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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NXT Silane/Chemical in Carbo NXT Silane

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

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

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Director
NICNAS

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NXT Silane/Chemical in Carbo NXT Silane

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Momentive Performance Material Australia Pty Ltd (ABN 47 105 651 063) of 175 Hammond Road, Dandenong, VIC, 3175.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Identity
Spectral data
Identity of impurities
Introduction Volume
Identity of Recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Europe (2001/2002), Canada (2004), Japan (2004), China (2006). The notified chemical is subject to a Significant New Activity Notice in Canada.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NXT Silane
Carbo NXT Silane (50% notified chemical on carbon black)

METHODS OF DETECTION AND DETERMINATION

METHOD	Gas chromatography-mass spectroscopy (GC-MS), Infrared Spectroscopy, Nuclear Magnetic Resonance (NMR), UV-Vis spectroscopy
Remarks	Reference spectra provided
TEST FACILITY	RCC (2001a)

3. COMPOSITION

DEGREE OF PURITY
93-96%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities are present below the relevant cut-offs for classification of the mixture as a hazardous substance.

ADDITIVES/ADJUVANTS
A granular form of the notified chemical Carbo NXT Silane contains 50% notified chemical and 50% carbon black.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is not manufactured in Australia. It is imported in liquid form (NXT Silane) and as a component of a granular form (Carbo NXT Silane).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5	< 10	< 20	< 20	< 50

USE
The notified chemical is used as an additive to tyre rubber to improve performance.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne & Adelaide

IDENTITY OF MANUFACTURER/RECIPIENTS
Tyre manufacturing facilities in South Australia and Victoria.

TRANSPORTATION AND PACKAGING
To be imported by sea and by road to the warehouse of the notifier then to recipients. NXT Silane will be packed in 1 tonne IBCs (Intermediate Bulk Containers), 200 L drums, 55 kg drums or 20 kg pails. Drums are stretch wrapped on pallets. Carbo NXT Silane will be imported in 1 tonne bulky bags or 25 kg polythene lined fibreboard cartons.

5.2. Operation description

Imported IBCs, drums, pails, bags or cartons will be taken from the warehouse to the production floor. The outlet stopcock of the IBC will be connected by hose to a pump and liquid will be pumped from the IBC to the production holding tank and then metered in-line to the rubber compounding mixer from this tank. In the case of drums, the bung would be removed and the material will be pumped via a hose and lance to the production holding tank (day tank) and then metered to the tread rubber compounding mixer. Transfer mechanisms from the pails are unknown and are assumed to be manual. Carbo NXT Silane will be scooped out of the import container with a hand scoop into a vessel where it is weighed and then poured into the mixer.

The notified chemical is mixed with rubber polymers, silica and other additives. The notified chemical is used at levels between 5 to 10% of the tread rubber content or approximately 0.5% to 1% of the tyre. The silica filler is used at levels of 35 to 45% of the rubber content. During the mixing operation, the substance reacts with the silica. After the notified chemical has been added, silica and other additives are mixed with the rubber, and curatives including sulphur and accelerators are added. The compound is calendered and extruded into long strips. These strips are taken to a tyre-making machine, where a tyre is built by wrapping the strips around the tyre carcass. The compound is then heated in a mould to cure the rubber and produce the tyre.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration <hours per day>*	*Exposure Frequency <days per year.*
Transport and storage	2	0.5	50
Process workers / operators	3	20 x 0.25 = 5	50
QC sampler	1	0.25	50
QC laboratory workers	1	0.5	15

Exposure Details

The liquid form of the notified chemical is transferred to the day tank using manual transfer (for pails), a pump and lance (for drums) or direct connection (for IBCs) and from the day tank to the mixer using a closed liquid dosing apparatus and mixed with the rubber, silica and other compounds in a closed system. There is potential for exposure via all routes during transfer to the day tank but exposure is unlikely thereafter. To control potential exposure, local exhaust ventilation is used during weighing and transfer and to capture any vapours during the mixing process. Inhalation exposure of the notified chemical itself is expected to be limited due to the low vapour pressure of the notified chemical.

When handling the Carbo NXT Silane granules containing the notified chemical, local exhaust ventilation systems are used to remove possible fugitive dust from all emission points and to extract any vapours that are formed during the mixing process. Inhalation exposure of the notified chemical itself is expected to be limited due to the low vapour pressure of the notified chemical and the particle size of the Carbo NXT Silane.

Dermal exposure is controlled by the use of gloves, goggles and protective clothing for either the liquid or granular form containing the notified chemical.

The notified chemical reacts with the silica during the rubber mixing process. During the curing process, the notified chemical also reacts with the rubber and is totally bound within the rubber so that exposure is no longer likely.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No manufacturing or reformulation will take place in Australia.

RELEASE OF CHEMICAL FROM USE

It is expected that approximately 80% (<40 tonne per annum) of the notified chemical will be imported in liquid form and 20% (< 10 tonne per annum) in granular form. All of the processes for both the liquid and granular form occur in enclosed systems. The release is therefore expected to be minimal. Similarly the notified chemical has low vapour pressure (0.002 Pa @ 25°C) and minimal release to the atmosphere is expected.

The IBCs, drums and pails in which the material is imported, will be thoroughly drained and rinsed with a process fluid that is added to the tread compound mixer. Assuming that approximately 1% residue will remain in the packaging after draining and that 95% of the residue will be removed by rinsing of the containers, then the final amount of residue will be 0.05% (<20 kg per annum). The IBCs and drums are expected to be sent to a drum recycling facility.

