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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dow Corning® 3-3541 Adhesion Promotor

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Director
NICNAS

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FULL PUBLIC REPORT

Dow Corning® 3-3541 Adhesion Promotor

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty. Ltd. (ABN 36 008 444 166)
3 Innovation Rd
Macquarie University Research Park
North Ryde, NSW, 2113

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:
Chemical Name
Other Names
Molecular and Structural Formulae
Molecular Weight
Spectral Data
Purity
Identity of hazardous and non-hazardous impurities
Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Boiling Point
Water Solubility
Vapour Pressure
Hydrolysis as a Function of pH
Partition Co-efficient
Absorption/Desorption
Dissociation Constant
Flash Point
Flammability Limits
Autoignition Temperature
Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA, 1992
Ministry of Environment, Korea, March 2004

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dow Corning® 3-3541 Adhesion Promotor

METHODS OF DETECTION AND DETERMINATION

METHOD IR Spectroscopy

Remarks Peaks consistent with proposed structure.
TEST FACILITY Dow Corning (2001)

3. COMPOSITION

DEGREE OF PURITY
>90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical Dow Corning® 3-3541 Adhesion Promoter is to be imported as a component of the liquid product Dow Corning® 3-3636 Catalyst Grey. The manufacture of the notified chemical and its formulation into Dow Corning® 3-3636 Catalyst Grey will not occur in Australia.

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

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

USE **Non-Confidential**
An adhesion promoter in industrial adhesives.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Dow Corning Australia Pty. Ltd.
3 Innovation Rd
Macquarie University Research Park
North Ryde, NSW, 2113

TRANSPORTATION AND PACKAGING
The notified chemical Dow Corning® 3-3541 Adhesion Promoter will be imported as a component of Dow Corning® 3-3636 Catalyst Grey in 18 kg or 200 kg steel drums and transported by road to the warehouses for storage until required.

The notified chemical is classified as a dangerous good. The imported product is also classified as a dangerous good (Class 3, Flammable Liquid).

5.2. Operation description

Adhesive mixing
The steel drums of liquid product containing the notified chemical (less than 30%) will be transported as required from the warehouse to the production area by forklift. The notifier recommends the solution is pumped by attachment of a hose to the steel drums transferring the liquid to the mixing tank. Following mixing the resultant adhesive contains less than 5% of the notified chemical. The adhesive is not repackaged but is fed through an enclosed system (a pumping line) to the application site. The notifier advises the mixing equipment will typically be cleaned by washing with water and an industrial detergent.

Application
The adhesive containing less than 5% of the notified chemical will be applied using specifically designed compressor-operated guns fed from dedicated pumping lines. The adhesive will be applied by workers using the applicator guns. At this stage no specific industrial end-users have been identified.

However, it is expected to be used in the fabrication of a variety of consumer articles intended for assembly and sale to the public.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hour per day)*	*Exposure Frequency (days per year)*
Stevedoring workers	1-5	1	5
Transport	1-5	2	5
Warehouse	1-5	5	10
Adhesive application	5-15	8	30

Exposure Details

Transport and Warehousing

Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified chemical (up to 30% notified chemical). The product will be handled in the warehouse by forklift handling of drums. During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Adhesive Mixing

The main routes of exposure to the notified chemical (up to 30% notified chemical) are dermal and accidental ocular exposure during attachment and detachment of pumping lines to the steel drums. Dermal and ocular exposure may also occur during cleaning of the mixing tanks after formulation (less than 5% notified chemical). Exposure to significant amounts of the notified chemical is limited because of the engineering controls and the personal protective equipment (PPE) worn by workers. Engineering controls include either local exhaust ventilation, good general ventilation or forced mechanical ventilation. PPE includes safety glasses, gloves, and coveralls.

Application

The main routes of exposure to the notified chemical (up to 5% notified chemical) are dermal and accidental ocular exposure during application of the adhesive to various surfaces. Exposure during application is minimised by the use of PPE including, safety glasses, gloves, and coveralls. During application engineering controls include local exhaust ventilation, good general ventilation or forced mechanical ventilation that further minimises exposure to the notified chemical. Once the adhesive is dried (by air) the notified chemical is cured into an inert matrix and not available to exposure.

