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July 2007

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Siloxane derivative in SilCare Silicone SEA / Siloxane derivative in Sandoperm SE1 Oil

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 the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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FULL PUBLIC REPORT**Siloxane derivative in SilCare Silicone SEA / Siloxane derivative in Sandoperm SE1 Oil****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
675 Warrigal Road
Chadstone VIC 3148

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, and Site of Manufacture/Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, 2003 (under the Polymer Exemption Certification)
Korea, 2002

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Silcare Silicone SEA; Sandoperm SE 1 Oil (both solutions 60-90% notified polymer)

OTHER NAME(S)

Trideceth-9 PG-Amodimethicone and Trideceth-12 (INCI name of the imported product mixture)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains potentially cationic functional groups, with a FGEW > 5000.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes

Not a Hazard Substance or Dangerous Good

Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Clear, light yellow liquid (60-90% polymer solution)
Melting Point/Glass Transition Temp	Not determined (polymer never isolated from solution)
Density	1000 kg/m ³ at 20°C (60-90% polymer solution)
Water Solubility	Said to be insoluble at pH 7 or higher, at which it appears to form microemulsions in water. (60-90% polymer solution). Chemicals containing silica are generally insoluble.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10	10	10	10	10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

Products containing the notified polymer (60-90%) in solution are to be imported via Sydney or Melbourne harbour in closed head polyethylene drums of 25 or 55 kg. The products will be transported by road to the notifier's warehouse for storage before being transported by road transport to customers without repackaging.

Reformulation/manufacture processes

The notified polymer will not be manufactured in Australia. Reformulation will not be carried out by the notifier. Reformulation will only be carried out when cosmetic products are manufactured. Reformulation will involve manual weighing out of the liquid product into batch containers before addition of the batch quantity of the notified polymer into the mixing tanks. The mixture of ingredients is to be blended by automated mixing. The mixed product will then be transferred by piping to sealed holding containers; and the finished products filled into containers via a series of pumps and pipes from the holding tank to an automated filling line, where it is automatically filled into 50 – 1000 mL containers. After reformulation, the notified polymer will be present at < 5% concentration in the cosmetic products.

Use

The notified polymer will be used in 2 different sectors. It will be used as a textiles finishing agent (at 1% weight of fabric) during the production of textile fabrics and as a component (< 5%) in cosmetic hair care and skin care products. The majority of the cosmetic products will be for export. The cosmetic products will also be used in Australia by professional hairdressers and by consumers.

Approximately 66% of the imported polymer will be used in the textile industry. This process involves the manual weighing of the notified polymer solution into a small vessel which is then manually

transferred to a side tank for stirring with other ingredients before the contents are gravity fed into the dye bath.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and storage

Transport and warehouse/stores personnel from both the textiles and cosmetics industries will only be exposed to the notified polymer in the case of a spill or damage to packaging. Warehouse/stores personnel will wear protective equipment (industrial clothing and gloves, as appropriate) when handling consignments of the commercial product containing the notified polymer.

Dyehouse (Textile industry)

Dermal exposure to the notified polymer via drips, spills and splashes may occur during preparation for use in dye baths when batch quantities are measured and during transfer of weighed dye bath materials to the semi-enclosed dye bath. Exposure of the dyehouse operators to significant amounts of the polymer is limited because of the use of personal protective equipment. After the treatment the damp fabric contains the notified chemical fixed to fabric fibres in an inaccessible form. Operator exposure to any residues of the notified chemical on treated fabric (wet or dry) is expected to be negligible.

Reformulation (Cosmetics industry)

Dermal exposure to the notified polymer by production operators during reformulation processes is possible when batch quantities are measured manually and subsequently transferred to the manufacturing vessel. Exposure to significant amounts of the polymer is limited because of the use of personal protective equipment. Exposure during blending and packing is unlikely as these processes are completely automated.

Beauty Industry

Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE (1997) modelling of this work environment, dermal exposure in the range of 1-5 mg/cm²/day of products containing < 5% of the notified polymer could result.

PUBLIC EXPOSURE

Public exposure to treated fabric will occur but the notified polymer will be bound to the textile fibres and leaching of the notified polymer from fabrics is not expected. The notified polymer is considered permanent to washing.

Cosmetics containing the notified polymer will be in products sold to the general public, and widespread public exposure is therefore expected. Exposure to the notified chemical will vary depending on individual use patterns. Typically, 5-14 g of product containing less than 1% notified polymer is applied to the hair up to 7 times per week. The hair is rinsed after application. The use of skin care products involves application of up to 8 g of product containing less than 5% of notified polymer once a day. This material is leave-on but will ultimately be washed to sewer during daily personal wash.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer solution (60-90% polymer).

