File No: STD/1240

December 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component 2 of NXT-LV

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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Component 2 of NXT-LV

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Momentive Performance Materials Australia Pty Ltd (ABN 47105651063)
175 Hammond Rd
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 Name
Other Names
CAS Number
Molecular and Structural Formulae
Molecular Weight
Spectral Data
Purity
Impurities
Import Volume

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
EU

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Component in NXT Low V (the notified chemical is a component (< 20%) of NXT Low V, another component of which is notified as STD/1218)

MARKETING NAME(S)
NXT LowV^{R}
Silquest NXT Low V

SPECTRAL DATA

METHOD	Infrared (IR), Mass (MS) and Nuclear Magnetic Resonance (NMR) spectroscopy.
Remarks	Reference spectra were provided.
TEST FACILITY	G E Silicones – OSi Specialties (2004).

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, GC-MS and NMR spectroscopy

3. COMPOSITION

DEGREE OF PURITY
> 80% (for the total reaction mixture comprising components notified as STD/1218 and STD/1240)

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
One impurity at 5% and several other impurities at < 1%.

ADDITIVES/ADJUVANTS
None.

A granular form containing the notified chemical (see section 6, Particle size), Carbo NXT LV contains 50% of the reaction mixture containing the notified chemical and the chemical notified as STD/1218 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 as a component of NXT-LV in liquid form and as a component of a granular form (Carbo NXT LV) by sea in full container loads (FCL).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 1	1 – 3	1 – 3	3 - 10

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. Bridgestone Australia, Salisbury, South Australia and South Pacific Tyres Ltd, Somerton, Victoria

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

5.2. Operation description

Imported IBCs or drums 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. Carbo

NXT LV granules may be used in which case they are manually scooped from the bag for weighing and then manually added to the mixer.

The NXT LowV system is claimed to have the advantage of avoiding the use of coupling agents that emit significant volumes of ethanol that need to be captured and treated.

NXT-LV is mixed with rubber polymers, silica and other additives. It is used at levels between 1 to 2% of the tread rubber content or approximately 0.1% to 0.2% 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 (hrs/day)*	*Exposure Frequency (days/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 a pump and lance 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.

When handling the Carbo NXT LV 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.

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% (< 24 tonne per annum) of the reaction mixture containing the notified chemical will be imported in IBCs and 20% (< 6 tonne per annum) in “Carbo” form. All of the processes for both the liquid and “Carbo” form occur in enclosed systems. The release is therefore expected to be minimal. Similarly the notified chemical has a and low vapour pressure (1×10^{-7} kPa @ 25°C) and minimal release to the atmosphere is expected.

The IBCs and drums in which the notified chemical 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% (<12 kg per annum: < 2.4 kg

notified chemical). The IBCs and drums are expected to be sent to a drum recycling facility.

The bags containing the "Carbo" form will be shaken out thoroughly. Assuming that 50 g remain in each 25 kg bag then approximately 0.2% (< 2.4 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 0.1% (< 6 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 government 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 a licensed contractor.

The residual in packaging for the "Carbo" 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).

5.6. Public exposure

The notified chemical is not available for sale to the public. The potential for public exposure to the notified chemical during transport, tyre manufacture 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 it is chemically bound in the rubber. Tyre particles from wear of tyres during normal functioning on roads could potentially be inhaled or ingested. Approximately 10% of PM_{10} (< 10μm diameter) particulates in the urban environment may be tyre dust and these would contain a maximum of 1% notified chemical in a chemically bound form.

6. PHYSICAL AND CHEMICAL PROPERTIES

All tests were conducted on NXT-LV containing the notified chemical at <80%.
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Appearance at 20°C and 101.3 kPa Pale yellow liquid

Appearance of Carbo NXT LV: black granules.

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	The freezing temperature was determined visually (no heat effect could be determined with thermocouples).
TEST FACILITY	RCC (2004a)

Boiling Point > 400°C at 101.3 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Starting at about 330°C, an exothermic reaction was observed, which was caused by the decomposition of the test item.

