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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

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 the Environment, Water, Heritage and the Arts.

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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Methyl Trimethicone

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Avon Products Pty Ltd (ABN 48 008 428 457)
120 Old Pittwater Rd Brookvale NSW 2100

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: Site of manufacture, use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flammability limits, auto-ignition temperature, explosive properties, reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
Not known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Methyl Trimethicone (INCI name)

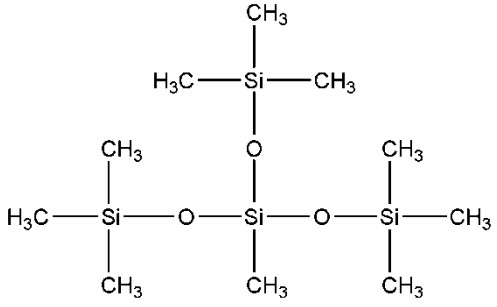
CAS NUMBER
17928-28-8

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

OTHER NAME(S)
TMF-1.5
Methyltris(trimethylsiloxy)silane

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

STRUCTURAL FORMULA



MOLECULAR WEIGHT
310.69 Da

ANALYTICAL DATA
Reference IR, GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

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

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Colourless transparent liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-83°C	MSDS
Boiling Point	191°C at 101.3 kPa	Technical Data Sheet (Shin-Etsu 2006)
Density	850 kg/m^3 at 25°C	MSDS
Vapour Pressure	< 1.38 kPa at 25°C	MSDS
Water Solubility	< 3.64 × 10^{-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)	Not determined	A high log K_{OW} (5.93) is predicted by EPIWIN modelling, which is consistent with the hydrophobic structure of the notified chemical and its low water solubility.
Adsorption/Desorption	Not determined	EPIWIN modelling predicted a high log K_{OC} of 4.41, 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.
Particle Size	Not determined	Notified chemical is in liquid form.
Flash Point	61°C at 101.3 kPa*	MSDS
Flammability	Not determined	Notified chemical is part of a mixture and not expected to be flammable under normal usage and environmental conditions.
Autoignition Temperature	Not determined	Not expected to auto-ignite under normal conditions.
Explosive Properties	Not determined	Not expected to be explosive based on absence of structural alerts for explosivity.

*Based on the flash point the notified chemical is not classified as flammable, but would be considered a C1 combustible liquid [NOHSC: 1015(2001)].

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A. The notified chemical is a volatile silicone chemical.

Reactivity
Stable under normal environmental and usage conditions.

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 lip 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
Port Botany, Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Shin-Etsu Chemical Co, Ltd. 6-1 Ohtemachi 2-chome, Chiyoda-ku Tokyo, Japan.

TRANSPORTATION AND PACKAGING
The finished products containing the notified chemical will be imported in 4 g containers. These containers will be packed in cartons with 12 cartons per cardboard shipper.
The shippers will be transported in a container from the wharf, to the Notifier's central warehouse. The cartons will be transported to households by a team of distributors and direct sales people.

USE
The notified chemical is used as a solvent and skin conditioning ingredient in lipsticks and other lip products at levels up to 15%.

OPERATION DESCRIPTION
Dockside and warehouse workers will transport the finished product from the wharf to the Avon central distribution centre and place the pallets of product into the warehouse. Warehouse workers will be involved in transferring pallets in the Avon central warehouse and operating a picking operation for stock to Distributors at the retailer's central distribution depots.

The notifier does not intend to reformulate the notified chemical in Australia, but have provided the following descriptions that outline typical scenarios and personnel involved if the products containing the notified chemical were to be formulated locally:

Store persons would receive the ingredient when first delivered and store it in the raw material store. The Chemist would take a sample and analyse for QA, after which quantities of the ingredient would be issued to the Compounder for production. A Compounder will weigh an appropriate amount of the ingredient into a separate container then add the amount directly into a mixing tank. The Chemist would sample and test the Lipstick for QA purposes. Packers would monitor the line filler and the capper where the finished product is filled into retail bottles. Store Persons would remove the pallets of finished product from the end of the packing line and store the finished product in the finished store.

Compounder, Packers, Chemists and Store Persons would be involved in the production of finished products on a monthly basis.

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	10	4	12
Professional compounder	1	8	12
Chemist	1	3	12
Packers (Dispensing and Capping)	2	8	12
Store Persons	2	4	12

End Users	3 x 10^5	8	365

EXPOSURE DETAILS
Dockside and warehouse workers are not expected to have any contact with the notified chemical, which is contained in sealed packages, except in the case of spills.