The bags containing the granular form will be shaken out thoroughly. Assuming that 50 g remain in each 25 kg bag with similar relative amounts in the 1 tonne bulky bags, then approximately 0.2% (< 20 kg per annum) of notified chemical (present on the remaining carbon black), will require disposal.

The equipment will require cleaning and maintenance. Fluid used for cleaning operations is expected to be reserved for charging to the next batch of tread rubber, to the extent practicable.

Spills and other releases are expected to amount to less than 0.3% (< 150 kg per annum). These are expected to be reused to the extent practicable, with the remainder being disposed of by licensed contractor in accordance with Federal, State and local legislation.

In the unlikely event that a spill reaches the drains at the manufacturers' facilities it will be treated in the trade waste system with negligible release to sewer.

5.5. Disposal

Liquid waste in drums is expected to be disposed of by licensed drum recyclers. Similarly any amount collected from spills is expected to be treated by licensed contractor.

The residual in packaging for the granular form is expected to be disposed of to authorised landfill.

The ultimate fate of the vast majority of the notified chemical is the reaction with silica and rubber. The fate of the silica reinforced rubber will be shared with the fate of the tyres. Tyres at the end of their useful lives may be disposed of to landfill, re-treaded, recycled for low grade rubber crumb, or possibly used as fuel in cement kilns (NOLAN-ITU, 2004). The notifier estimates that approximately 50% of tyres are recycled.

5.6. Public exposure

The potential for public exposure to the notified chemical during transport, reformulation or disposal is assessed as low. Members of the public making occasional dermal contact with tyres manufactured using the notified chemical will not be exposed to it as the notified chemical reacts during tyre manufacture and is expected to be totally bound within the rubber. Tyre particles from wear of tyres during normal functioning on roads could potentially be inhaled or ingested. Approximately 10% of PM_{10} (Particulate matter with < 10μm diameter) particulates in the urban environment may be tyre dust. Whilst the notified chemical is used at levels of up to 1% in the tyre, the notified chemical reacts during tyre manufacture and is therefore is expected to be totally bound within the rubber.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Pale yellow liquid

Melting Point/Freezing Point < -70°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined visually and by thermal analysis. The test item did not freeze during the conditions of the test (cooled to – 70°C)
TEST FACILITY	RCC (2001b)

Boiling Point > 320°C at 101.3 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined by Differential Scanning Calorimetry. The test substance did not boil under the conditions of the test. An exothermic effect was observed starting at about 320°C. After the experiment, the sample had lost about 93% of its mass and the colour of the sample residue was changed to yellow.
TEST FACILITY	RCC (2001c)

Density 968.6 kg/m^3 at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using an oscillating densitometer.
TEST FACILITY	RCC (2001d)

Vapour Pressure 2 x 10^{-6} kPa at 25°C

METHOD	OECD TG 104 Vapour Pressure.

	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using the Gas Saturation Method. Vapour pressure measured as 3.95×10^{-2}, 1.04×10^{-1} and 3.07×10^{-1} at 50ºC, 60ºC and 70ºC respectively. Vapour pressure at 25ºC extrapolated by linear regression. No test could be conducted at 25°C due to the test substance's low vapour pressure.
TEST FACILITY	RCC (2001e)

Water Solubility <0.28 g/L at room temperature

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	During the preliminary test no dissolution was observed after 24 hours of stirring. The notified chemical contains nearly all hydrophobic groups and is therefore likely to have low solubility in water.
TEST FACILITY	RCC (2001f)

Fat (or n-octanol) Solubility > 5000 mg/100 g in n-octanol

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water) EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Preliminary tests by visual inspection determined the test substance to have solubility in n-octanol of > 5000 g/L.
TEST FACILITY	RCC (2001 g)

Surface Tension 52.1 mN/m at 20.1±0.2ºC

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions EC Directive 92/69/EEC A.5 Surface Tension, using the ring method.
Remarks	Concentration: 0.1 %
TEST FACILITY	RCC (2001 h)

Hydrolysis as a Function of pH Not determined

METHOD	Expert statement provided.
Remarks	The notified chemical is expected to be unstable to hydrolysis. As no analytical technique exists for analysing the test substance or its degradates, Gas Chromatography (GC) analysis was not applicable. Furthermore the buffer solution suitable to stabilise the test substance is unsuited to GC analysis, with the test substance likely to degrade in the carrier for GC analysis.
TEST FACILITY	RCC (2001i)

Partition Coefficient (n-octanol/water) log Pow = > 4.2 (Temperature not specified.)

METHOD	Direct measurement of solubility in n-octanol and comparison with solubility in water. Compliant with OECD TG 117 Partition Coefficient (n-octanol/water) EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Preliminary tests by visual inspection determined the test substance to have solubility in water and n-octanol of < 0.28 g/L and > 5000 g/L respectively. (See relevant sections above)
TEST FACILITY	RCC (2001g)

Adsorption/Desorption – screening test log K_{oc} ~ 3.66 or higher. (Temperature not specified.)

METHOD	Not Tested.
Remarks	The estimation was based on the log Kow value and estimated from the regression log Koc = 0.544 log Pow + 1.377 (Lyman et al.).
TEST FACILITY	RCC (2001j)

Dissociation Constant Not determined

Remarks The notified chemical does not contain any functional groups likely to dissociate in the environmental pH range (4-9).

TEST FACILITY

Particle Size Not determined.

Remarks Not applicable to a liquid.

Particle size of a related product also carried as 50% on Carbon black is 200 µm – 2 mm.