Workers have access to the MSDS and attend training courses on the use of PPE and safe working practices.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Since the notified chemical will not be manufactured or reformulated in Australia there will be no releases due to these activities.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical will become crosslinked as the adhesive cures, thus subsequently it will not be released to the environment. During the use of the industrial adhesives containing the notified chemical, the notified chemical may be released mainly via cleaning of application equipment (0.25%, up to 2 kg annually) and in residues in empty containers (0.25%, up to 2 kg annually). The wash-water generated during equipment cleaning will be collected for disposal. Residues in empty containers will be left to harden before disposal. There may be minor releases due to spills.

5.5. Disposal

Cleaning wash-water will be disposed of via a licensed waste contractor who will treat the effluent and subsequently send any solids to landfill or by incineration. Containers, and hardened adhesive, will be disposed of to landfill. The notifier chemical could be disposed of via incineration, if available,

generating water and oxides of carbon, nitrogen and silicon.

Ultimately, the majority of the notified chemical will be disposed of to landfill in the cured adhesive on the article when the article to which the adhesive has been applied comes to the end of its useful life.

5.6. Public exposure

Public exposure to the notified chemical is not expected under normal use conditions as it imported and used under industrial conditions. Exposure to the product containing up to 30% of the notified chemical could occur if an accident occurred in transport. Although the public may contact articles to which the adhesive has been applied the notified chemical will be part of a solid matrix and not available for exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Pale amber liquid.

Melting Point/Freezing Point <20°C

Remarks Test Not Conducted. Liquid at room temperature.

Boiling Point >35°C

Remarks In-house method.

Density 1050 kg/m^3 at 25ºC

METHOD In-house method.

Vapour Pressure Not determined

Remarks Although vapour pressure data was provided for an experimental sample of the notified chemical, the reported vapour pressure value related to impurities no longer present in the notified chemical and as such this value was not considered relevant and has not been reported. The vapour pressure of the notified chemical as produced is expected to be similar to the volatile impurities present (12.3 kPa at 20 ºC), however, this volatile impurity will be stripped off prior to introduction of the notified chemical into Australia. The notified chemical is expected to have a low vapour pressure.

Water Solubility Not determined.

Remarks The notified chemical reacts with water and moisture in air, therefore a test could not be conducted. It is expected that due to its hydrophobic structure that the notified chemical will have a low water solubility.

Hydrolysis as a Function of pH Not determined.

Remarks The notified chemical is unlikely to hydrolyse in the environmental pH range of 4–9 as it contains no groups generally recognised as hydrolysable. However, hydrolysis may occur at extreme pH values.

Partition Coefficient (n-octanol/water) Not determined.

Remarks The notified chemical reacts with water and moisture in air, therefore a test could not be conducted. Reaction products are expected to partition to the organic phase.

Adsorption/Desorption Not determined.

Remarks The notified chemical reacts with water and moisture in air, therefore a test could

not be conducted. Reaction products are expected to associate with soils/sediments.

Dissociation Constant Not determined.

Remarks The notified chemical reacts with water and moisture in air, therefore a test could not be conducted. However, the notified chemical has a potentially cationic group which is expected to have a pKa of 9-10.

Flash Point Not determined

METHOD In-house method.
Remarks Although flash point data was provided for an experimental sample of the notified chemical, the reported vapour pressure value related to impurities no longer present in the notified chemical and as such this value was not considered relevant and has not been reported. The flash point of the notified chemical as produced is expected to be similar to the volatile impurities present (11ºC), however, this volatile impurity will be stripped off prior to introduction of the notified chemical into Australia. The notified chemical is expected to have a flash point > 65 ºC due to the low vapour pressure.

Flammability Not determined

Remarks The notified chemical once the volatile impurities have been stripped off is not expected to be a flammable liquid, however, the notified chemical may produce methanol which is highly flammable on contact with water or humid air.

Autoignition Temperature Not determined

Remarks Typically this class of chemicals have thermal stability, therefore, the notified chemical is not expected to autoignite under normal conditions of use.

Explosive Properties Not expected to be explosive.

Remarks Test Not Conducted. From examination of the structure, there are no chemical groups that would infer explosive properties.

Reactivity

Remarks Reacts with water and moisture. Will react with strong oxidizing agents. If heated >150 °C, trace quantities of formaldehyde may be emitted.

