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

**PUBLIC REPORT**

**Silane, ethenyltris[(1-methylethenyl)oxy]-**

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**

## TABLE OF CONTENTS

SUMMARY .....	3
CONCLUSIONS AND REGULATORY OBLIGATIONS .....	3
ASSESSMENT DETAILS.....	5
1. APPLICANT AND NOTIFICATION DETAILS.....	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION .....	6
4. PHYSICAL AND CHEMICAL PROPERTIES .....	6
5. INTRODUCTION AND USE INFORMATION.....	7
6. HUMAN HEALTH IMPLICATIONS .....	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	7
6.2. Human Health Effects Assessment .....	8
6.3. Human Health Risk Characterisation .....	8
6.3.1. Occupational Health and Safety .....	8
6.3.2. Public Health.....	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment .....	9
7.1.1. Environmental Exposure.....	9
7.1.2. Environmental Fate .....	9
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration.....	10
7.3. Environmental Risk Assessment.....	10
<u>Appendix A: Physical and Chemical Properties</u> .....	11
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS</u> .....	12
B.1. Acute toxicity – oral.....	12
B.2. Acute toxicity – inhalation.....	12
B.3. Repeat dose toxicity .....	13
BIBLIOGRAPHY.....	15

## 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/1628	Threebond Singapore (Australia)	Silane, ethenyltris[(1-methylethenyl)oxy]-	ND*	≤ 0.36 tonnes per annum	Adhesive for automotive industries

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard classification**

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 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 in the proposed manner, 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, the notified chemical is not considered to pose an unreasonable risk to the environment.

### **Recommendations**

#### REGULATORY CONTROLS

#### CONTROL MEASURES

##### Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to acetone released during use of products containing the notified chemical:
  - Good general ventilation including local exhaust ventilation where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the products containing the notified chemical:
  - Avoid inhalation of vapours
  - Avoid contact with skin and eyes
- 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 use of products containing the notified chemical:
  - Coveralls
  - Safety glasses
  - Impermeable gloves

Guidance in 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.

#### 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;
  - the notified chemical is imported in any form other than as a component of adhesives for automotive industries;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from adhesive for automotive industries, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 0.36 tonnes per annum, or is likely to increase 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 product containing the notified chemical provided by the notifier was 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)

Threebond Singapore (Australia) (ABN: 13 062 564 229)  
2/38 Jellico Drive  
SCORESBY VIC 3179

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 for all physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Notified Chemical: VPS, V-PS, VIPS

Mixture containing the notified chemical: TB-1280E, TB-1216E, TB-1282B, Toyota Seal Packing, TB-1207C, TB-1207D

CAS NUMBER

15332-99-7

CHEMICAL NAME

Silane, ethenyltris[(1-methylethenyl)oxy]-

OTHER NAME(S)

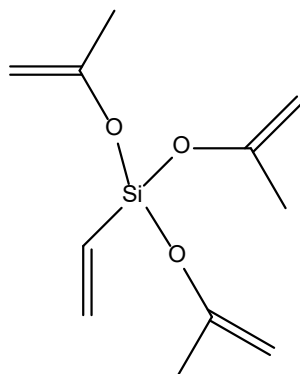
Vinyltris(isopropenyloxy)silane

Tri(isopropenyloxy)vinylsilane

MOLECULAR FORMULA

C<sub>11</sub>H<sub>18</sub>O<sub>3</sub>Si

STRUCTURAL FORMULA



MOLECULAR WEIGHT  
226.34 Da

### 3. COMPOSITION

DEGREE OF PURITY ~95%

#### IMPURITIES

*Chemical Name* 2-Propanone  
*CAS No.* 67-64-1 *Weight %* < 1  
*Hazardous Properties* R36: Irritating to eyes  
 R66: Repeated exposure may cause skin dryness or cracking  
 R67: Vapours may cause drowsiness and dizziness

*CHEMICAL NAME* Disiloxane, 1,3-diethenyl-1,1,3,3-tetra[(1-methylethenyl)oxy]-  
*CAS No.* Not assigned *Weight %* < 1  
*Hazardous Properties* Unknown. Expected to be similar to notified chemical.