Hazardous monomers are present only at low levels, below the cut-off concentration for classification as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	no	OECD TG 423
2. Rabbit, skin irritation	slightly irritating	no	yes	OECD TG 404
3. Rabbit, eye irritation	slightly irritating	no	yes	OECD TG 405
4. Skin sensitisation - non-adjuvant test	no evidence of sensitisation.	no	yes	OECD TG 406 (Buehler test)
5. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

Dermal irritation

At the 1 hour observation 2/3 animals showed well defined erythema with slight oedema, while the remaining animal showed slight erythema. At 24 hours 1 animal showed well-defined erythema with slight oedema, while the remaining 2 animals showed slight erythema. After 48 hours 1 animal still displayed well-defined erythema with slight oedema; and 1 animal showed slight erythema. After 72 hours only slight erythema was observed in 1 animal. All treated skin sites appeared normal at the 7 day observation.

Eye irritation

One animal showed some hyperaemic blood vessels in the conjunctiva from 1 hour up to 24 hours after application, as well as slight swelling of lids 1 hour after application.

The other 2 animals showed some hyperaemic blood vessels up to diffuse, crimson red colour in the conjunctiva from 1 hour up to 72 hours, as well as slight up to obvious swelling with partial eversion of the lids up to 24 hours after application.

Two animals showed reddened iris 1 hour after application. The irritations were attended by serous colourless discharge from the eye.

All irritations had disappeared by 7 days post-application.

Skin sensitisation

During the first two weeks of induction discrete/patchy erythema was observed in 13/20 test animals treated with undiluted test substance. During the third week 16/19 test animals treated with the undiluted test substance showed the same reaction.

After the first challenge treatment, performed with 50% commercial product in water (highest non-irritating concentration), grade 1 skin reactions (discrete and patchy erythema) were observed in 4/19 of test animals at the 24 and 48 hour readings. No reactions were observed in the control animals. Rechallenge under identical conditions on the opposite flank showed that the responses were not reproducible as no skin reactions were observed in any of the test animals. Based on the rechallenge results and the known skin irritancy properties of the test substance, the skin reactions observed during the first challenge were determined to be due to skin irritation rather than skin allergy.

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Exposure to the notified polymer could occur during operations to measure and transfer the polymer solutions for both textile industry use and personal care product manufacture. However, the risk to workers is considered to be low due to the low hazard of the notified polymer as well as due to engineering controls and personal protective equipment used by workers.

Due to the slight skin and eye irritancy properties of the notified polymer personal protective equipment (including protective clothing, safety glasses and impervious gloves) is recommended for use by workers handling the notified polymer solutions (60-90%).

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of hair care and skin care products the risk to public health is considered to be low due to the predicted low hazard of the notified polymer and the low concentrations of notified polymer in cosmetic products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Textile industry:

It is expected that two-thirds of the total annual volume of notified polymer will be used in the textile industry. Initially the notified polymer will only be used at one textile plant in rural Victoria.

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the packaging drums. Under normal use procedures, losses from residues in containers have been estimated to be a maximum of 25 kg per annum. The major environmental exposure to the notified chemical will be from release to sewer via dyehouse effluent discharge.

During application to fabrics, the notified polymer will be taken up by fabric fibres from the pad bath process with a high exhaustion rate on to fibres of >98%, supported by an exhaustion rate study report. Waste pad bath liquor will be disposed of at the end of the day directly to the local municipal sewerage treatment plant. Therefore, it is assumed that 2% of the notified polymer used daily will be released to sewer in the pad bath waste.

Initially the worst case predicted environmental concentration (PEC) is calculated for a small country plant assuming there is no removal in the sewer/STP, as follows:

PEC for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	1.333%	
Annual quantity of chemical released to sewer	133.333	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.513	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	4.000	ML/day
Removal within STP	0%	
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	128.21	µg/L
PEC - Ocean:	12.82	µg/L

The inherent biodegradation study, (see Environmental Fate section) indicates removal of 70% due to adsorption to sludge and organic matter in the STP. A mitigated PEC, allowing for this removal, is provided below.

Mitigated PEC for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	1.333%	
Annual quantity of chemical released to sewer	133.333	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.513	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	4.000	ML/day
Removal within STP	70%	Mitigation
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	38.46	µg/L
PEC - Ocean:	3.85	µg/L

Under normal operational circumstances, the treated effluent from the municipal STP is used to irrigate nearby farmland. Consequently, residues of the notified polymer from the proposed end-user will not be released to the aquatic environment. The majority of the notified polymer in the pad bath waste will end up in the biosolids from the STP. The biosolids from the STP are not applied to the agricultural land, so will either go to landfill or be incinerated. In landfill the notified polymer will not be mobile and will degrade overtime via abiotic and biotic means.

Personal care products

During reformulation a small amount of the notified polymer could be washed from machinery during cleaning. This is normally treated as site industrial waste and dealt with by licensed disposal contractors. Empty import containers with any remaining residual material will be disposed of to landfill.

Environmental exposure to the notified chemical will result from reformulation and use of the notified chemical as well as from the disposal of import and end-use containers. The main exposure to the environment in Australia is expected to come from the quantity of the notified polymer that is not exported as a component of personal care products.