Viscosity 50 cSt (temperature unspecified)

METHOD In-house Test.
Remarks

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, acute dermal	LD50 >2000 mg/kg bw, low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritant
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome Aberration Test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: None. Test-item administered as supplied.
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	1/5

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: There were no remarkable body weight changes during the study period.
- Effects in Organs: No macroscopic findings were recorded at necropsy for animals that survived until scheduled for death.
- Remarks - Results: One female died spontaneously and showed gross tissue changes consistent with acute gastritis with regurgitation and this finding was attributed to be (inspiration of the test-item) a result of oral gavage injury and was not considered a test-item related occurrence.

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

TEST FACILITY — Dow Corning (1990a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Vehicle: None. Test-item administered as supplied.
- Type of dressing: Semi-occlusive.
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	At gross necropsy, all animals showed changes in the skin and subcutis, which consisted of petechial haemorrhages, dermal thickening and yellowish-brown discolouration. This findings were observed on both treated and untreated skin and were attributed to mechanical trauma of handling and/or restraint of the animals and were therefore not considered test-item related.
Signs of Toxicity - Systemic	There were no deaths or test substance related clinical signs or remarkable body weight changes during the study period.
Effects in Organs	No macroscopic findings were observed at necropsy.

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

TEST FACILITY Dow Corning (1990b)

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	4 males
Vehicle	None. Test-item administered as supplied.
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	-	-
Oedema	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

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

TEST FACILITY Dow Corning (1990c)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (two groups of three)
Observation Period	14 days
Remarks - Method	Statement of GLP. There were no significant protocol deviations for Group I animals. However, Group II test eye were washed 30 seconds after the exposure. Fluorescein stain was used to facilitate corneal observations.

RESULTS

GROUP I

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	3	3	3	3	7-14 days	0
Conjunctiva: chemosis	2	3	2	3	3-7 days	0
Conjunctiva: discharge						
Corneal opacity	1.67	1.67	1.67	2	3-7 days	0
Iridial inflammation	1	1	1	1	3-7 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

GROUP II

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.33	0.33	1	2	3-7 days	0
Conjunctiva: chemosis	0.66	0.33	0.66	2	3-7 days	0
Conjunctiva: discharge						
Corneal opacity	0	0	0.66	1	3-7 days	0
Iridial inflammation	0	0	0.33	1	3-7 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results: The severity of the irritation response was reduced in eyes washed with water after 30 seconds.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: Dow Corning (1990d)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

METHOD: EC Directive 1984/No L251, Vol. 27 pp 137-139, Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2

Metabolic Activation System: Aroclor 1254 induced rat liver S9

Concentration Range in Main Test:
Test 1
a) With metabolic activation: Test 1: 312.5 - 5000 µg/plate
b) Without metabolic activation: Test 1: 312.5 - 5000 µg/plate
Test 2
a) With metabolic activation: Test 2: 312.5 - 5000 µg/plate
b) Without metabolic activation: Test 2: 312.5 - 5000 µg/plate

Vehicle: Dimethyl Sulfoxide

Remarks - Method: Statement of GLP.
Deviations from OECD TG471 2: aminoanthracene used as sole indicator of efficacy of the S9 mix.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5000	> 5000	Negative
Test 2	-	> 5000	> 5000	Negative

Present				
Test 1	-	> 5000	> 5000	Negative
Test 2	-	> 5000	> 5000	Negative

Remarks - Results: No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate either in the presence or absence of activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Dow Corning (1990e)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Chinese hamster ovary cells

Cell Type/Cell Line: CHO-K1

Metabolic Activation System: Aroclor 1254 induced rat liver S9

Vehicle: Ethanol

Remarks - Method: Statement of GLP.
No significant protocol deviations.
The dose levels for the main test were chosen based on the results of the preliminary tests where 100% cell growth inhibition was observed in the absence of activation (both 4 and 20 hour exposure) and 27% inhibition in the presence of activation at a concentration of 5000 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	125, 250, 500*, 1000, 2000*, 3000, 4000*	4	20
Test 2	125, 250, 500*, 1000, 2000, 3000, 4000	20	20
Present			
Test 1	500*, 1000, 2000*, 5000*	4	20

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	5000	4000	None	Negative
Test 2	5000	3000	None	Negative
Present				
Test 1	5000	5000	None	Negative

Remarks - Results: A statistically significant increase in with respect to structural aberrations was observed in the 5000 µg/mL dose group with metabolic activation compared to vehicle controls. However, the percentage of aberrant cells (2.5%) was within historical solvent controls and is not considered statistically significant. No other statistically or biologically significant increases in the percentage of cells with numerical or structural aberrations above the vehicle control levels were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the

	sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster ovary cells CHO-K1 treated in vitro under the conditions of the test.
TEST FACILITY	BioReliance (2001)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

Inoculum — Supernatant of sieved, aerated, homogenised activated sludge from Denton Wastewater Treatment Plant.