ADDITIVES/ADJUVANTS  
None

### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear, colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 0 °C	Estimated. Liquid at ambient temperature.
Boiling Point	198 °C at 101.3 kPa	(M)SDS
Density	935 kg/m <sup>3</sup> at 25 °C	(M)SDS
Vapour Pressure	9.33 x 10 <sup>-2</sup> kPa at 25 °C	(M)SDS
Water Solubility	Not determined	Rapidly hydrolyses on contact with water
Hydrolysis as a Function of pH	pH 4: Half-life = 0.66 h at 25 °C; pH 7: Half-life < 0.25 h at 25 °C; pH 9: Instantly hydrolysed.	Measured analogue data. The notified chemical rapidly hydrolyses on contact with water, acids and bases to release acetone
Partition Coefficient (n-octanol/water)	Not determined	Rapidly hydrolyses on contact with water
Adsorption/Desorption	Not determined	Rapidly hydrolyses on contact with water
Dissociation Constant	Not determined	Rapidly hydrolyses on contact with water
Flash Point	56 °C at 101.3 kPa	(M)SDS
Flammability	Flammable	Based on flash point
Autoignition Temperature	> 200 °C	(M)SDS
Explosive Properties	Not expected to be explosive	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not expected to oxidise	Contains no functional groups that would imply oxidative properties

#### DISCUSSION OF PROPERTIES

##### *Reactivity*

The notified chemical on contact with water, acids or bases hydrolyses to release a highly flammable gas (acetone) and form siloxane polymer.

##### *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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Flammable Liquids (Category 3)	H226 – Flammable liquid and vapour

## 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 silicone adhesives at  $\leq 5\%$  concentration in the form of highly viscous liquids or pastes.

### 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>	0.33	0.36	0.36	0.36	0.36

### PORT OF ENTRY

Melbourne (by sea)

### TRANSPORTATION AND PACKAGING

The adhesive containing the notified chemical will be imported into Australia in 100-150 g tubes, 330 mL cartridges, and 20 L pails, and transported by road to contracted warehouse and end-users.

### USE

The notified chemical will be used as a cross-linking agent in silicone adhesives for automotive industries.

### OPERATION DESCRIPTION

The silicone adhesives will be applied to automobile parts using an automated robotic unit or by hand. Excessive adhesive will be removed with a cloth.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

##### EXPOSURE DETAILS

Waterside, storage and transport workers may come into contact with the notified chemical as a component of adhesives at  $\leq 5\%$  concentration only in the unlikely event of an accident.

Dermal exposure to the notified chemical at concentrations up to 5% may occur during application of the adhesives containing the notified chemical to the automobile parts.

Whilst inhalation exposure to the notified chemical is not expected given the low vapour pressure, workers may be exposed to vapours of acetone that is released during curing of the adhesive containing the notified chemical. Dermal exposure to acetone may also occur.

Exposure to the notified chemical and the breakdown product acetone will be minimised by the use of safety glasses, impervious gloves and coveralls. Typically, the automobile repair and maintenance work is carried out in an outdoor area or within an automotive repair workshop which is a large area with good natural ventilation. However, local exhaust ventilation or mechanical ventilation may be required where general ventilation is inadequate to prevent inhalation exposure to acetone.

Once the adhesives are cured and dried, the notified chemical becomes bound within a silicone matrix and will be unavailable for exposure.

#### 6.1.2. Public Exposure

The notified chemical is intended for industrial use only. The public may come into contact with the cured adhesive containing the notified chemical. However, once cured and dried, the notified chemical becomes

bound within a silicone matrix and will be unavailable for exposure.

## 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.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 20 mL/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 4.31 mg/L/4 hours; low toxicity
Rat, repeat dose inhalation toxicity – 93 days	NOEL 0.081 mg/L 6 hours/day

### *Toxicokinetics.*

The notified chemical has a low molecular weight (226.34 Da) and rapidly hydrolyses to form acetone and siloxane polymer. Due to this reaction, the notified chemical is expected to undergo hydrolysis if in contact with mucous membranes lining the respiratory system, eyes and to a lesser extent the skin. Given the low molecular weight, the notified chemical may be absorbed by all routes. This is supported by the evidence of toxicity in the acute oral study and the 93 day repeat dose inhalation study.