Flash Point 176ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Determined using Pensky-Martens closed cup test. The notified chemical is classified as a C2 combustible liquid according to NOHSC *National Code of Practice for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001).
TEST FACILITY RCC (2001k)

Flammability Limits Not determined

Remarks Based on the flash point the notified chemical is not classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998)

Autoignition Temperature 240ºC (rounded down)

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY ISS (2002)

Explosive Properties Not predicted to be explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Test not conducted. From examination of the structure, there are no chemical groups that would infer explosive properties. The exothermic decomposition temperature was determined using differential scanning calorimetry. One very small exothermic peak was detected starting at about 225ºC. The decomposition energy was found to be 23 J/g. Substances are not considered to be self-reactive substances (Class 4.1 Dangerous Goods) if their heat of decomposition is less than 300 J/g.
TEST FACILITY RCC (2001l)

Oxidising Properties Not predicted to be oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Based on the oxygen balance (negative), it was concluded beyond reasonable doubt that the notified chemical is incapable of causing fire or enhance the risk of fire when in contact with combustible material.
TEST FACILITY RCC (2001m)

Reactivity

Remarks The notified chemical is expected to be stable under normal conditions of storage and transport but will decompose and autoignite at high temperatures. The notified chemical reacts with the silica during use releasing ethanol.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute dermal	low toxicity, LD50 > 2000 mg/kg bw
Rat, acute inhalation	not determined
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	inadequate evidence of sensitisation
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Human, skin sensitisation – repeat insult patch test	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 150 mg/kg bw/day/NOEL 30 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	non genotoxic
Genotoxicity – in vivo	not determined

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method – Limit Test EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method – Limit Test
Species/Strain	Rat/HanBrl: Wist
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 female	2000	0
II	3 male	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs or remarkable bodyweight changes were observed during the course of the study.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks - Results	The LD50 cut-off estimated using the flow chart in annex 2d of the OECD TG423 would be $\geq$ 5000 mg/kg bw
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC (2001n)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/HanBrl: Wist
Vehicle	Test substance administered as supplied.
Type of dressing	Semi-occlusive.

Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No local signs of toxicity were observed during the study period.
Signs of Toxicity - Systemic	No systemic signs of toxicity were observed 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	RCC (2001o)

7.3. Acute toxicity – inhalation

Not determined. The notified chemical is of low vapour pressure and does not contain particles within the respirable range. Hence inhalation toxicity is not necessary for this assessment as inhalation exposure is not considered to be significant.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	1 male/2 females
Vehicle	Test substance administered as supplied
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.33	1.67	0.33	2	< 7 days	*0*
Oedema	0	0	0	0	N/A	0

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

Remarks - Results	Well-defined erythema was observed in all animals 1-hour after treatment. Slight to well-defined erythema persisted in one animal up to 24-hour reading and in the other two animals up to the 72 hour reading. No clinical signs of systemic toxicity were observed during the study and no mortality occurred.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	RCC (2001p)

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	1 male/2 female
Observation Period	72 hours
Remarks - Method	No significant protocol deviations. Statement of GLP.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	0.67	0	1	< 72 hr	0
Conjunctiva: chemosis	0	0	0	1	< 24 hr	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results	Slight reddening of the conjunctivae was observed in all animals 1 hour after treatment and persisted in two animals up to the 48-hour reading. A single incidence of swelling of the conjunctivae was also noted in the male 1 hour after treatment. No abnormal findings were noted in the cornea or iris. All effects had reversed by the 72-hour reading. No clinical signs of systemic toxicity were observed during the study and no mortality occurred.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	RCC (2001q)

7.6.1. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Modified Buehler Method EC Directive 96/54/EC B.6 Skin Sensitisation – Modified Buehler Method
Species/Strain	Guinea pig/Hartley [Crl:(HA)BR)
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 10% in dried peanut oil (very slight dispersed erythema observed)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 5
INDUCTION PHASE	Induction Concentration: topical: 100% (test substance administered as supplied)
Signs of Irritation	Very slight to discrete erythema was observed in all animals 24 and/or 48 hours after each induction. Moderate erythema was observed in one male 24 hours after the third induction.
CHALLENGE PHASE	
1st challenge	topical: 10% test substance in dried peanut oil

2nd challenge Not performed

Remarks - Method Deviation from Protocol:

80% ethanol/water is the preferred vehicle for induction and acetone for challenge. Where alternative vehicles are proposed, vehicles should be non-irritating. This is not the case with the chosen vehicle.

Statement of GLP.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	10%	20/20	20/20	-	-
	0% (vehicle only)	19/20	20/20	-	-
Control Group	10%	10/10	10/10	-	-
	0% (vehicle only)	10/10	10/10	-	-

Remarks - Results The incidence and severity of reactions was similar between test animals and control animals challenged with the test substance. The incidence and severity of reactions was similar when animals were challenged with the test substance and the vehicle only.

CONCLUSION The notified chemical may have skin sensitising ability but the test conditions employed are inadequate. On the basis of inadequate evidence, no conclusion is made.

TEST FACILITY WIL (2001)

7.6.2. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Maximization Test
EC Directive 96/54/EC B.6 Skin Sensitisation – Maximization Test

Species/Strain Guinea pig/Himalayan Spotted

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: discrete or patchy erythema observed at 25, 50 and 100%.
topical: 100%

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal: 100%
topical: 100%

Signs of Irritation The test sites were pre-treated with 10% sodium lauryl sulphate 24-hours before topical induction. Discrete/patchy erythema was observed in all test animals at the 24- and 48-hour after treatment.

CHALLENGE PHASE

1st challenge topical: 100%

2nd challenge Not performed

Remarks - Method No significant protocol deviations. Statement of GLP.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		1st challenge	*2nd challenge*

		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	8/10	9/10	-	-
Control Group	100%	0/5	0/5	-	-

Remarks - Results

Discrete/patchy to moderate/confluent erythema were observed in eight (at the 24-hour reading) and nine (at the 48-hour reading) out of ten test animals after treatment with the undiluted test item.

