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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Ulti-Pro® 100

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Director
NICNAS

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Ulti-Pro® 100

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Amtrade International Pty Ltd (ABN: 49 006 409 936)
Level 6, 574 St Kilda Road
Melbourne VIC 3004

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:

Data items and details claimed exempt from publication:

- Chemical identity (Chemical name, Other names, CAS Number, Molecular Formula, Structural Formula. Molecular weight, Spectral Data)
- Composition (Purity, identity of toxic or hazardous impurities, % weight of toxic or hazardous impurities, non-hazardous impurities, identity of additives/adjuvants, % weight of additives/adjuvants).
- Specific use
- Import volumes
- Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

PHYSICAL AND CHEMICAL DATA

Hydrolysis as a function of pH
Absorption/Desorption
Dissociation Constant
Flammability limits
Autoignition temperature

TOXICOLOGICAL INFORMATION
Acute inhalation toxicity – Not determined – The notified chemical was demonstrated to have low acute oral toxicity in rats (LD50 > 2010 mg/kg bw) and low acute dermal toxicity in rats (LD50 > 2010 mg/kg bw) a low vapour pressure and a low level of particles of respirable size.

Repeat Dose Toxicity: Variation of data requirements granted on the basis of predicted low and intermittent exposure, that transfers to an enclosed mixing vessel will be carried out using mechanical aids, there were data available on an acceptable, although not close analogue.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Korea (2004).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Ulti-Pro® 100

SPECTRAL DATA

METHOD Infrared (IR) spectroscopy.
Remarks A reference spectrum was provided.

METHODS OF DETECTION AND DETERMINATION

METHOD IR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
The notified chemical contains hazardous impurities at < 10%.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
The notified chemical contains non-hazardous impurities at < 10%.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
ULTI-PRO® 100 will be imported in 90 kg fibre drums with plastic lining, with metal ring lever lock. It will be transported by road from wharf directly to the customer's warehouse.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 - 30	10 - 30	10 - 30	10 - 30	10 - 30

USE
The notified chemical will be used as a component of rubber products.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturers of rubber components.

TRANSPORTATION AND PACKAGING
Imported in 90 kg fibre drums.

5.2. Operation description

Transport and storage

ULTI-PRO®100 (the notified chemical) will be imported in 90 kg fibre drums with plastic lining. It will be transported from the wharf to customer's warehouse in Victoria for storage and used for manufacture of rubber goods. ULTI-PRO®100 will be stored in a dry and well-ventilated area at the customer's site. Two incoming goods receiving personnel will unload the drums of ULTI-PRO®100 and store them in designated storage areas.

I. Tyre manufacture

Mixing of materials

The ULTI-PRO®100 fibre drums are manually transferred to a weighing station before the notified chemical in the form of flakes is manually scooped into internal mixer with other ingredients. Various grades of natural and synthetic rubber are combined with carbon black, sulphur and chemical products in an internal mixer to meet specific compound requirements. The resulting blend is called the "master batch", which is formed into rubber sheets, and cooled. It is then prepared for the extruding stage.

Extruding the thread

Heat is applied to the rubber to make it more elastic and then it is put through extruders machines where the tread and sidewalls, which require two different rubber compounds, are formed into the required shapes. The extruders produce a continuous sheet of tread rubber, which is then cooled and cut to specific tyre lengths.

Weaving the piles

Spinning cords such as rayon, nylon, steel and polyester undergo a process called "calendering", where they are woven into sheets and coated with rubber on both sides.

Once this is finished, the sheets are then cut at the proper angle into specific widths and lengths and eventually used for casing and cap plies, while steel cords are used for the belts.

Preparing the bead core

The bead core is formed by aligning, and then coating plated steel wires with rubber. After, it is wound on a coil a certain number of times to form bead rings, which provide a specific diameter and strength for a particular tyre.

Building process

The building process involves two stages.

Stage 1: Beginning with the woven sheets, the inner liner, body plies and sidewalls are placed on the building drum. The correctly-positioned beads rings are then attached, which results in the automatic wrapping of the ply edges around the bead core, and the simultaneously movement of the sidewalls into position.

Stage 2: The tyre is shaped by inflating the rubber and applying side tread rubber, two steel belts and a cap ply to achieve a "green" tyre.