### *Acute toxicity.*

The notified chemical was found to be of low acute oral toxicity in a study conducted in rats (LD50 > 20 mL/kg bw). There was one mortality out of 20 animals tested and light discoloured kidneys were noted for all animals.

The notified chemical was found to be of low acute inhalation toxicity in a study conducted in rats (LC50 > 4.31 mg/L/4 hours). There were no mortalities and treatment related effects were limited to slight apathy and piloerection on the day of treatment only.

### *Irritation and sensitisation.*

No information on the irritation and sensitisation potential of the notified chemical was provided. However, the notified chemical is classified on the European Chemical Agency Classification and Labelling Inventory Database as a skin (H315), eye (H319) and respiratory irritant (H335).

The notified chemical does not contain a structural alert for sensitisation.

### *Repeated Dose Toxicity.*

In a 93 day repeat dose inhalation toxicity study in rats, the notified chemical was administered as an aerosol by nose only at doses of 0.0078, 0.081 and 1.105 mg/L. No mortalities were recorded during the period of study. There were no changes of toxicological significance in clinical chemistry, haematology and urinalysis. No changes in organ weights were noted in any group at the end of study. However the relative lung weights were significantly increased in male animals only in the high dose group. Histopathological findings revealed there were alveolar macrophage aggregations and associated chronic interstitial pneumonia and alveolar epithelisation in the high-dose group. These findings were considered to be treatment-related and indicative of lung lipidosis. The No Observable Effect Level (NOEL) was therefore established as 0.081 mg/L in this study.

### **Health hazard classification**

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004)*.

## 6.3. Human Health Risk Characterisation

### 6.3.1. Occupational Health and Safety

Based on available information, the notified chemical is a skin, eye and respiratory irritant and may also present as an inhalation hazard from repeated exposure. Systemic toxicity from repeated exposure by the oral and dermal route cannot be ruled out, although the notified chemical was found to be of low acute oral toxicity.

The notified chemical also releases acetone vapour during curing. Acetone is an eye irritant and a defatting agent to the skin, and is of low acute oral (LD50 (rat) 8,400 mg/kg bw) and inhalation (LC50 50,000 mg/m<sup>3</sup>) toxicity (OECD SIDS, 1999). However, vapours may cause drowsiness and dizziness.

During application of the silicone adhesive products containing the notified chemical, there is potential for



dermal exposure to the notified chemical at < 5% concentration. Inhalation exposure is not expected given the low vapour pressure of the notified chemical and high viscosity of the adhesive in which it is contained. The main risk posed by the notified chemical is therefore as a skin and eye irritant. Given the low concentration in the silicone adhesive product the risk of irritation should be low.

Risk of systemic toxicity from repeated dermal exposure to the notified chemical is not expected given the low concentration (< 5%) in the silicone adhesive products and the use of PPE including impermeable gloves and coveralls.

There is also potential dermal and inhalation exposure to acetone released during curing. Given the low hazardous nature of acetone, the expected low concentration released and control measures in place to reduce exposure (PPE and mechanical or local ventilation where general ventilation is considered inadequate), the risk to workers health is not considered unreasonable.

Overall, the risk to works from use of the notified chemical under the occupational settings described is not considered unreasonable.

### **6.3.2. Public Health**

The silicone RTV adhesive containing the notified chemical will be used in automobile industries and will be only used by qualified workers. The notified chemical after application on automobile surfaces would be cured and dried, thus it is expected that there would be no public exposure. As such, the risk to the public from the use of the notified chemical 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 be imported into Australia as a minor ingredient in finished products (one-part silicone RTV adhesive) for automotive industries. No reformulation of the notified chemical is expected to occur in Australia. Minor releases can be expected from accidental spills and leaks during transport only, which are expected to be physically contained for disposal to landfill.