No signs of systemic toxicity were observed in the animals.

CONCLUSION

There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

RCC (2001r)

7.6.3 Skin sensitisation – human volunteers

TEST SUBSTANCE

Notified chemical

METHOD

In house method - Repeat Insult Patch Test

Study Design

Induction Procedure: Test substance was administered as supplied based on the results of an 8-day range finding study. The test substance was applied semi-occlusively. Nine consecutive applications were made at 48-hour intervals. Participants were instructed to remove patches after 24 hours. Evaluation of the test site occurred prior to re application of the test item.

Sodium lauryl sulphate solution (0.1%) was applied occlusively to a positive control site to assess subject compliance.

Rest Period: 10-15 days

Challenge Procedure: Identical patches of the test substance were applied to sites previously unexposed to the study material. Patches were removed by subjects after 24 hours and the sites graded after an additional 24-hour and 48-hour period.

Rechallenge Procedure: Rechallenge was performed whenever there was evidence of possible sensitisation. The rechallenge was conducted on naïve sites when challenge reactions had resolved. Patches were applied for 24 hours and the sites evaluated 48, 72 and 96 hours after patch application.

Two-week provocative stage: Product was applied by the subject to a small area of the antecubital fossa twice a day for a period of 2 weeks. The initial application was demonstrated by the clinical evaluator. The site was evaluated 48 and 96 hours following the initial application and on Monday, Wednesday and Friday of the following week.

Study Group

108 subjects enrolled in the study (25 male, 83 female).

Dose

Test substance administered as supplied (100%).

Remarks - Method

98 subjects completed the study. 5 were lost to follow-up, 1 voluntarily withdrew, 3 did not comply with protocol and 1 experienced a serious non-product related adverse effect.

Rechallenge was conducted on one subject under semi-occlusive conditions 2 weeks after challenge. Two weeks after completing rechallenge the same subject began a 2-week provocative use phase.

RESULTS

Remarks - Results

Induction
One subject showed definite erythema after the 7th, 8th and 9th induction. The same subject showed > 50% papular response on day 7. Another subject showed a minimal and doubtful response, slightly different from surrounding normal skin after the 7th and 8th application (no grading after the 9th application occurred).

Challenge
The subject showing definite erythema in the induction phase, showed definite erythema and > 50% papular response 24 and 48 hours after challenge patch removal. The papular response appeared to have spread beyond the patch site at the 48 hour observation.

Rechallenge
The subject showed erythema, oedema and a papular response 48 and 72 hours after patch application and erythema and a papular response 96 hours after patch application. The subject reported pruritus (itching) at all evaluations.

Provocative use
No reactions were observed five minutes after the initial application, Erythema was observed and pruritus reported at the evaluation 48 hours after the first application (the product had been applied 5 times by this evaluation). The product was applied one more time and then application was discontinued due to itching and redness. Approximately 72 hours after the initial application, erythema and a papular response spreading beyond the application site were observed and pruritus was reported. Reactions had resolved in an evaluation 5 days after the last application.

CONCLUSION

A repeat insult patch test was conducted using the notified chemical (100%) under semi-occlusive dressing. The notified chemical was sensitising under the conditions of the test.

TEST FACILITY

TKL (2002)

7.7. Repeat dose toxicity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain: Rat/HanBrl:Wistar
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 29 days or 28 days for recovery groups
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle: Peanut oil (dessicated)
Remarks - Method: No significant protocol deviations. Statement of GLP.
Doses based upon the results of a non-GLP 5-day dose-range finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0
II (low dose)	5 per sex	30	0

III (mid dose)	5 per sex	150	0
IV (high dose)	5 per sex	750	0
V (control recovery)	5 per sex	0	0
VI (high dose recovery)	5 per sex	750	0

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
A decrease in locomotor activity was observed in high dose males and females. This was statistically significant in males overall and at the 15minute and 30 minute measurement intervals and in females at the 15 minuted measurement interval.

A statistically significant decreased mean bodyweight gain was observed in high dose males and females. During the recovery period the mean bodyweight gain of males and females previously treated at the high dose exceeded controls. Bodyweight gain was also observed to be decreased in mid-dose females.

Mean daily food consumption was similar between treated and control animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry
A dose dependent increase in total cholesterol was noted in treated females, achieving statistical significance at the mid and high doses. A significant increase was still noted in the treated animals at the end of the recovery period.

Statistically significant increased albumin, globulin and total protein levels were noted in high dose males and females. Effects appeared to reverse during the recovery period. A statistically significant (but less than 10%) increase in globulin levels was also noted in the mid dose females.

Haematology
Significantly prolonged activated partial thromoboplastin times were noted in high dose males and females. These were either above or at the top end of the 95% tolerance limits of the historical control data. Significantly prolonged thromoplastin time was noted in high dose males but not high dose females where a statistically significant reduced time was noted. There were no differences in these endpoints at the end of the recovery period.

Urinalysis
When compared to controls ketone was present on greater quantities in the urine of high dose males and females. This effect appeared to reverse during the recovery period.

Effects in Organs
Organ Weight
A dose dependent increase in absolute and relative liver weights was noted in treated males and females, reaching statistical significance in the high dose group.

A statistically significant increase in relative kidney weight was noted in high dose males.

A decrease in absolute and relative thymus weight was noted in high dose males and females. The decrease was more pronounced and reached statistical significance in the males.

All organ weight effects appeared to reverse during the recovery period.

Macrosopic Findings
There were no remarkable necropsy findings.