TEST FACILITY RCC (2004a)

Density 1040 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Method: oscillating densitometer.
TEST FACILITY RCC (2004b)

Vapour Pressure 6.5×10^{-6} kPa at 55°C
1.9×10^{-5} kPa at 65°C
1×10^{-7} kPa at 25°C (extrapolated from data above)

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks No test substance was detected at 25°C, so the vapour pressure test was conducted at 55 and 65°C, using the gas saturation method. The vapour pressure at 25°C was calculated by extrapolation based upon the simplified Clausius-Clapeyron equation.
TEST FACILITY RCC (2004c)

Water Solubility 34 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Test item samples were taken after equilibrium times of 1 and 24 hours. In the 24 hours sample, no test item could be detected (complete decomposition). Therefore the test item content determined in the 1 hour samples was taken as an estimate of water solubility. Gas Chromatography (GC) was used for analysis. A value derived from the log Pow for the monomer was measured by HPLC ("in house method") and was determined to be 2.4 mg/L, whilst in the ecotoxicity testing a maximum of 0.224 mg/L was found.
TEST FACILITY RCC (2004d) & GE Advanced Materials (2004)

Fat Solubility Miscible in standard fat HB307.

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Analytical Method: visual – simplified flask.

The miscibility of the test item and standard fat was tested at 3 different ratios (1:20,
1:1, 20:1). The result was evaluated visually. Only one clear and colourless phase was observed in each flask.

The substance is miscible in each relation with the standard fat at 37°C.
TEST FACILITY RCC (2004e)

Surface Tension 64.6 mN/m at 21ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: test performed at 90% of saturation concentration. The test substance is not surface active.
TEST FACILITY RCC (2004f)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ hours*
4	50	< 2.4
7	50	< 2.4
9	50	< 2.4

Remarks A further test ("in house method") was conducted using pH 7 buffered water at 20°C (room temperature) over 50 hours with periodic analysis of the notified chemical (details not submitted). The estimated half life was 1.1 hours.

TEST FACILITY RCC (2004g) & GE Advanced Materials (2005)

Partition Coefficient (n-octanol/water)

log Pow Peak 1 3.9
log Pow Peak 2 4.6
log Pow Peak 3 5.0
log Pow Peak 4 6.0
log Pow Peak 5 6.3

No temperature specified.

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method. The notified chemical is a complex mixture of unintended by-products as well as the notified chemical. Consequently several elution peaks are expected. These were all within the range of the reference standards. A further test ("in house method") determined the log Pow for the monomer of the notified chemical to be 5.62. The dimer, trimer and tetramer had log Kow values of 8.39, 9.96 and 10.4 respectively. Again all of the values were within the range of the reference standards.

TEST FACILITY RCC (2004d) & GE Advanced Materials (2004)

Adsorption/Desorption – screening test

log K_{oc} Peak 1 0
log K_{oc} Peak 2 1.6

METHOD OECD TG 121 HPLC Method.

Remarks The Koc value is surprisingly low, meaning that the chemical is surprisingly mobile in soils, given that the notified chemical is miscible in fat and only sparingly soluble in water. Similarly the chemical contains many lipophilic portions, which would be expected to have affinity for organic carbon. The two peaks both with retention times less than the first reference standard may represent the only elutable compounds from the complex mixture that comprises the test substance.

TEST FACILITY RCC (2004h)

Dissociation Constant

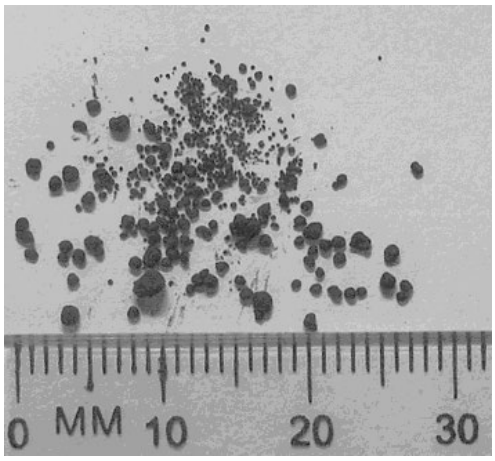
The notified chemical does not contain any functional groups capable of dissociation in the environmentally relevant pH range (4-9).

Remarks Expert statement (RCC, 2004i)

Particle Size

Not applicable to a liquid.

Particle size of Carbo NXT LV (200 μm – 2 mm):



Flash Point 162ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Pensky-Martens closed cup.
TEST FACILITY RCC (2004j)

Flammability Limits Not determined.

Remarks Not expected to be flammable.

Autoignition Temperature 265ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY RCC (2004k)

Explosive Properties Not expected to be explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Expert statement:

The compounds present in the substance do not contain any

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nd is below -200. In a calorimetric test using DSC no exothermic peak was found.