##### **RELEASE OF CHEMICAL FROM USE**

Upon application as an adhesive, the notified chemical will react rapidly and become part of the cured inert adhesive matrix. No significant release of the notified chemical to the aquatic compartment is expected from use. Small amounts of accidental spills and leaks are expected to be physically contained for disposal to landfill.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

The notified chemical will be used as part of adhesives to the automobile surface and will share the fate of the joined plastic or metal articles. At the end of the useful life, the articles are expected to be sent to landfill or thermally recycled for reuse of the plastics or metal material. Hence the associated notified chemical is expected to be sent to landfill or thermally decomposed. Empty containers are expected to be sent to landfill, and the residual notified chemical contained is expected to be fully cured prior to disposal. Therefore, no environmental release of notified chemical is expected from disposal.

#### **7.1.2. Environmental Fate**

No environmental fate data were submitted for the notified chemical. The majority of the notified chemical is expected to be associated with automotive surface as part of the adhesive matrix. The notified chemical is expected to readily hydrolyse on contact with water, generating acetone. For details please refer to Appendix A. Since the notified chemical is expected to be cured upon application and become inert part of the adhesives matrix, it is not expected to be bioavailable to aquatic organisms.

Some of the notified chemical is expected to be sent to landfill with the joint automotive surface articles at the end of their useful life, or as collected spills/leaks and residues in containers. The remainder may be thermally decomposed in the processes for plastic or metal articles recycling. In either way, the notified chemical is expected to be degraded/decomposed into water, and oxides of carbon and silicon.

**7.1.3. Predicted Environmental Concentration (PEC)**

Calculation of the Predicted Environmental Concentration (PEC) is not considered necessary since no significant release of the notified chemical to the aquatic environment is expected from the proposed use pattern.

**7.2. Environmental Effects Assessment**

No ecotoxicity data were submitted. This is considered acceptable given no significant release of the notified chemical to the aquatic environment is expected from the proposed use pattern.

**7.2.1. Predicted No-Effect Concentration**

The Predicted No-Effect Concentration (PNEC) has not been calculated since no significant release of the notified chemical to the aquatic environment is expected from the proposed use pattern.

**7.3. Environmental Risk Assessment**

A Risk Quotient (PEC/PNEC) has not been calculated since no significant release of the notified chemical to the aquatic environment is expected from the proposed use pattern and no ecotoxicity data is available for the notified chemical.

Since there is expected to be very limited exposure to aquatic organisms, the notified chemical is therefore not considered to pose an unreasonable risk to the aquatic environment based on the assessed use pattern.

### Appendix A: Physical and Chemical Properties

**Hydrolysis as a Function of pH**      Half-life = 0.66 h at 25 °C and pH 4, < 0.25 h at 25 °C and pH 7, and instantly hydrolysed at pH 9.

Method      OECD TG 111 Hydrolysis as a Function of pH

<i>pH</i>	<i>T</i> (°C)	<i>t</i> <sub>1/2</sub> <hours>
4	15	1.59
	25	0.66
7	15	> 90% hydrolysis reached
	25	within 0.25 hours
9	25	hydrolysis completed upon solution preparation

Remarks      The test was conducted on tri(isopropenyloxy)phenylsilane, which is considered to be an acceptable analogue of the notified chemical with respect to the hydrolysis properties. The test was conducted at 10 mg test substance/L in buffer solutions of pH 4, 7 and 9, with temperatures of 15 °C (pH 4 and 7 buffers only) and 25 °C. High performance liquid chromatography (HPLC) was used for quantitative analysis of the test solutions. Regression analysis of the test data was used for determination of the hydrolysis constant. The test results indicated the half-life for hydrolysis is ≤ 1.59 hours in the pH range of 4 – 9 at temperatures 15 °C and 25 °C.

Test Facility      CITI (1992)

**APPENDIX B: TOXICOLOGICAL INVESTIGATIONS****B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Wistar
Vehicle	Undiluted
Remarks - Method	Initial screening was conducted in order to find the general level of acute toxicity of the test liquid. Test procedure suggests OECD TG 401 guidelines were followed for this study. No details on food and water consumption were available.

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose ml/kg bw</i>	<i>Mortality</i>
1	10F	20	0/10
	10M	20	1/10

LD50	> 20 mL/kg bw
Signs of Toxicity	One male rat died after 2 days. Sluggishness, signs of ataxia and rough coat were observed in the first 24 hours after treatment. Thereafter the rats gradually recovered and appeared healthy at the end of the observation period. There was no treatment-related body weight change.
Effects in Organs	Light, discoloured kidneys in all rats. No other treatment related gross alterations were seen.
Remarks - Results	There was one mortality and discolouration of the kidneys was observed in all animals indicating the notified chemical can be absorbed across the gastrointestinal tract. Given the low mortality rate (1/20) at a dose of 20 mL/kg bw, the notified chemical is considered to be of low toxicity via the oral route.