Histopathology
Liver: Centrilobular hepatocellular hypertrophy was noted in all high dose treated animals. This effect appeared to reverse during the recovery period.

Kidney: Tubular degeneration/regeneration was noted in the high dose males (3/5) and females (4/5) at the end

of the treatment period and all treated high dose animals at the end of the recovery period. This effect was also observed in the control animals but at a lower frequency and severity. Papillary mineralisation was noted in the mid dose males (4/5) and females (3/5) and high dose males (4/5) and females (3/5). This effect was still noted in the treated animals at the end of the recovery period. A dose related increase in the severity of hyaline droplet accumulation was noted in the treated males when compared to controls. This effect was still noted at the end of the recovery period.

Remarks – Results

The increase in liver weight in the high dose animals, correlated with hepatocellular hypertrophy observed microscopically is considered to be potentially adverse. In the absence of histopathological changes in the livers in the low and mid dose animals the slightly elevated absolute and relative organ weights were considered to be an indication of metabolic adaptation.

Renal tubular hyaline droplet accumulation (characteristic of α2-microglobulin nephropathy) is a phenomenon known to occur only in adult male rats; as such, this finding is without any interspecies toxicological significance. However, the other effects observed in the kidney were considered to represent a persistent treatment related effect.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on treatment related effects observed at 750 mg/kg bw/day including effects in the liver and persistent effects in the kidney. A No Observed Effect Level (NOEL) was established as 30 mg/kg bw/day in this study, based on the clinical chemistry findings observed in females treated with 150 mg/kg bw/day generally indicative of changes in lipid metabolism.

TEST FACILITY RCC (2001s)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 microsomal fraction from Phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Ethanol
Remarks - Method	Test 1: Plate incorporation method Test 2: Pre-incubation method Deviation from Protocol: 2-Aminoanthracene was used as the sole indicator of the efficacy of the S9-mix. The following positive controls were used in the absence of S9-mix: Methyl methane sulphonate (WP2uvrA) 4-nitro-o-phenylene diamine (TA1537 and TA98) Statement of GLP.

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	> 5000	Negative

Test 2		> 5000*	> 5000	
Present				
Test 1	> 5000	> 5000	> 5000	negative
Test 2		> 1000	> 5000	

* For strain TA100 a reduction in the number of revertants was observed at 100 and > 1000µg/plate.

Remarks - Results: The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Negative controls were within historical limits. 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: RCC (2001t)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

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

Species/Strain: Chinese Hamster
Cell Type/Cell Line: V79
Metabolic Activation System: S9microsomal fraction from Phenobarbital/β-naphthoflavone induced rat liver
Vehicle: Ethanol
Remarks - Method: No significant protocol deviations. Statement of GLP.

Concentrations in main test chosen due to cytotoxicity observed in the preliminary test in the absence of activation and precipitation observed in the preliminary test in the presence of activation.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5*, 10*, 15*, 25, 37.5, 50	4	18
Test 2a	0.94, 1.88, 3.75*, 7.5*, 15*	18	18
Test 2b	3.78, 7.5, 10, 15*	28	28
Present			
Test 1	5, 10, 20, 40*, 80*, 160*	4	18
Test 2	20, 40*, 60, 80*, 120, 160*	4	28

*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	≥ 28.5	15	≥ 57	negative
Test 2a	≥ 28.5	15	≥ 57	negative
Test 2b	-	15	-	negative
Present				
Test 1	> 3650	> 160	≥ 57	negative
Test 2	-	> 160	-	negative

* based on reduced cell numbers or mitotic index below 50% of controls
** based on preliminary test

Remarks - Results	No biologically relevant increase in the number of cells carrying structural chromosome aberrations was observed in any test either in the absence or presence of metabolic activation.
CONCLUSION	The notified chemical not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.
TEST FACILITY	RCC (2001u)

7.10. Genotoxicity – in vivo

Not determined.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated Sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD) - Manometer
Remarks - Method	Duplicate test samples of ~ 100 mg/L were added to activated sewage sludge. Controls containing only the inoculum and no test substance as well as procedure controls containing 100 mg/L of reference substance (Sodium Benzoate), were run in duplicate. A further abiotic control containing the test substance and the inoculum poisoned with $HgCl_2$ was run. A further toxicity test was also run by adding 100 mg/L of test substance and 100 mg/L of Sodium Benzoate. The test substance was not dispersed using ultrasound. Light: Darkness Temperature: 22°C

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation**
1	2	1	16
4	20	4	69
11	40	11	85
28	57	28	93

* Average

Remarks - Results	The test substance is unstable and slowly reacts in water (see Section 6, Hydrolysis as a function of pH). The abiotic control showed no degradation suggesting that any abiotic degradation of the notified chemical does not involve the consumption of O_2. The toxicity control showed 60% degradation over 28 days, demonstrating that the test substance was not toxic to the inoculum. The ThOD was calculated as 2.33 mg O_2/mg. The pH for all of the tests was between 7.4 – 7.9.
CONCLUSION	The test substance is biodegradable, but cannot be regarded as readily biodegradable.
TEST FACILITY	RCC (2001v)

8.1.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	GC, HPLC, AA, HPLC-MS and BOD / TOC
Remarks - Method	Activated sludge from ten locations including domestic and industrial sewage plants; river, lake and estuarine environments, was cultivated and mixed. Triplicate samples of 100 mg/L of test substance were subjected to

30 mg/L of activated sludge. A control blank containing sludge but no test substance was run. A further blank containing test substance but no activated sludge was also run. A reference substance (Aniline) was run as well. Dissolved Organic Carbon (DOC), ethanol by Gas Chromatography (GC), the test substance and caprylic acid by HPLC and water soluble silicon by atomic absorption (AA) were determined. A recovery test was also run for the water + test item and sludge + test item samples.
Temperature: 25°C

