4}$ g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	SafePharm (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/SD [Crj:CD(SD)IGS]
- Vehicle: Olive oil
- Remarks - Method: Non-GLP study

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5F/5M	1,000	0/10
II	5F/5M	2,000	0/10

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: Watery diarrhoea and a soiled perineal region were noted in animals of both treatment groups on Day 1 of treatment. However, these effects were attributed to the vehicle (particularly given that the watery diarrhoea was observed in the control group).
- Effects in Organs: None

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: NEMRI (2001a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: Repeated dose, in-house method
- Species/Strain: Rabbit/Japanese White
- Number of Animals: 3
- Vehicle: Olive oil
- Observation Period: 15-days
- Type of Dressing: Not occluded
- Remarks - Method: Non-GLP study.

0.25 mL each of a 50% and 90% solution of the notified chemical in the vehicle were applied to sites (~2.5 x 2.5 cm, fur clipped) on the backs of the rabbits. The solutions were applied to identical sites daily for a total of 14 applications. Observations were recorded before subsequent treatments and at 24 hours post final treatment.

RESULTS: No irritation was recorded at any observation time point.

CONCLUSION: The notified chemical is non-irritating to the skin.

TEST FACILITY: NEMRI (2001b)

B.3. Irritation – eye

TEST SUBSTANCE	Notified Chemical
METHOD	Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	72 hours
Remarks - Method	Non-GLP study. Solutions of the notified chemical in olive oil (50% or 90%) were instilled in the right eyes of 2 groups of animals (3 animals/group). The left eyes were treated with the vehicle.
Remarks - Results	No irritation was recorded at any observation time point.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	NEMRI (2001c)

B.4. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 406 Skin Sensitisation - Magnusson and Kligman guinea pig maximisation test.
Species/Strain	Guinea pig/Hartley
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 50% topical: 50%
Signs of Irritation	No signs of irritation were noted following induction.
CHALLENGE PHASE	
1st challenge	topical: 50% or 90% (10 animals for each concentration)
Remarks - Method	The vehicle for the test substance was olive oil. The positive control was 0.1% 2,4-dinitrochlorobenzene (DNCB) in 80% ethanol solution.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group I	50%	0/10	0/10
Test Group II	90%	0/10	0/10
Control Group I	50%	0/5	0/5
Control Group II	90%	0/5	0/5
Positive Control (0.1% DCNB)	0.1%	3/5	3/5

Remarks - Results	Following the challenge phase, no signs of skin reaction were noted in animals in any of the test and control groups. The positive response observed in the positive control validates the test system used in this study.

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	NEMRI (2001d)

B.5. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/ Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 5 days per week Post-exposure observation period:
Vehicle	Sesame oil
Remarks - Method	Non-GLP study. The study included a total of nine groups and included six other silicone oligomers as well as two controls. The control groups were treated with either distilled water or sesame oil. Doses were adjusted once per week based on changes in body weight and only a single dose of test substance was tested.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control (distilled water)	6M/6F	-	0
Control (sesame oil)	6M/6F	-	0
Test substance	6M/6F	1500	0

Mortality and Time to Death
There were no test substance related mortalities during this study.

Clinical Observations
No treatment related changes were recorded by physical examination for the test substance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment related changes were recorded by urinalysis and no haematology or clinical tests were conducted.

Effects in Organs
No statistically significant treatment related changes were recorded in organs post necropsy.

Remarks – Results
No significant effects were recorded following treatment with the test substance.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1500 mg/kg bw/day in this study, based on no adverse effects being observed through the course of the study.

TEST FACILITY	Dow Corning (1990)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbitone/5,6-benzoflavone-induced rat liver (S9 homogenate)
Concentration Range in Main Test	With and without metabolic activation: 156.3, 312.5, 625, 1250, 2500 and 5000 µg/plate
Vehicle	Acetone
Remarks - Method	Non-GLP study. A range-finding study (Test 1) was conducted using 7 concentrations of the test substance (5, 10, 50, 100, 500, 1000 and 5000 µg/plate). Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: sodium azide (TA1535), 9-aminoacridine (TA1537), 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide (TA98, TA100, WP2uvrA); ii) with S9: 2-aminoanthracene (all strains).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>5,000	≥5,000	≥5,000
Test 2	>5,000	≥5,000	≥5,000
Present			
Test 1	>5,000	≥5,000	≥5,000
Test 2	>5,000	≥5,000	≥5,000

Remarks - Results	The test substance did not cause a visible reduction in the growth of the bacterial background lawn at any dose level. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or without metabolic activation.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NEMRI (2001e)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Chinese hamster lung (CHL)
Metabolic Activation System	Phenobarbitone/5,6-benzoflavone-induced rat liver (S9 homogenate)
Vehicle	1% Carboxymethyl cellulose sodium salt
Remarks - Method	A preliminary toxicity study (4 to 3,107 µg/mL) was performed to define the dose levels for the main test. Vehicle and positive controls (mitomycin C) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	777, 1554, 3107	6 h	24 h
Test 2a	777, 1554, 3107	24 h	24 h
Test 2b	777, 1554, 3107	48 h	48 h
Present			
Test 1	777, 1554, 3107	6 h	24 h

All Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>3,107	>3,107	>3,107
Test 2	>3,107	>3,107	>3,107
	>3,107	>3,107	>3,107
Present			
Test 1	>3,107	>3,107	>3,107

Remarks - Results: No statistically significant increase in the number of cells with aberrations was noted at any concentration, with and without metabolic activation.

CONCLUSION: The notified chemical was not clastogenic to Chinese hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY: NEMRI (2001f)

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