Applying the internationally recognised UN Recommendation criteria, the substance is not to be classified as explosive material and no experimental determination according to the EC test guideline A.14 has to be performe

d.

Thus it can be concluded beyond a reasonable doubt, that the substance is not a potential explosive and does not have the potential for rapid energy release. Nevertheless, this judgement is in respect to classification; it does not necessarily mean that any processing hazards can be discounted.

TEST FACILITY RCC (2004l)

Oxidising Properties Not oxidising

Remarks The oxidising properties of the substance were screened based on the UN Recommendations on the Transport of Dangerous Goods (Orange Book, 3rd edition, 1999). The substance contains oxygen but most of the oxygen atoms are bonded in a way that, from a formal point of view, means the conditions of the UN Recommendations are not fulfilled. However, general chemical knowledge indicates that the oxygen binding is very stable and inert and that the oxygen will not exhibit oxidizing properties.

TEST FACILITY RCC (2004m)

Reactivity Hydrolytically unstable (see Hydrolysis as a function of pH above).

7. TOXICOLOGICAL INVESTIGATIONS

All tests were performed on NXT LV which contains the notified chemical (<20%). The other component was notified under STD/1218.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse – LLNA test.	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 200 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	non genotoxic
Genotoxicity – in vivo mouse micronucleus	non genotoxic
Pharmacokinetic/Toxicokinetic studies	Submitted

7.1. Acute toxicity – oral

TEST SUBSTANCE Y-15654

METHOD EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain Rat/Hanbrl Wist SPF

Vehicle None

Remarks – Method No deviations from protocol noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0
2	3F	2000	0

Signs of toxicity related to dose level used, time of onset and duration:

LD50 > 2000mg/kg bw

Signs of Toxicity Slightly ruffled fur was noted in all three animals of the first group at 2 hours after test item administration. This clinical sign persisted in two animals up to 5 hours after test item administration. No clinical signs were noted in the second group.

Effects in Organs No macroscopic findings were recorded at necropsy.

Remarks – Results The body weights of the animals were within the range commonly recorded for this age and strain.

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

TEST FACILITY RCC (2004n)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Y-15654

METHOD EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain Rat/Hanbrl – Wist SPF

Vehicle None

Type of dressing Semi-occlusive.

Remarks – Method No deviations from protocol noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
M	5	2000	0
F	5	2000	*0*

Signs of toxicity related to dose level used, time of onset and duration.

LD50		> 2000 mg/kg bw
Signs of Toxicity -	Local	No local signs of toxicity were observed during the study period. The body weights of the animals were within the range commonly recorded for this age and strain.
Signs of Toxicity - Systemic		No systemic signs of toxicity were observed during the study period.
Effects in Organs		Effect on organs (related to dose level): No macroscopic findings were observed at necropsy.
Remarks – Results		

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

TEST FACILITY — RCC (2004o)

7.3. Acute toxicity – inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE — Y-15654

METHOD — EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks – Method	No deviation from protocol noted.

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	0.67	0.33	1	1	72 hr	0
Oedema	0	0	0	0	0	0

*Cal1culated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results	No mortalities occurred and no clinical signs of systemic toxicity were observed throughout the study period. Changes fully reversible within 7 days Scaling was noted in two animals at 72 hours after test item application. The body weights of the animals were within the range commonly recorded for this age and strain.

CONCLUSION — The notified chemical is slightly irritating to skin but not classified as irritant.

TEST FACILITY RCC (2004p)

7.5. Irritation – eye

TEST SUBSTANCE Y-15654

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3 M
Observation Period 3 days
Remarks – Method No deviations from protocol noted.

RESULTS All changes reversible within 2 days.

No mortalities occurred and no clinical signs of systemic toxicity were observed throughout the study period.

Neither discoloration of the eyes nor corrosion of the cornea were observed during the study period. Slight reddening of the sclerae was noted in one animal at 1 and 24 hours after test item application.

The body weights of the animals were within the normal range of variability.

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	0	0	1	24 hr	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks – Results None

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY RCC (2004q)

7.6. Skin sensitisation

TEST SUBSTANCE Y-15656

METHOD OECD TG 406 Skin Sensitisation – Buehler test.
The Chinese State Environmental Protection Administration (SEPA), The Guidelines for the Testing of Chemicals, Guideline 406 Skin Sensitisation, published May, 2004.
Species/Strain Guinea pig/Crl: (HA) BR (Albino Hartley).
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal:
topical: 100%
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal:
topical: 100%
Signs of Irritation None

CHALLENGE PHASE

1st challenge	intradermal: topical: 100%
2nd challenge	topical:

Remarks - Method None.