RESULTS

Test substance		*Aniline*	
Day	*% Degradation**	*Day*	*% Degradation*
7	45	7	59
14	60	14	75
21	65	21	83
28	67	28	84

* Average

Remarks - Results: The test substance was not dissolved. HPLC analysis for the test substance showed 100% degradation at 28 days. The AA result was also consistent, with 101% degradation in the sludge + test item samples and 47% degradation in the water + test item samples. These results would include all forms of degradation and not just that where oxygen is consumed. No ethanol or caprylic acid was detected in the sludge + test item samples. However ethanol and caprylic acid were found in the test item + water samples. It is likely that the ethanol and caprylic acid which are formed during abiotic degradation is rapidly consumed by biotic processes. Similarly the dissolved organic carbon in the water + test item was 59% of the theoretical amount, whilst it averaged 20% in the sludge + test item. The recovery tests were 95-96%

CONCLUSION: The test substance is biodegradable, but cannot be regarded as readily biodegradable.

TEST FACILITY: Kurame (2002 a)

8.1.2. Bioaccumulation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 305 Bioconcentration: Flow-through Fish Test.
Method for testing the Degree of Accumulation of Chemical Substances in Fish Body[1]" & Bioconcentration: Flow- through Fish Test (Guideline 305, June 14, 1996).

Species: Orange-red killifish (*Oryzias latipes*)
Exposure Period: Exposure: 60 days Depuration: not performed
Auxiliary Solvent: Hydrogenated castor oil dispersant (HCO-20, HCO-40)
Concentration Range: Nominal: 0.25; 2.5 mg/L
Actual: 0.216; 2.45 mg/L; Standard Deviation (SD) 0.0302 and 0.168 respectively.
Analytical Monitoring: AA
Remarks - Method: Ten fish were exposed to nominal concentrations of 0.25 (Level 1) and 2.5 mg/L (Level 2) in flow though conditions and a control containing the dispersant. The stock solutions were 100 and 1000 mg/L respectively and added at a rate of 2 mL/min. The dilution water was added at 800 mL/min. Two fish from each test level were analysed at 10, 18, 32, 46 and 60 days. A recovery test was run for both the test water and spiked samples of fish by adding 200 and 2000 µg respectively.

	Temperature 25.1-25.8°C Dissolved O2: 7.3-8.1 mg/L pH: 7.6-8.2

RESULTS

Bioconcentration Factor	20 (Level 1); ≤ 80 (Level 2).
CT50	
Remarks - Results	No abnormal behaviour was observed for any fish. The recovery test for the water was ~84%. The Level 2 sample had 19.6 µg subtracted as this was the amount found in the blank. The recovery from the spiked fish sample was 70.5%. A steady state Bioconcentration Factor (BCF) for the Level 2 test could not be calculated but it was assumed that it was reached as all BCFs were below 100.

CONCLUSION	The test substance is not considered bioaccumulating.
TEST FACILITY	Kurame (2003)

[1] "Method for Testing the Degree of Accumulation of Substances in Fish Body" stipulated in the Testing Methods for New Chemical Substances" (July 13, 1974, Revised October 8, 1998, No.5, Planning and Coordination Bureau, Environment Agency; No.615, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare; and No. 392 Basic Industries Bureau, Ministry of International Trade and Industry, Japan.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test & EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi-static.
Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; GC
Remarks – Method	A water available fraction (WAF) of the test substance was prepared by stirring a nominal 100 mg/L dispersion for 48 hours at room temperature in the dark. A range finding test was then conducted by subjecting 7 fish to the WAF and a control. The WAF was replaced daily. pH: 7.9-8.2 O2 concentration 7.4-9.1 mg/L Temperature 21-23°C. Light: 16 hour light 8 dark with 30 minute transition; 50-500 Lux

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0	0
100	0.017*	7	0	0	0	0	0

* mean value determined from freshly prepared samples and after 24 hours. After 24 hours the value was < 0.007, which was the limit of quantification (LOQ) for the test substance. A value of half of the LOQ (0.0035) was used to calculate the average for values below the LOQ.

LC50	> 100 mg/L
NOEC	100 mg/L at 96 hours.
Remarks – Results	No fish exhibited abnormal behaviour. The decrease of the measured test substance concentrations was considered to be caused by hydrolysis of the test substance during the test medium renewal period of 24 hours.

CONCLUSION	The notified chemical is not toxic to *Brachydanio rerio* up to the limits of its water solubility and stability.
TEST FACILITY	RCC (2001w)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test & EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; GC
Remarks - Method	A water available fraction (WAF) of the test substance was prepared by stirring a nominal 100 mg/L dispersion for 48 hours at room temperature in the dark. The supersaturated dispersion was filtered (0.45 µm). The filtrate was then diluted. A test was then conducted by subjecting duplicate samples of 10 daphnids to the WAF test concentrations (detailed below) and a control. Loading rate < 1 daphnid/2 mL pH: 8.0 O_2 concentration 8.5-8.6 mg/L Temperature 21°C Light: 16 hour light 8 dark with 30 minute transition; 200-1200 Lux

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hours*	*48 hours*
Control	n.a.	20	0	0
1:22 (4.5)	n.a.	20	0	0
1:10 (10)	n.a.	20	0	0
1:4.6 (22)	n.a.	20	0	0
1:2.2 (45)	n.a.	20	0	0
Undiluted (100)	0.046*	20	0	0

n.a. not analysed

* Average value of all samples taken from the initial and final (48 hours) measured concentrations.