Valcanisation

The "green" tyre is placed in a curing press for a certain period of time (10-15 minutes) at a specific pressure and temperature. Once heat and pressure has been applied to the tyre, it is then removed from the mould having achieved its final size, shape and tread pattern.

Trimming

Excess rubber from the curing process is removed, and the tyre is trimmed to order.

Final Inspection

Each tyre is visually and electronically inspected for balance, quality and uniformity. This final check ensures consistent and reliable performance.

The concentration of the notified chemical in the end-use product (finished rubber tyre) is 2%.

The finished tyres are stored in a warehouse before it is sold to wholesalers.

Major Steps Involved in tyre manufacture
(Diagram below was extracted from http://www.etyres.co.uk/tyre-construction)

II. Conveyor Belt Manufacture

Mixing of materials

The ULTI-PRO®100 fibre drums are manually transferred to weighing station before the notified chemical in the form of flakes is manually scooped into Ethyl Vinyl Acetete (EVA) bags with other ingredients for rubber mixing in a Banbury mixer. Various grades of natural and synthetic rubber are combined with carbon black, sulphur and chemical products to meet specific compound requirements. The first pass blend is called the "master batch", which is formed into rubber sheets, and cooled. It is then passed through the banbury a second time to mix curatives. All batches are laboratory tested before being released for further processing.

Calendering the rubber

Heat is applied to the rubber to make it more elastic by processing it through a series of rubber mills. The rubber is extruded into a flat sheet by passing the hot rubber between large heated rollers of a calender. The rubber is laminated to specified thickness and materials then made into rolls for the belt cure operation.

Curing the rubber

The “green” rubber is then cold pressed onto continuous steel cords for vulcanising in long belt curing press’s for times up to one hour. Time varies depending upon thickness and type of rubber used.

Trimming

Excess rubber or flash is removed from the belt edges, and the conveyor belt is rolled into steel shells of up to 40 tonnes or 6 meters maximum diameter.

Final Inspection

Each roll of belt is visually inspected for quality and uniformity, any defects are cut out of the belt and vulcanised in a repair press. This final check ensures consistent and reliable performance to quality standards ISO9001.

The concentration of the notified chemical in the end-use product is up to 2%.

The finished belt rolls are stored in the factory before delivery to customers.

Steps Involved in conveyor Belt Manufacture

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage			

Transportation from dock to tyre manufacturers warehouse	< 4	2-3 hours/day	10 – 15 days/year
Rubber Goods Manufacture			
Material preparation	< 4	10 minutes/day	52 days/year
Rubber Goods Building	< 4	6 hours/day	52 days/year
Curing	< 4	6 hours/day	52 days/year
Final Inspection	< 4	6 hours/day	52 days/year
End users – wholesale tyre dealerships (this area does not apply for conveyor belts)	> 1000	8 hours/day	300 days /year

Exposure Details
Transport and storage
Exposure to the polymer is unlikely during transportation and storage. Exposure may result in case of an accidental spill or leak in the container. Gloves, coveralls and goggles are available if required.

Manufacturing of rubber goods
Manufacture of the rubber goods involves mixing, blending and moulding of the rubber containing the notified chemical into rubber goods using automated, self-contained machinery. Dermal and accidental ocular contact with the notified chemical may occur during weighing and introduction into internal mixer. Inhalation exposure is unlikely as the notified chemical is in flake form.

All workers involved in the production of master batch (rubber sheet) will wear personal protective equipment including gloves, safety glasses and overalls. The processing equipment operates under local exhaust ventilation systems to remove any fugitive dust and Local exhaust ventilation is employed during weighing, and dispensing of flakes containing the notified chemical into an enclosed internal mixer. Respiratory equipment is available for use if the local exhaust ventilation is inadequate.

During the extrusion process the machine operates at temperature of up to 200ºC under local exhaust ventilation systems to remove heat and rubber processing fumes. Processing fumes are passed through a scrubber before being emitted to the atmosphere. Operators handling rubber sheet wear gloves and eye protection. They may also wear dust mask during the cutting of rubber sheet.