Exposure Period — 28 days

Auxiliary Solvent — None

Analytical Monitoring — CO_2 production measurement – KOH trapping solution

Remarks - Method — Treatments:

- blank control: inoculum
- reference control: inoculum, sodium benzoate + test substance (10 mg/L) in duplicate
- treatment: inoculum + test substance (10 mg/L) in duplicate
- killed control: inoculum, test substance (10 mg/L) + mercuric chloride (50 mg/L)
- toxicity control: inoculum + test substance (10 mg/L) + reference substance (10 mg/L).

Total suspended solids (TSS) of the inoculum averaged at 133.3 mg/L, thus TSS in the test solution was 1.33 mg/L.
CO_2 traps removed on days 1, 3, 6, 8 10, 13, 15, 20, 23 and 27.

Environmental parameters remained within acceptable ranges: temperature 20-22^{o}C and pH 7.3-7.5.

RESULTS

Day	*Test substance average % TOC evolved (% Degradation)*	*Sodium benzoate average % TOC evolved (% Degradation)*	*Toxicity control % TOC evolved (% Degradation)*
1	0.15	0.45	0.8
3	9.4	34.4	25.5
8	26.5	73.9	55.4
13	38.4	86.4	61.5
20	45.6	94.1	72.8
29	48.1	95.8	80.4

Remarks - Results — By day 8 the degradation of the reference substance exceeded 60% thus meeting the test validity criteria.
The toxicity control evolved approximately 80% TCO_2, thus indicating that the test substance was not toxic to the inoculum.
The killed control did not evolve any measurable CO_2.

CONCLUSION — Under the conditions the study conditions, the test substance was not readily biodegradable.

TEST FACILITY — Wildlife International (2002)

8.1.2. Bioaccumulation

Remarks - Results — This was not determined. The notified chemical has a molecular weight greater than 451 and thus the potential to bioaccumulate but since release to the environment will be low this is not expected.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Only minor amounts of the notified chemical will be released during use of the adhesive. Approximately 4kg of the notified chemical will be disposed of to landfill annually via application equipment cleaning and container residues. In landfill, the notified chemical is likely to become associated with the soil and will not be mobile. The majority of the notified chemical will become part of the inert matrix of the cured adhesive, thus will be disposed of with the article, at the end of its useful life, it has been applied to. A PEC cannot be estimated, however the adhesive will be used across the nation so releases will be diverse and very low.

If the notified chemical is disposed of by incineration, water and oxides of carbon, nitrogen and silicon will be generated.

9.1.2. Environment – effects assessment

No ecotoxicity data were provided, therefore a PNEC cannot be estimated.

9.1.3. Environment – risk characterisation

A risk quotient cannot be estimated. However, due to the limited environmental release and exposure, the risk associated with the use of the adhesive containing the notified chemical is expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

No exposure to the product containing the notified chemical by transport or warehouse workers is expected, except in the case of accidental breaching of the containers.

The notified chemical is not manufactured in Australia and imported only as a component at up to 30% of a product. No repacking of the imported product will occur.

The most likely route of exposure is dermal and/or ocular during transfer of the product containing the notified chemical for mixing of the two part adhesives and during application of the mixed adhesives to various surfaces. Engineering controls such as local exhaust ventilation and the use of PPE should minimise exposure to the notified chemical.

9.2.2. Public health – exposure assessment

The public is not expected to have other than incidental exposure to the notified polymer. It is possible that spills during transport of the adhesive component may lead to accidental exposure. Once the adhesive components are mixed applied and cured to a variety of consumer articles, the notified chemical will be contained in a solid matrix and will not be bioavailable. As such, public exposure is expected to be negligible

9.2.3. Human health – effects assessment

Acute toxicity

The notified chemical is considered to be of low acute toxicity when administered orally or when applied to the skin. No acute inhalation for study was available for the notified chemical, however, based on the acute inhalation studies of the precursor to the notified chemical it is expected that the notified chemical will be of low acute inhalation toxicity. Furthermore, it is expected that the notified chemical has a low vapour pressure and therefore inhalation exposure

would not be expected.