If the notified chemical were to be locally reformulated in the future, workers involved in mixing and dispensing (compounders) may experience dermal and ocular exposure from drips and spills when weighing the material and adding to mixing tanks. Respiratory exposure is also possible due to the volatile nature of the notified chemical. Chemists may come into skin contact with the notified chemical during sampling and testing for QA purposes. Packers may have skin contact, and although unlikely, may experience accidental eye contact through splashes or spills.

6.1.2. Public exposure

The notified chemical is an ingredient at up to 15% in commercially available cosmetic products and there will be widespread public exposure to consumers. As the products are directly applied to the lips, there will be potential dermal and oral exposure. Because of the volatility of the notified chemical there is also the potential for inhalation exposure after the product is applied to the lips. The estimated daily use for lipsticks is 0.04 g/day, as 4 applications of 0.01g (SCCP 2006). Based on a concentration of 15% in products, potential exposure to the notified chemical is estimated to be up to 6 mg/day or 0.1 mg/kg bw/day using a default body weight of 60 kg and dermal absorption assumed to be 100% in the absence of absorption data.

6.2. Human health effects assessment

Toxicological studies were conducted on the notified chemical and the summary reports were provided (Shin-Etsu Chemical Co Ltd 2008). These reports contained brief descriptions of the methods used and the overall results. The full toxicological reports were not made available to NICNAS. There is no indication from the summaries whether the studies were conducted in accordance with OECD guidelines, or whether they were GLP compliant. The results of the tests on the notified chemical are listed in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation (non-adjuvant)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro, Mammalian chromosome aberration test	non genotoxic

Toxicokinetics, metabolism and distribution
No information was provided. The notified chemical is not soluble in water (< 3.64×10^{-4} g/L) and the partition coefficient (log P) is estimated to be 5.93 (ChemIDplus Advanced). The notified chemical will be applied to the lips and the primary route of entry into the body is through the skin and through the gut after oral ingestion. After ingestion, micellar solubilisation and uptake into the lymphatic system may occur although absorption through the gastrointestinal tract (GIT) wall may be limited due to its very low water solubility. Given the relatively high log P, absorption through the stratum corneum is expected, although penetration into the dermal layer is likely to be limited based on the very low water solubility. The notified chemical is considered to be volatile, and although inhalation exposure is possible, it is not expected to be a major route of exposure when applied as a lip product.

Acute toxicity
In an acute oral toxicity study, groups of 5 Sprague-Dawley rats of each sex were given a single dose of 1000 mg/kg and 2000 mg/kg and observed for signs of toxicity for 15 days. No clinical signs were observed and there were no changes in body weight or changes in organs at necropsy. The LD50 was determined to be above 2000 mg/kg bw.

The notified chemical is considered to be of low acute toxicity via the oral route.

Skin Irritation
Two different skin irritation studies were performed to evaluate effects after 24 hours of exposure and repeated

exposure over 14 days. In the 24-hour study, fur was clipped from the back 6 rabbits and 4 application sites were selected (2 intact and 2 abraded skin sites). 0.5 ml solutions of 90% and 50% test substance in olive oil were applied on occlusive 2.5 cm x 2.5 cm lint patches to both intact and abraded skin sites for a period of 24 hours. Test sites were evaluated according to the Draize scoring method at 1, 24, 48 and 72 hours after exposure. Investigators observed no skin reaction in any animal at any observation time point at either concentration and concluded that the notified chemical was non-irritating to the skin after acute exposure.

In the 14-day evaluation, two sites (approx 2.5 cm x 2.5 cm) were selected on the left and right of the back median line on the previously clipped skin of 3 rabbits. 0.25 ml of 90% and 50% test substance solutions were applied once daily for 2 weeks (14 times total) and the skin was not occluded. The sites were observed before each treatment and at 24 hours after the last treatment on day 14. No skin reactions were observed on any application site at any observation point throughout the study period, and the notified chemical was found to be non-irritating to the skin after repeated exposure.

Based on the above information the notified chemical is considered non-irritating to the skin.

Eye Irritation

In an eye irritation study on 6 male Japanese white rabbits, 0.5 ml of 50% or 90% solution of the notified chemical in olive oil was administered to the conjunctival sac of the right eye of each of 2 groups of animals (3 rabbits per group). 0.1 ml of olive oil was put into the left eyes and served as the control. The cornea, iris and conjunctiva of each animal was macroscopically observed 1, 24, 48 and 72 hours after exposure, and rated according to the Draize score. No irritation was observed in either the right eye (test substance) or left eye (control) of any animal at any observation time point after treatment and the investigators concluded that the notified chemical is non-irritating to the eye.