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%	0/20	0/20		
Control Group	100%	0/10	0/10		

Remarks - Results The positive control demonstrated the sensitivity of the test.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY NBCDSER (2006).

7.7. Skin sensitisation - mouse local lymph node assay

TEST SUBSTANCE NXT-LV

METHOD

Species/Strain	Mouse/ CBA/CaOlaHsd
Vehicle	Acetone, olive oil 4:1 (v/v)
Remarks – Method	Application of 25 microliters at 25%, 50% and 100% to each dorsal ear lobe.

RESULTS No deaths occurred during the study period.

No symptoms of local toxicity at the ears of the animals and no systemic findings were observed during the study period.

The body weights of the animals were within the range commonly recorded for animals of this strain and age.

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
25%	2620	11.4
50%	3989	17.3
100%	3216	14
Control		
0% vehicle	231	

Remarks – Results No dose-response relationship could be observed.

An EC3-value could not be determined because this calculation would require a Stimulation Index (S.I.) value of less than 3.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY RCC (2004r)

7.8. Repeat dose toxicity

TEST SUBSTANCE	Y-14654
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 SPF
Route of Administration	Oral - gavage
Exposure Information	Dose regimen: 7 days per week; Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks – Method	No protocol deviations noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	5/sex	0	0
Low dose	"	50	0
Mid dose	"	200	0
High dose	"	1000	0
Control recovery	"	0	0
High dose recovery	"	1000	0

Mortality and Time to Death

No deaths occurred during the study period.

Clinical Observations

No clinical signs of toxicological relevance were noted during daily observations. During weekly behavioural observations, salivation was noted at week 3 in one high dose female and at week 4 in one mid dose female and three high dose males. The high dose males had initially elevated and thereafter reduced locomotor activity.

No differences in the mean food consumption were noted between the study groups and no test-item related changes in mean body weight were noted between the study groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology: No changes of toxicological relevance were noted in the haematology parameters. A shorter relative thromboplastin time in high dose males and a lowering in mean absolute reticulocytes in high dose animals were within the historical control ranges.

Clinical Chemistry: Reversible (after the recovery period) elevated alanine aminotransferase activity was noted in the high dose males and females and may have been adaptive. Changes in electrolytes seen only in males; elevated sodium at all dose levels, elevated potassium at the high dose, elevated chloride at the low and high doses and reduced calcium at the low dose were within historical control ranges or were not dose-dependent. Globulins were lower in high dose females and the A/G level was accordingly increased but were within the historical control range.7

Urinalysis: Reversible (after the recovery period) presence of ketone was noted in high dose males and females.

Effects in Organs

No differences in mean absolute or relative organ weights were noted at any dose level.

Remarks – Results

Macroscopic Findings:
No test item-related macroscopic findings were noted in any animals.

Microscopic Findings:
In the mesentery lymph node of some animals dose related minimal to severe amounts of foamy macrophages were recorded at all dose levels. At 1000 mg/kg/day, the incidence and mean grade of foamy macrophages was higher and additionally, follicular mineralization and formation of giant cells was recorded. All findings showed a slightly higher incidence after the recovery period.

In the thymus minimal to slight amounts of foamy macrophages were recorded in 1 of 5 males at 200 mg/kg and 1000 mg/kg including the recovery group. In females this finding was only observed at 50 mg/kg (2/5).

In the liver, a slightly increased mean grade of fatty change was recorded in both sexes treated at all doses including controls. This finding is not considered dose related.

In the thyroid, a minimal follicular hypertrophy was recorded in some males of all groups. In females treated with 50 mg/kg and 1000 mg/kg, an increased incidence of thyroid activation was noted but the incidence was reduced after recovery. These findings resolved during the recovery period.

CONCLUSION
A No Observed Effect Level (NOEL) could not be established in this study. However, the No observed adverse effect level (NOAEL) is established at 200 mg/kg bw/day based on the foamy macrophages observed at this dose level being assessed as possibly representing the physiological route of lymphatic elimination of foreign material.