Irritation and Sensitisation

Rabbit studies of eye and skin irritation found that the notified chemical is irritating to eyes but non-irritating to skin. No sensitisation studies were conducted on the notified chemical however an acceptable analogue (no 2) was found to be non-sensitising in an adjuvant type test in guineapigs. In a human patch test on the precursor of the notified chemical there was evidence of skin sensitisation. Unreacted residual precursors of the notified chemical may cause skin sensitisation.

Repeated Dose Toxicity

No repeat dos toxicity studies were conducted on the notified chemical. Short-term repeated exposure (5 days) to trimethoxysilane resulted in high inhalation toxicity. In a 20 day repeat dose inhalation study of trimethoxysilane resulted in chronic inflammatory changes to the lung and dose related change in haematological indices and morphological changes to the bone marrow in treated rates. Changes in leucocyte counts were seen at the lowest dose tested and it was not possible to determine a NOAEL. Methoxy silanes such as trimethoxysilane may produce methanol toxicity. Methanol is metabolised to formaldehyde and formic acid by alcohol dehydrogenase. Formaldehyde and formic acid are highly toxic and produce severe metabolic acidosis, ocular toxicity and neurotoxicity. The notified chemical is expected to have low vapour pressure and therefore inhalation exposure would not be expected, however any unreacted alkoxysilanes contained therein will have similar toxicity to that of trimethoxysilane.

Mutagenicity

The notified chemical was found to be non-mutagenic in the Ames tests. The notified chemical was not clastogenic in an *in vitro* chromosomal aberration tests in cultured CHO cells.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) and assigned the following risk phrases Xi: R36 Irritant: Irritating to eyes.

The notified chemical is not reported to contain any unreacted precursor material or unreacted trimethoxysilane and any impurities are removed prior to introduction into Australia, however, the presence of any impurities should be considered in hazard classification of the notified chemical and/or formulations containing it.

The notified chemical may produce methanol on contact with water or humid air. Methanol is classified as toxic by inhalation, in contact with skin and if swallowed.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is irritating to eyes and any residual impurities have the potential to lead to respiratory irritation and/or sensitisation characteristics. There is potential exposure to workers to the notified chemical via dermal/ocular contact during adhesive mixing and end-use, however, engineering and PPE controls, in conjunction with appropriate safe work practices, are expected to limit dermal and ocular exposure and hence the risk of irritation and potential sensitisation effects. In addition the low concentration of the notified chemical in the adhesive (< 5%) should reduce the irritation effect if contact occurs during application.

The notified polymer is supplied in solution and mixed with other hazardous chemicals, and the precautions against exposure to these chemicals such as adequate ventilation and use of PPE will reduce exposure and risk from the notified chemical, any residual volatile impurities and any formed methanol.

Overall the risk to workers can only be considered low if appropriate controls are in place at all workplaces where the notified chemical is handled or used.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical is expected to be negligible and as such the risk to the public is also considered to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Xi: R36 Irritant: Irritating to eyes;

and

As a comparison only, the classification of 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***
Irritant	2B	Mildly irritating to eyes

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as a component of industrial adhesives.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health, and physico-chemical hazard classification for the notified chemical:
  - Xi: R36 Irritant: Irritating to eyes;

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20%: risk phrases Xi: R36 Irritant: Irritating to eyes

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in the product Dow Corning® Q3-3636 Catalyst Grey
  - Handling to be carried out under mechanical ventilation where possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in the product Dow Corning® Q3-3636 Catalyst Grey and formulated adhesive products:
  - Avoid eye contact;
  - Avoid breathing vapour;
  - Avoid spills and splashes, and clean up any spilt material promptly.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product Dow Corning® Q3-3636 Catalyst Grey and formulated adhesive products:
  - Protective clothing and equipment to prevent dermal and/or ocular exposure during all processes;
  - Appropriate respiratory protection where adequate ventilation is not available.

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end-user to minimise environmental exposure during use of the notified chemical:
  - The adhesive should be used in a controlled environment,
  - All wash-water should be disposed of via licensed waste contractors and NOT placed down drains.

Disposal

- The notified chemical should be disposed of via licensed waste contractors to landfill or incineration, where available.

Emergency procedures

- Spills and accidental release of the notified chemical should be handled by containment and collection as indicated in the MSDS.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical; or

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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