The notified chemical is considered non-irritating to the eye based on the available information.

Sensitisation

A skin sensitisation test was performed on 20 guinea pigs using induction concentrations of 50% and 90% of the notified chemical. There were no signs of irritation at either concentration after the intradermal injections. The animals were challenged with a topical patch administration of 50% test solution, and the area was occluded for 48 hours. Two weeks after the first challenge, the animals were re-challenged with a topical dose of 50% or 90% test substance solutions, and the test skin sites were occluded for a period of 24 hours. No skin reaction was observed in any challenged site in any of the 20 animals and it was concluded that the notified chemical has no sensitising potential under these test conditions.

The notified chemical is not considered to be a skin sensitiser based on these results.

Repeat Dose Toxicity

No studies on the notified chemical were submitted. Published information is available on a 28-day oral gavage study conducted on a low molecular weight silicone compound hexamethyldisiloxane on 12 rats using a dose of 1500 mg/kg/day (Dow Corning Corp 1994). The report notes that there was no significant difference between the test group and the control group except the relative kidney weights of males treated with hexamethyldisiloxane showed a statistically significant increase when compared to the control. Another study on hexamethyldisiloxane has also reported that histopathological changes were observed in the kidneys when rats were dosed for 13 weeks (SEHSC 2006). Studies on the cyclic silicone chemical octamethylcyclotetrasiloxane (D4) have shown adverse effects after repeated exposure. The liver was identified as the most sensitive target organ in rats and rabbits in resulting in increased liver weights and an increase in liver enzymes (Zhang et al 2000, Falany and Li 2005, Dow Corning 1992). However it is not clear whether liver weight increases indicate adaptive changes or signs of hepatotoxicity (Environment Canada 2008).

On the basis of available data on other low molecular weight silicone compounds, no conclusions can be made on the repeated dose toxicity of the notified chemical.

Mutagenicity

A bacterial reverse mutation test was performed on the notified chemical using *Salmonella* and *E.coli* strains recommended in OECD TG 471, both with and without metabolic activation. The bacterial strains were exposed to up to 5000 µg/plate of the test substance and there was no significant increase in the frequency of revertant colonies in any test plate. It was concluded that the notified chemical has no mutagenicity potential under the experimental conditions. The results of a mutagenicity (Ames) test on Salmonella published by the NTP (1993)

also confirms that the notified chemical has no mutagenicity potential at up to 30% concentration, with and without metabolic activation by rat and hamster liver S9.

A chromosomal aberration test on a mammalian cell line was also conducted using cultured Chinese hamster lung cells (CHL/IU). The cells were exposed to doses of 0.777, 1.554 and 3.107 mg/ml of the test substance with and without S9 for a period of 24 and 48 hours. The report noted that was no difference in incidences of cells with chromosomal aberrations (structural or numerical) in any of the treatment groups in comparison to the negative controls of each respective group, and that the notified chemical has no potential to induce chromosomal aberrations.

Based on the results of these tests, the notified chemical is not considered to be genotoxic.

Toxicity for reproduction

No information on the reprotoxicity of the notified chemical was provided. The cyclic silicone chemical Octamethylcyclotetrasiloxane (D4) has been shown to cause reproductive effects in the rat, associated with inhibition of the luteinizing hormone surge, and has been classified as Category 3 for reproductive toxicity (R62; possible risk of impaired fertility) (HSIS, ESIS). However the relevance of these findings to humans is uncertain, as there are conflicting opinions in this area (SCCP 2005; European Commission 2007). These effects have not been reported in studies on other siloxanes, including lower molecular weight linear siloxanes, such as hexamethyldisiloxane (SEHSC 2000). Published data on another silicone based substance phenyl trimethicone (which may be polymeric) showed that it was not teratogenic to rats and rabbits at 500 mg/kg/day. However an increase in the number of embryonic or foetal resorptions was noted in two of three studies, but this was statistically significant in only one dose. A fetotoxic dose for phenyl trimethicone was established at 200 mg/kg/day (Elder 1986).

On the basis of available data on other low molecular weight silicone compounds, no conclusions can be made on the reproductive toxicity of the notified chemical.