TEST FACILITY RCC (2004s)

7.9. Genotoxicity – bacteria

TEST SUBSTANCE NXT-LV

METHOD EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.Annex 4D

Species/Strain	TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA.
Metabolic Activation System	Microsomal fraction from Phenobarbital/β-naphthoflavone-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 3 - 5000 µg/plate. b) Without metabolic activation: 3 - 5000 µg/plate.
Vehicle	DMSO
Remarks – Method	No deviations from protocol noted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	>5000	>5000	None	negative
Test 2		"	"	"
Absent				
Test 1	>5000	>5000	None	negative
Test 2		"	"	"

Remarks – Results Positive controls displayed the sensitivity of the test and negative controls were within acceptable limits.

CONCLUSION The notified chemical is not mutagenic in bacteria.

TEST FACILITY RCC (2004t)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE	NXT-LV
METHOD	EC Directive 2000/32/EC, L1362000, Annex 4A.
Cell Type/Cell Line	Chinese Hamster V79 cells.
Metabolic Activation System	Microsomal fraction from Phenobarbital/β-naphthoflavone-induced rat liver
Vehicle	DMSO
Remarks – Method	No deviations from protocol noted.

Metabolic Activation	*Test Substance Concentration (μL/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	0.100, 0.200, 1.25	4 hr	18 hr
Test 2	0.050, 0.100, 1.250, 2.500, 5.000	4 hr	28 hr
Absent			
Test 1	0.006, 0.013, 0.025	4 hr	18 hr
Test 2	0.006, 0.013, 0.025	18 hr	18 hr
Test 3	0.003, 0.006, 0.013/ 0.005, 0.010, 0.015, 0.020, 0.025	28 hr	28 hr

*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*
Present				
Test 1	5.0	5.00	0.200	negative
Test 2		5.00	0.100	"
Absent				
Test 1	0.04	0.025	0.050	negative
Test 2		0.050	0.025	"
Test 3		0.006	0.006	"

Remarks – Results	Positive controls demonstrated the sensitivity of the test and negative controls were within historical limits. A single positive result for the test substance was not part of a dose response.
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster V79 cells.
TEST FACILITY	RCC (2004u)

7.11. Genotoxicity – in vivo

TEST SUBSTANCE	NXT-LV
METHOD	EC Directive 2000/32/EC Annex 4C EPA, Health Effects Guidelines OPPTS 870.5395
Species/Strain	Mouse, NMRI
Route of Administration	Oral (gavage)
Vehicle	Dried corn oil
Remarks – Method	10 animals (5 males, 5 females) per test group were evaluated. The remaining 6th animal had been evaluated in case an animal died in its test group.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
1	6M	500	24
2	6M	1000	24
3	6M	2000	24

4	6M	2000	48
5	6F	500	24
6	6F	1000	24
7	6F	2000	24
8	6F	2000	48

CP=cyclophosphamide. M=mitomycin C.

RESULTS

Doses Producing Toxicity	>2000 mg/kg, estimated by a pre-experiment to be suitable.
	No cytotoxic effects were exerted in the bone marrow.
Genotoxic Effects	
Remarks – Results	No deaths occurred during the study period.
	Dose-dependently reduced spontaneous activity and ruffled fur was observed in both males and females of the high- and mid-dose groups. Ruffled fur was noted in two males and two females of the low-dose group.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this mouse micronucleus test.
TEST FACILITY	RCC (2004v)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: NXT-LV

METHOD: In accordance with OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test and EU Commission Directive 92/69 EEC, C.4-D.

Inoculum	Activated Sewage Sludge.
Exposure Period	28 Days
Auxiliary Solvent	None specified
Analytical Monitoring	Manometer
Remarks - Method	The test was conducted using activated sewage sludge organisms collected from a wastewater treatment plant (ARA Ergolz II, Fullinsdorf, Switzerland) treating predominantly domestic wastewater. Duplicates tests were conducted using containing 100 & 101 mg/L [219 & 222 mg O_2/L Chemical Oxygen Demand (COD)] and inoculum. Duplicate inoculum controls were run, containing no test item as well as duplicate reference substances {100 mg/L sodium benzoate [167 mg O_2/L Theoretical Oxygen Demand (ThOD)]}. A further toxicity control was run using 100 mg/L of test item and 100 mg/L of reference substance. An Abiotic Control was also run using 100 mg/L of test item and inoculum poisoned with $HgCl_2$ at a concentration of 10 mg/L. Temperature: 22°C; Light: Darkness; pH 7.4-7.8.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation**
1	2	1	19
7	20	7	79
10	26	10	82
14	32	14	85
21	36	21	87
28	41	28	89

* Mean value

Remarks - Results: The cumulative oxygen consumption after 28 days of:

Inoculum control	8 mg/L
Abiotic Control	0 mg/L
Toxicity Control	208 mg/L
Test Item	99 mg/L
Reference Substance	156 mg/L

The percentage degradation was corrected for the inoculum control. The toxicity control showed 52% degradation showing that the test substance was not inhibitory to the inoculum.