LC50	> 100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours
Remarks - Results	No daphnids showed abnormal behaviour.
CONCLUSION	The notified chemical is not toxic to daphnia up to the limits of its water solubility and stability.
TEST FACILITY	(RCC 2001x)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test & EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours

Concentration Range	Nominal: 100 mg/L Actual: 0.0018 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Electronic Particle Counter; GC
Remarks - Method	A water available fraction (WAF) of the test substance was prepared by stirring a nominal 100 mg/L dispersion for 48 hours at room temperature in the dark. The supersaturated dispersion was filtered (0.45 µm). Triplicate analyses were performed by subjecting 1×10^4 cells per mL to the test substance WAF. Six control replicates were also run.

RESULTS

Remarks - Results	The actual concentration value was determined from the mean of freshly prepared samples and at the end of the test (72 hours). After 72 hours the value was < 0.018, which was the limit of quantification (LOQ) for the test substance. A value of half of the LOQ (0.009) was used to calculate the average for values below the LOQ. The EbC50 and ErC50 could not be calculated as the mean algal mass and algal growth rate were higher than that of the control.

CONCLUSION	The test substance is not toxic to alga up to the limits of its water solubility and stability.
TEST FACILITY	RCC (2001y)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. & EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10-1000mg/L
Remarks – Method	Aerobic activated sewage sludge from a wastewater treatment plant (ARA Ergolz II Füllinsdorf, Switzerland) treating predominantly domestic wastewater was used. Nominal concentrations of 10, 32, 100, 320 and 1000 mg/L of test substances were added to sewage sludge. Duplicate blanks were also run as well as 5, 16 and 50 mg/L of a reference substance (3,5 dichlorophenol).

RESULTS

IC50	> 1000 mg/L
LOEC (EC20)	1000 mg/L
Remarks – Results	The test substance is unstable and slowly reacts in water (see Section 6, Hydrolysis as a function of pH). Up to and including the nominal concentration of 320 mg/L the test substance showed no significant inhibitory effect (<15%). Test concentrations of 32 and 100 mg/L showed an increase in respiration rate. The saturation concentration was reached between the nominal concentrations of 100 and 320 mg/L. The oxygen consumption rate between the two controls was 12% (less than the 15% recommended guideline). The EC50 of 3,5 dichlorophenol was 8.5 mg/L (4-13 mg/L 95% confidence limits), within the guideline recommended range.

CONCLUSION	The test substance practically non-toxic to micro-organisms
TEST FACILITY	RCC (2001z)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Although the wearing of tyres (~50% of tread) in which the notified chemical is incorporated would result in environmental exposure, this is expected to be negligible as the notified chemical is expected to be almost entirely reacted with the rubber before the manufacture of the tyre.

Small amounts (< 0.2%; < 100 kg per annum) from spills and container residues are likely to be disposed of by licensed waste disposal or authorised landfill, with minimal environmental exposure.

Used tyres containing the reacted chemical are expected to be used as low grade rubber crumb, landfilled or possibly used as fuel in cement kilns. The reacted notified chemical is expected to eventually undergo in-situ degradation by biotic and abiotic processes to form simple compounds of sulphur and carbon; silicates; and water vapour. If combusted the reacted chemical is expected to be combusted to form oxides of sulphur and carbon; silicates; and water vapour.

9.1.2. Environment – effects assessment

The notified chemical showed no toxicity to any of the aquatic species to the levels tested (100 mg/L). Although a predicted no effect concentration (PNEC) cannot be calculated, it can be stated to be > 1 mg/L. (LD(C)50 divided by a safety factor of 100, as three trophic levels were tested.)

9.1.3. Environment – risk characterisation

No exposure of the chemical to the aquatic environment is expected. The toxicity of the chemical to the level of availability to aquatic species was non-toxic. Furthermore the notified chemical is unstable in water. The notified chemical is unlikely to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be transported to rubber tyre manufacturing facilities as a neat raw material and formulated into tread rubber to be converted into tyres. The final concentration of notified chemical in the tread rubber is low (< 10%) and lower in the tyres (< 1%).

Typical exposure scenarios for tread rubber formulation involve transfer of the raw material to a storage tank, thence to a mixing vessel and finally the tread rubber is converted to tyres in a separate process. Other operations involve sampling and testing rubber and cleaning equipment and vessels. The greatest potential for exposure is considered to be during the transfer of the raw material (liquid or granular form) to the storage tank. The liquid form of the notified chemical is transferred by manual transfer (for pails), a pump and lance (for drums) or direct connection (for IBCs). The liquid form of the notified chemical will mainly be imported in drums.

For the liquid form of the notified chemical, the estimated dermal exposure to the notified chemical, based on EASE model (EASE) using reasonable worst case defaults for particular activity (European Commission, 2003) is as follows:

Activity	*Estimated exposure for activity <mg/day>*	*Estimated exposure for notified chemical <mg/kg bw/day>**
Manual addition of liquids	420	6
Coupling and decoupling of transfer line	42	0.6
Quality control sampling	21	0.3

* for a 70 kg worker and a 100% dermal absorption factor

Exposure would be limited by the use of PPE.

It is possible that certain customers may use Carbo NXT LV a solid granule comprised of 50% notified chemical and 50% carbon black. For transfer of this granular form, the estimated dermal exposure is 21-210 mg/day, based on the EASE model (EASE) using the following inputs: non-dispersive use, direct handling (LEV not effective), intermittent contact (2-10 events per day) and assuming an exposed surface area of 420 cm^2 (one hand only) and a concentration of 50%. (The surface area has been selected based on default values in the EU Technical Guidance Document (European Commission, 2003) and on the granular nature of the solid.) Therefore, for a 70 kg worker and a 100% dermal absorption factor, systemic exposure is estimated to be 0.3 – 3 mg/kg bw/day. If local exhaust ventilation is effective dermal exposure is estimated by the EASE model to be very low. Exposure would be limited by the use of PPE.

