File No: LTD/1552

October 2011

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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1552	Estee Lauder 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 data the notified chemical cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used at ≤34% concentration in make-up and face care products (including face cream, foundation and eye liner) and ≤20% 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

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself. However, these should be selected on the basis of all ingredients in the formulation.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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

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% in make-up and face care products (including face cream, foundation and eye liner) 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 repeated dose, reproductive toxicity, and/or carcinogenicity of the notified chemical becomes available;
  - the chemical is intended for use in product types other than face cream, foundation, eye liner and lip products;
  - the concentration of the notified chemical exceeds or is intended to exceed 34% in make-up and face care products (including face cream, foundation and eye liner) 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 MSDS of the notified chemical and a product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Estee Lauder Pty Ltd (ABN: 63 008 444 719)
21 Rosebery Avenue
Rosebery, NSW 2018

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: All physico-chemical endpoints (exception: water solubility).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
TMF-1.5

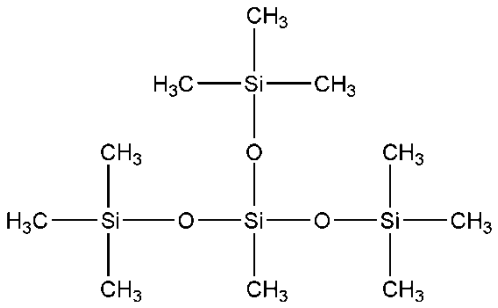
CAS NUMBER
17928-28-8

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

OTHER NAME(S)
Methyl Trimethicone (INCI name)
Methyltris(trimethylsiloxy)silane

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%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-83 ºC	MSDS
Boiling Point	191 ºC	MSDS
Density	850 kg/m^3 at 20 ºC	MSDS
Vapour Pressure	0.075 kPa at 25 ºC	Estimated - mean VP of Antoine & Grain methods (US EPA, 2009)
Water Solubility	<3.64×10^{-4} g/L at 20 ºC	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical has low water solubility.
Partition Coefficient (n-octanol/water)	Log K_{OW} = 5.93	Estimated - a high log K_{OW} is predicted (KOWWIN v1.67, US EPA, 2009) 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, 2009) 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 ºC (closed cup)	MSDS. Classified as a C1 combustible liquid (NOHSC, 2001)
Flammability	Not determined	Based on the flash point, not classified as flammable (NTC, 2007)
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

DISCUSSION OF PROPERTIES

Reactivity

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

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be introduced as a component (≤34%) of finished cosmetic products.

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

IDENTITY OF MANUFACTURER/RECIPIENTS
Estee Lauder Pty Ltd

TRANSPORTATION AND PACKAGING
The products containing the notified chemical (at ≤34%) will be imported in tubes/containers suitable for retail sale (typically ~30 mL size). These will be packaged in cardboard cartons. The cartons will be distributed within Australia by road.

USE
The notified chemical will primarily be used as a solvent and skin conditioning agent in skin care products at ≤34% concentration. It may also be used in make-up products (including lip products) and products designed for use around the eyes.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of finished cosmetic products. Reformulation will not take place in Australia.

The finished products containing the notified chemical 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

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	12	4	12
Store persons	5	4	12
Salon workers	unspecified	unspecified	unspecified

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified chemical as a component of end-use products (at ≤34%) only in the event of accidental rupture of containers.

Exposure to the notified chemical 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 (shown in the below table) 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).

Product type	**Amount** (mg/day)	**Skin surface Area** (cm^2)	**C** (%)	**RF**	**Daily systemic exposure** (mg/kg bw/day)
Body lotion	7820	15670	34	1	0.27
Face cream	1540	565	34	1	0.054
Foundation	510	565	34	1	0.018
Eye liner	5	3.2	34	1	0.00017
Lipstick	57	4.8	34	1	0.17
Total					0.51

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 0.51 mg/kg bw/day.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B. The studies were not GLP compliant.

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	no evidence of sensitisation (50% induction concentration)
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 opinion and associated references should be consulted.