CONCLUSION: The test substance is biodegradable but is not considered readily biodegradable.

TEST FACILITY: RCC (2004w)

8.1.2. Bioaccumulation

NXT-LV has a high log Pow value, indicating a potential for bioaccumulation. However, it is unstable in water and is biodegradable. It is therefore unlikely that the notified chemical will bioaccumulate. Furthermore release to the aquatic environment is expected to be minimal.

8.2. Ecotoxicological investigations

I

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	NXT-LV
METHOD	In accordance with OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish -static.
Species	Zebra Fish *(Brachydanio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	239 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; Gas Chromatography (GC)
Remarks – Method	A water accommodated fraction (WAF) was prepared by stirring for 3 hours. The short time was chosen as the chemical is unstable in water. Similarly the dispersion was not subjected to ultrasonic treatment to avoid accelerating hydrolysis. The dispersion was then filtered through a membrane filter (0.45 µm). Seven fish were subjected to the WAF (detailed below) and a control.
	Fish Length: 3.3±0.2 cm
	Fish Mass: 0.30±0.07g
	pH: 8.2-8.7
	O_2 Concentration: 8.3-9.1 mg/L
	Temperature: 21-22°C
	Light: 16 hours light, 8 hours dark 30 minute transition.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	ND	7	0	0	0	0	0
100	0.036*	7	0	0	0	0	0

ND= Not Determined

* Detected at the start of the test; no test substance was detected at 48 and 96 hours.

LC50	> 100 mg/L WAF at 96 hours.
NOEC	100 mg/L WAF at 96 hours.
Remarks – Results	The test item is poorly soluble in water and is unstable. The test medium appeared clear with no other remarkable observations. No abnormalities in the fish's behaviour were observed.
CONCLUSION	The test item is not toxic to fish within the limits of its solubility and stability.
TEST FACILITY	RCC (2004x)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	NXT-LV
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test Part 1 and 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 WAF was prepared by stirring for 3 hours. The short time was chosen as the chemical is unstable in water. Similarly the dispersion was not subjected to ultrasonic treatment to avoid accelerating hydrolysis. The dispersion was then filtered through a membrane filter (0.45 µm). Four replicates of five daphnids were subjected to the WAF of the test substance (detailed below) and a control. pH: 7.8-7.9 O_2 Concentration: 8.6-8.7 mg/L Temperature: 20-21°C Light: 16 hours light, 8hours dark 30 minute transition, with the intensity between 520 and 710 Lux.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hours*	*48 hours*
Control	ND	20	0	0
100	0.038*	20	0	0

ND = Not Detected
* Detected at the start of the test; no test substance was detected at 48 hours.

LC50	> 100 mg/L WAF at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	The test item is poorly soluble in water and is unstable. The test medium appeared clear with no other remarkable observations. No abnormalities in the daphnias' behaviour were observed. The last result of the reference substance (potassium dichromate) run in the year that the test was conducted was 0.83 mg/L. This was within the historical range of 0.55-1.1 mg/L.
CONCLUSION	The test item is not toxic to Daphnia within the limits of its solubility and stability.
TEST FACILITY	RCC (2004y)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	NXT-LV
METHOD	In accordance with OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green algae (*Desmodesmus subspicatus* formerly *Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: 0.224 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	Electronic particle counter; GC
Remarks - Method	A WAF was prepared by stirring for 3 hours. The short time was chosen as the chemical is unstable in water. Similarly the dispersion was not subjected to ultrasonic treatment to avoid accelerating hydrolysis. The dispersion was then filtered through a membrane filter (0.45 µm). Triplicate tests of approximately 1×10^4 cells/mL were subjected to the WAF and a control comprising of six replicates.

	pH:	8.3-8.4
	Temperature:	22-23°C
	Light:	Continuous at approximately 8400 Lux

RESULTS

Biomass		*Growth*	
EbC50	*EbC50*	*ErC50*	*ErC50*
Nominal mg/L at 72 h	*Actual mg/L at 72 h*	*Nominal mg/L at 72 h*	*Actual mg/L at 72 h*
> 100	> 0.224*	> 100	> 0.224*

*Detected at the start of the test; and 0.015 mg/L of test substance was detected at 72 hours.