The notified chemical reacts with the silica during the rubber mixing process. During the curing process, the notified chemical also reacts with the rubber and is totally bound within the rubber so that exposure is no longer likely. Workers have the potential to be exposed to ethanol generated during these reactions. LEV is used to capture any vapours including the produced ethanol during the mixing/curing process.

9.2.2. Public health – exposure assessment

Although members of the public may occasionally make dermal contact with tyres manufactured using the notified chemical, the exposure is expected to be negligible because the notified chemical is present at very low concentrations and unlikely to be bioavailable.

The public may inhale and/or ingest road dust containing the notified chemical, however, whilst the notified chemical is used at levels of up to 1% in the tyre, the notified chemical reacts during tyre manufacture and is therefore expected to be totally bound within the rubber. Up to 10% of road dust in urban environments may contain tyre particles.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified chemical is considered to be of low acute toxicity via the oral and dermal routes.

Irritation and Sensitisation.
Based on the results of irritation studies in rabbits, the notified chemical is considered to be slightly irritating to skin and eyes. The notified chemical is considered to be a skin sensitiser based on the results of a guinea pig maximisation test and a human repeat insult patch test.

Repeated Dose Toxicity.
In a 28-day oral repeat dose study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day, based on treatment related effects observed at 750 mg/kg bw/day including effects in the liver and persistent effects in the kidney. A No Observed Effect Level (NOEL) was established as 30 mg/kg bw/day in this study, based on the clinical chemistry findings observed in females treated with 150 mg/kg bw/day generally indicative of changes in lipid metabolism.

Mutagenicity.
The notified chemical was negative in an Ames test and an in vitro chromosome aberration test. Based on these studies, the notified chemical is not considered to be a potential mutagen.

Hazard classification for health effects.
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).

Reaction products
The notified chemical reacts with the silica during use releasing ethanol. Ethanol is not classified

as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). However ethanol is considered a hazardous substance as it is included in the hazard substances information system (HSIS, 2006) with an exposure standard of 1880 mg/m3 (TWA). The OECD SIAR for ethanol concluded that ethanol possesses properties that indicate a hazard for human health but these are manifest only at doses associated with consumption of alcoholic beverages. In the context of an industrial chemical, these hazards do not warrant further work as they are not likely to result from the manufacture and use of ethanol and ethanol containing products (SIAR, 2005).

9.2.4. Occupational health and safety – risk characterisation

Exposure and hence the risk to workers is expected to be greatest during handling of the raw material. Following mixing/curing, exposure to the notified chemical is the not expected and hence the risk to workers is considered to be low.

Systemic effects
Based on a NOAEL of 150 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) for various activities are as follows:

Activity	*Estimated exposure for notified chemical <mg/kg bw/day>*	*Margin of Exposure*
Manual addition of liquid form	6	25
Manual addition of granular form	0.3-3	50-500
Coupling and decoupling of transfer line	0.6	250
Quality control sampling	0.3	500

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data may not be acceptable for workers involved in the manual transfer of the liquid and granular form of the notified chemical in the absence of PPE. The risk is considered to be acceptable with the described use of PPE (gloves, goggles and protective clothing). The notifier has indicated that PPE will always be required to be worn. In addition, as the liquid form of the notified chemical will mainly be introduced in drums, manual transfer of the liquid form of the notified chemical is expected to be rare.

Although workers have the potential to be exposed to ethanol generated during these reactions, the risk is expected to be low due to the presence of LEV and the low toxicity of ethanol at the dose levels expected.

Local effects
Given the possible exposure of workers during transfer operations and other activities involving the handling of the raw material, there is a significant risk of skin sensitisation. Therefore, adequate PPE is required to manage this risk. The use of PPE would also minimise the risk of slight irritant effects.

9.2.5. Public health – risk characterisation

The highest potential for public exposure resulting from introduction of the notified chemical is assessed as occurring from exposure to road dust containing tyre particles. However, whilst the notified chemical is used at levels of up to 1% in the tyre, the notified chemical reacts during tyre manufacture and is therefore is expected to be totally bound within the rubber. Thus the public health risk from introduction of the notified chemical is assessed as low.

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:

R43: May cause sensitisation by skin contact

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***
Skin sensitiser	1	May cause allergic skin reaction

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 Moderate Concern to occupational health and safety under the conditions of the occupational settings described. This concern would be mitigated by the described use of PPE.

10.3.2. Public health

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

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 2003). It is 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 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - Xi: R43: May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc > 1%: R43

- The following safety phrases should appear on the MSDS and label for the notified chemical:
  - S24: Avoid contact with skin
  - S37: Wear suitable gloves

Health Surveillance

- As the notified chemical is a skin sensitiser employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Pumps, couplings and transfer lines should be selected to avoid spillage.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin contact
  - 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:
  - Protective clothing
  - Protective gloves
  - Eye protection

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

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

- 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.

Disposal

- The notified chemical should be disposed of by licensed waste disposal and authorised landfill.

Storage

- The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection and re-use to the extent possible for the granular form. For the liquid stop leak if safe to do so and physically contain using inert adsorbent (sand, montmorillonite

clay (kitty litter etc.)). Re-use liquid to the extent practicable, collect adsorbed material for disposal. Wash residue with detergent and water and prevent runoff from entering sewer and waterways.

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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