	Notified chemical	*D4*	*D5*
Molecular weight (Da)	310	296	371
Water solubility	$<3.64\times10^{-4}$ g/L at 20 °C	$2x10^{-5}$ g/L at 25 °C	$1.7\text{-}2\ x10^{-5}$ g/L
Partition co-efficient (log K_{ow})	5.93 (estimated)	5.1	5.2
Vapour pressure	0.075 kPa at 25 °C (estimated)	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).

Acute toxicity.
The notified chemical was found to be of low acute oral toxicity in rats (LD50 >2000 mg/kg bw). Based on studies conducted on D4 and D5, low acute dermal and inhalation toxicity is expected.

Irritation and Sensitisation.
The notified chemical was not a skin irritant in rabbits (14-day repeated application study). It is also reported (full study not provided) that the notified chemical was non-irritating to the skin of rabbits following exposure for 24 hours under occlusive conditions.

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

Repeated Dose Toxicity, Toxicity for Reproduction and Carcinogenicity.
No repeated dose toxicity studies on the notified chemical were provided. Several studies on D4 and D5 have been conducted via the oral, dermal and inhalation routes. Notable effects included increased liver weights and enzyme activities. However, in general, these were considered to be adaptive and/or reversible.

No reproductive toxicity studies on the notified chemical were provided. Several 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 noted in rats following inhalation, which may be associated with suppression of luteinising hormone surge, included reductions in corpora lutea, implantation sites and the number of pups born to exposed dams. The relevance of these findings to humans and to the notified chemical is uncertain.

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, 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 data the notified chemical cannot be classified 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.

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 excluded.

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 0.51 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 body lotion, face cream, foundation, lipstick and eyeliner 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 0.17 mg/kg bw/day. A MoE of 104 is then estimated.

Therefore, the risk to the public associated with the use of the notified chemical at ≤34% concentration in make-up and face care products (including face cream, foundation and eye liner) 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
The notified chemical will not be manufactured or reformulated in Australia.

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

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 h, based on reactions with hydroxyl radicals (AopWIN v1.92, US EPA, 2009). 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, 2009). 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, 2009). Therefore, any release of the notified chemical 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} (5.93, KOWWIN v1.67, US EPA, 2009) and a predicted BCF of

3819 (BCFBAF v3.00, regression-based model, US EPA, 2009).

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 up to 94% 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:	0.00	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 0.1615 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 0.8077 µg/kg and 1.615 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 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, 2009). 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 $< 3.46 \times 10^{-4}$ g/L at 20 ± 0.5 ºC

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. Sample solutions of 2.0 g/L (nominal) were prepared by shaking at 30 ˚C for 3 hours and standing at 20 ˚C for 24 hours, followed by centrifugation at 13,500 rpm for 15 min. The concentrations of the notified chemical in solution were determined by gas chromatography after solid-phase extraction of the settled test mixtures; analytical results were corrected for the relatively low recovery efficiency of 20%. The column elution method was not used since the notified chemical was expected to cause the beads to adhere together forming a plug in the column.
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 and 5M	1,000	0/10
II	5F and 5M	2,000	0/10

- LD50: >2,000 mg/kg bw
- Signs of Toxicity: Watery diarrhea 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 diarrhea 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/Japanese 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.
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: 20 Positive 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	Non-GLP study. The vehicle for the test substance was olive oil. In addition to the positive control group (2,4-dinitrochlorobenzene), additional challenge-only control groups were treated with the relevant test substance (notified chemical – 10 animals; and positive control – 5 animals).

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	0.1%	5/5	5/5

Remarks - Results	Following the challenge phase, no signs of skin reaction were noted in animals in both the test groups.
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. 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	Negative
Test 2	>5,000	≥5,000	Negative
Present			
Test 1	>5,000	≥5,000	Negative
Test 2	>5,000	≥5,000	Negative

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. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NEMRI (2001e)

B.6. 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	Non-GLP study.

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	-	Negative
Test 2a	>3,107	-	Negative
Test 2b	>3,107	-	Negative
Present			
Test 2	>3,107	-	Negative

Remarks - Results

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

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

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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