Remarks - Results	The test item is poorly soluble in water and is unstable. The test medium appeared clear with no other remarkable observations. No abnormalities in the cells' size or shape were observed. The last result of the reference substance (potassium dichromate) run in the year previous to that of the test was conducted was 0.69 mg/L. This was within the historical range of 0.44-1.16 mg/L.
CONCLUSION	The test substance is practically non-toxic to algae to the limits of solubility and stability.
TEST FACILITY	RCC (2004z)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	NXT-LV
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test and EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge micro-organisms
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	A test substance was prepared by adding the test item to tap water. The dispersion was stirred for three hours in the dark. The short time was chosen as the chemical is unstable in water. The activated sludge inoculum (from a wastewater treatment plant ARA Ergolz II, Fullinsdorf, Switzerland, treating predominantly domestic wastewater) and synthetic wastewater were added to result in the concentration detailed above. Duplicate blanks were also run along with 5, 16 and 50 mg/L of a reference substance (3,5 dichlorophenol). pH: 7.4-8.5 O_2 Concentration: 8.0-8.6 mg/L Temperature: 20°C
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The test item is poorly soluble in water and is unstable. The test substance showed no inhibition of activated sludge micro-organisms, with an increase in respiration of 10.7%. The reference substance had an IC50 of 23 mg/L. This was within the historical range of 5-30 mg/L.
CONCLUSION	The test substance is not inhibitory to micro-organisms.
TEST FACILITY	RCC (2004aa)

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%; < 60 kg total per annum (< 12 kg notified chemical) from spills and container residues are likely to be disposed of by licensed waste disposal or authorised landfill, with minimal environmental exposure.

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. Therefore a predicted no effect concentration (PNEC) cannot be calculated.

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

NXT-LV 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 NXT-LV is transferred by a pump and lance (for drums) or direct connection (for IBCs).

For the liquid form of NXT-LV, 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>**
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 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

The notified chemical is not available for sale to the public. Although members of the public may occasionally make dermal contact with tyres manufactured using the notified chemical, the risk to public health from the notified chemical is likely to be low because the notified chemical is present at very low concentrations in a chemically bound form and unlikely to be bioavailable.

The public may inhale and/or ingest road dust containing the notified chemical in chemically bound form at 1%. Up to 10% of road dust in urban environments may contain tyre particles.

9.2.3. Human health – effects assessment

Based on studies in animals the notified chemical is likely to be of low acute toxicity via the oral and dermal routes of exposure. It is also unlikely to produce severe effects on repeated or prolonged exposure. It may be a slight skin and eye irritant and is likely to be a skin sensitiser. It is unlikely to be genotoxic.

A NOEL could not be established in the 28 day repeated dose study based on reported dose related pathological changes observed in mesentery lymph nodes at the lowest dose tested. However the a NOAEL of 200 mg/kgbw/day was set for this study.

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 risk phrase R43: May cause sensitisation by skin contact.

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/m^3 (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 not expected and hence the risk to workers is considered to be low.

Systemic effects

Based on a NOAEL of 200 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 granular form	0.3-3	17-167
Coupling and decoupling of transfer lines	0.6	83
Quality control sampling	0.3	167

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 granular form of the notified chemical in the absence of PPE and to a lesser extent for workers involved in coupling and decoupling transfer lines. The risk is considered to be acceptable with the described use of PPE (gloves, goggles and protective clothing).

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.

9.2.5. Public health – risk characterisation

The highest public exposure resulting from introduction of the notified chemical into Australia is assessed as occurring from exposure to road dust containing tyre particles. These particles contain the notified chemical in chemically bound form at a maximum of 1% and the notified chemical should be covalently bound. 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 the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Skin sensitiser, Hazard category 1: May cause allergic skin reaction

For the aquatic environment no classification is required.

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 as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was 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 provided by the notifier was 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:
  - R43: May cause sensitisation by skin contact

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

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 ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective clothing
  - Protective gloves
  - Eye protection
  - Respirators during casting operations, and masks during mechanical operations.

  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

Disposal

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

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 "Carbo" 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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