A predicted environmental concentration (PEC) in the aquatic environment is estimated below. This is based on a worst-case scenario where the total quantity of the notified chemical to be used in personal care products in Australia (3300 kg) is discharged to sewer i.e. no quantities exported. Under this scenario, the daily release on a nationwide basis to receiving waters is estimated to be 9.0 kg/day.

PEC for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	33.333%	
Annual quantity of chemical released to sewer	3,333.333	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	9.13	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	2.23	µg/L
PEC - Ocean:	0.22	µg/L

ENVIRONMENTAL FATE

<i>Endpoint</i>	<i>Results and Conclusion</i>	<i>Test Guideline</i>
Ready Biodegradability	Not readily biodegradable	OECD TG 301 F
Inherent biodegradability	Not biodegradable, but elimination occurred.	OECD TG 302 B

Ready biodegradability: No significant biodegradability based on O₂ consumption was observed after 28 days as compared to the chemical oxygen demand (COD). Due to the limited water solubility of the test material, biodegradation based on DOC measurements could not be assessed. Reference material (sodium benzoate) reached 88% biodegradation by day 14, thereby confirming the validity of the study conditions.

Inherent biodegradability: Not biodegradable since less than 20% degradation was attained after 28 days of contact time. When the biodegradation was determined in relation to the generation of CO₂ and the % theoretical CO₂ (ThCO₂), after 28 days 8% ThCO₂ had been reached. This indicated that very little mineralisation occurred. Based on DOC measurement it was determined that with the addition of the sludge there was an elimination of 15% and after 3 hours this had increased to 70% and after 7 days to 89%. This elimination was due to adsorption on the activated sludge, on the glass and due to other physico-chemical properties. The reference material (diethyleneglycol) reached 100% biodegradation after 14 days, thereby confirming the validity of the study conditions.

7.2. Environmental Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Fish Toxicity	LC50 55.2 mg/L	yes	OECD TG 203
Inhibition of Bacterial Respiration	EC50 >2000 mg/L	no	OECD TG 209

All results were indicative of low hazard. The fish toxicity indicates that the notified polymer is slightly toxic to fish. All fish died at 100 mg/L after 24 hours, and at 50 mg/L 2 out of 7 fish died after 96 hours. No deaths were observed in other concentrations. At 25 and 50 mg/L fish were observed exhibiting abnormal behaviour. The NOEC was 12.5 mg/L since hypoactivity at 25 mg/L was considered to be a significant toxic effect. Based on the most sensitive ecotoxicity result and using a conservative safety factor of 1000, as data for only two trophic levels has been provided, the Predicted No-Effect Concentration has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
LC50 (Fish).	55.20 mg/L
Assessment Factor	1,000.00
PNEC:	55.20 µg/L

7.3. Environmental Risk Assessment

Textile industry

Using the PEC and PNEC values calculated in sections 7.1 and 7.2 respectively, the unmitigated risk quotient has been calculated as follows:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	128.21	55.2	2.323
Q - Ocean:	12.82	55.2	0.232

The unmitigated risk quotient indicates that risk to the aquatic environment from release to rivers is unacceptable. However, when allowing for 70% adsorption in STPs, the mitigated risk quotient below indicates that the risk to the aquatic environment from release to rivers will be acceptable, as shown below:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	38.46	55.2	0.697
Q - Ocean:	3.85	55.2	0.070

The risk is further mitigated as it is not intended to release the effluent to a water body but rather to use it for irrigation where further removal will occur due to adsorption to organic material in the soils, this use pattern should not pose a risk to the aquatic compartment. In addition, biosolids from the STP are not expected to be applied to land, but rather be disposed of to landfill or via incineration. In landfill the notified polymer will not be mobile.

Personal care products

Using the PEC and PNEC values calculated in sections 7.1 and 7.2 respectively, the unmitigated risk quotient has been calculated as follows:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	2.23	55.2	0.040
Q - Ocean:	0.22	55.2	0.004

Since the risk quotients for release to river and ocean are below 1, the risk to the aquatic environment is expected to be acceptable. Bioaccumulation is not expected as the notified polymer is not expected to cross biological membranes due to its high molecular weight.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

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

8.2. Level of Concern for Public Health

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

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and as diluted for use in blended products:
 - Avoid skin and eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and as diluted for use in blended products:
 - Chemical resistant gloves
 - Protective clothing

- Safety goggles

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.

Environment

- The following control measures should be implemented by formulators and dyehouses to minimise environmental exposure during formulation and use of the notified polymer:
 - The notified polymer should be prevented from entering drains or water courses.

Disposal

- The notified polymer should be either recycled or disposed of to landfill.

Emergency procedures

- Spills/ accidental release of the notified polymer should be handled by absorbing with a liquid binding material e.g. sand, soil or diatomaceous earth.

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria; and/or

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.