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

TEST FACILITY TNO-CIVO (1983)

**B.2. Acute toxicity – inhalation**

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	Rat/Albino Wistar
Method of Exposure	Nose-only exposure.
Exposure Period	4 hours
Physical Form	Aerosol
Remarks - Method	No deviations from the study protocol were noted. The aerosol generation system was chosen in order to achieve the required aerosol concentrations with a mass median aerodynamic diameter of 3 µm or less.

## RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration mg/L Actual</i>	<i>Mortality</i>
1	5F	4.31	0/5
	5M	4.31	0/5

LC50 > 4.31 mg/L/4 hours

Signs of Toxicity	Slight clinical signs (apathy and piloerection) were observed in male and female rats on the day of treatment only.
Effects in Organs	There were no macroscopic findings upon necropsy.
Remarks - Results	There were no mortalities and limited treatment related effects when exposed to the notified chemical at 4.31 mg/L/4 hours indicating that the notified chemical is of low toxicity by inhalation.
CONCLUSION	The notified chemical is of low toxicity via inhalation.
TEST FACILITY	RCC (1989a)

### B.3. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 413 Subchronic Inhalation Toxicity: 90-day Study.
Species/Strain	Rats/SPF-Wistar
Route of Administration	Inhalation – nose only
Exposure Information	Total exposure: 93 days Dose regimen: 5 days per week Duration of exposure (inhalation): 6 hours/day Post-exposure observation period: Not conducted.
Physical Form	Aerosol
Particle Size	3 µm
Remarks - Method	A 14-day repeated dose inhalation toxicity range finding study (5 males and 5 females per group, 5 days/week, 6 hours/day) was carried out by the study authors at exposure doses of 0.2, 1.0 and 5.0 mg/L air concentration in rats (RCC, 1989b). Possible treatment-related histopathological findings were recorded in two females at the highest dose. In one kidney of each of these rats, moderate necrosis of the proximal tubular epithelial cells was noted. Both rats also had a unilateral slight acute pyelitis. At the highest dose, a decrease in body weight and body weight gain in male animals was noted. No other treatment-related effects were noted.

### RESULTS

Group	Number and Sex of Animals	Dose/Concentration mg/l air		Mortality
		Nominal	Actual	
control	15F/15M	-	-	Nil
low dose	15F/15M	0.0249	0.0078	Nil
mid dose	15F/15M	0.289	0.081	Nil
high dose	15F/15M	2.025	1.105	Nil

#### *Mortality and Time to Death*

No mortality was recorded for the duration of study.

#### *Clinical Observations*

No clinical signs were seen in male animals in any group. Starting from week 11, there were clinical signs noted in female animals in the low- and mid-dose group only which included paresis, abdominal skin swelling, alopecia and slight body weight loss (one animal). No treatment related abnormalities were noted in the eyes of any animal at the end of study. No change was observed in body weights or body weight gains in any group. There was no change in food consumption in any of the groups. In males, there was an increase in relative water consumption in the mid- and high-dose groups in weeks 8 and 9. In females, there was a decrease in the same parameter in groups at all doses in week 3.

#### *Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*

The assessment of haematological, biochemical and urinalysis data indicated no changes of toxicological significance at termination of the treatment.

#### *Effects in Organs*

There was no change in organ weights in any group. However the relative lung weights were significantly increased in male animals only in the high dose group. Histopathological findings revealed there were alveolar macrophage aggregations and associated chronic interstitial pneumonia and alveolar epithelisation in the high-dose group. These findings were considered to be treatment-related and indicative of lung lipodosis.

Remarks – Results

Treatment-related effects were only observed in the lung at the high dose and were indicative of lipodosis.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 0.081 mg/L in this study, based on treatment-related effects in the lung indicative of lipodosis.

TEST FACILITY

RCC (1989c)

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