Classification

Based on the available data provided in the summary toxicological reports, the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical will be imported as pre-packaged finished products and the likelihood of worker exposure is very low. However if the notified chemical were to be manufactured or reformulated in Australia, workers may experience inadvertent skin and eye contact, particularly during the mixing and blending process. To minimise exposure, appropriate training and PPE (eye protection, gloves and skin covering) is expected to be worn by workers. Respiratory exposure is also a possibility from inhalation of the vapour of the notified chemical and adequate ventilation is expected to be in place in all areas of handling. The notified chemical is a combustible liquid (flashpoint 61°C), and the notifier notes that enclosed flame-proof mixing tanks should be used as a fire prevention measure. Although there are several possible routes of exposure if the notified chemical were to be locally manufactured or reformulated in the future, given the expected low hazard of the notified chemical based on available data, the overall risk to workers is considered to be acceptable under the proposed conditions.

6.3.2. Public health

The lipstick products are sold to the general public and there will be oral, dermal and possible inhalation exposure to the notified chemical at a concentration up to 15%. Based on available data, the notified chemical is not acutely toxic, irritating or sensitising. *In vitro* mutagenicity and chromosome aberration tests were negative. No information on the effects of long-term exposure is available, and it is not possible to predict the effects from available information on other low molecular weight silicone chemicals. Studies on repeated dose toxicity and reprotoxicity would be required to ascertain the overall risk to the public. However based on the predicted exposure from the proposed use in lipsticks at up to 15% (0.1 mg/kg bw/day), the risk to public health is not considered unacceptable.

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. It is imported as a component of a finished cosmetic product (lipstick) in 4 g containers. The notifier does not intend to reformulate the notified chemical in Australia, however, information for release of the notified chemical from reformulation was provided.

There is unlikely to be any significant release to the environment from storage and reformulation of the notified chemical, given the proposed relatively low level use for the product containing the notified chemical, the formulation and closed dispensing systems. Accidental releases during product formulation should be dealt with as described under Occupational Emergency Procedures. It is estimated that 1% of the finished product goes into the garbage collection system as dry waste.

RELEASE OF CHEMICAL FROM USE

Given the use pattern of the product containing the notified chemical, and the removal of lipstick via some ingestion and on tissues, initial release is mainly expected to occur to atmosphere and landfill (which will eventually migrate to the atmosphere due to the volatile nature of the notified chemical). Some losses will take place in bathrooms, but disposal to the sewage system will be limited. The final product will have a wide dispersive use and the fraction released to the aquatic environment can be expected to be low.

RELEASE OF CHEMICAL FROM DISPOSAL

Any release including residues in tissues and unused lipstick will be disposed of to landfills.

7.1.2 Environmental fate

As the notified chemical is volatile and used in cosmetics, most of the chemical is expected to be released to the air compartment of the environment. In the atmosphere, the notified chemical is expected to be photodegraded to dimethylsilanediol, and ultimately, to inorganic silicate and carbon dioxide (Dow Corning 1998).

While direct release is unlikely to be to sewer, if it does then the chemical is likely to reside initially in the non-aqueous phase. Consequently, if it gets into a sewage treatment plant, the chemical will end up in sludge or volatilize. According to SEHSC (2006), 80-90% of octamethylcyclotetrasiloxane (D_4) used in personal care application will evaporate after application. In soil, D_4 degrades or volatilizes within a week, and will ultimately degrade into inorganic silicate, water and carbon dioxide. The notified chemical is expected to have a similar environmental fate given its similarity in chemical structure to D_4.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC has not been calculated given the limited potential for release of the notified chemical to aquatic ecosystems.

7.2. Environmental effects assessment

As no ecotoxicological data have been submitted, the PNEC has not been calculated.

7.3. Environmental risk assessment

The major fraction of the imported quantity of notified chemical is expected to volatilize into air and finally degrade into small molecules. No significant amounts of the notified chemical will be released to aquatic ecosystems. As there is no significant aquatic exposure based on the current use pattern, the notified chemical is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Flammable liquid	4	Combustible liquid

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

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the low potential for aquatic exposure and the diffuse release pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical if introduced in the liquid form:
  - Appropriate ventilation should be in place to reduce vapour levels
  - Use flame-proof tanks for mixing and blending and keep away from ignition sources

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical if introduced in the liquid form:
  - Gloves
  - Eye protection
  - Coveralls/aprons

  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 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.

- The notified chemical should be handled consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - The notified chemical should be stored consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

Emergency procedures

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

Transport and Packaging

- The notified chemical should be transported in appropriate containers and in compliance with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.

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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from an ingredient in lipsticks and other lip products, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1 tonne, or is likely to increase, significantly;
  - if 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility $< 3.46 \times 10^{-4}$ g/L at 20 ± 0.5°C

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)

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