End-use
The finished product (rubber goods) contain the notified chemical at 2% concentration. At this stage is chemically bound within the rubber matrix and is not available for separate exposure during handling of rubber goods.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured or repackaged in Australia. Local operation will include transport and storage, manufacture of rubber goods and end use in tyres or conveyor belts.

During the manufacture of rubber goods the estimated annual losses of notified chemical are:

Spills	(less than 0.5%)	< 150 kg
Import drum residuals	(less than 0.5%)	< 150 kg
Total Annual Loss		< 300 kg

All the manufacturing waste, including that arising from the trimming of tyres (~5%) will be disposed to landfill.

RELEASE OF CHEMICAL FROM USE
The finished product (rubber goods) containing the notified chemical will be incorporated into vehicles in the case of tyres. Conveyor belts are used for industrial application only. It is expected that as tyres wear, the notified chemical, stated by the notifier to be entrapped within the rubber, will be released in

a diffuse manner across Australia. The mode of entrapment is expected to be physical as opposed to chemical, based on the structure of the notified chemical and of the rubber. The notifier states that the notified chemical in the environment will remain firmly entrapped within the inert rubber matrix of the rubber and therefore, is not expected to leach out. At the end of their useful life, the rubber goods containing the notified chemical will typically be disposed of to landfill or be incinerated.

Used rubber goods will be disposed of directly to landfill. Chemical in rubber articles disposed of to landfill will remain bound to rubber and undergo slow degradation. If the waste or used rubber article is incinerated, the notified chemical will be destroyed by conversion to oxides of carbon, nitrogen and sulphur and water vapour.

5.5. Disposal

All the manufacturing waste, including that arising from the trimming of tyres will be disposed to landfill.

At the end of their useful life, the rubber goods containing the notified chemical will typically be disposed of to landfill or be incinerated.

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, manufacturing of rubber goods or disposal is negligible. Members of the public may make occasional dermal contact with rubber goods. However, at this stage the notified chemical is chemically bound within the rubber and will not be bioavailable.

Tyre particles from wear of tyres during normal functioning on roads could potentially be inhaled or ingested. Approximately 10% of particulate matter (< 10μm diameter) particulates in the urban environment may be tyre dust and these would contain a maximum of 2% notified chemical in bound form.

6. PHYSICAL AND CHEMICAL PROPERTIES

A number of physico-chemical properties measured by INDSPEC were reported as the result only and the reports consisted of interoffice memos which are listed in the Bibliography.

Appearance at 20ºC and 101.3 kPa	Purple flakes.
Melting Point/Freezing Point	[a]81 - 82ºC (for the notified chemical). [b]Softening Point for Ulti-Pro®100 is 81.2ºC
METHOD	Not specified.
Remarks	[a]Test report is not available. Information cited in NTP Chemical Repository (Radian Corporation, August 29, 1991). [b]INDSPEC Chemical Corporation - Lab Analysis for Softening Point
Boiling Point	[a]340ºC (for the notified chemical) [b]Calculated Boiling point for the notified chemical – 340.68±15.00ºC [c]366.2ºC (Test report for vapour pressure of notified chemical)
Remarks	[a]Test report is not available. Information cited in NTP Chemical Repository (Radian Corporation, August 29, 1991). [b]ACD/Boiling Point and Vapour Pressure 8.02, Web Service

[c]Test report – Wiltec (2004)

Density 1240 kg/m^3 at 25°C

METHOD Not specified.
TEST FACILITY INDSPEC (2002)

Vapour Pressure 0.28 kPa at 180°C

METHOD Not specified.
Remarks Vapour pressure was measured using a glass still at temperatures from 180°C to 358°C.
TEST FACILITY Wiltec (2004)

Water Solubility 0.796 g/L at 20°C

METHOD Not specified (minimal details provided).
Remarks This value was derived by a liquid chromatographic technique while deriving the log P_{ow} (see below). Measured concentration was found to be 0.0043 moles/L.
TEST FACILITY INDSPEC Chemical Corporation (2004)

Hydrolysis as a Function of pH Not determined.

Remarks Not determined. The notified chemical does not contain any group which can undergo hydrolysis.

Partition Coefficient (n-octanol/water) log P_{ow} = 2.45

METHOD Not specified (minimal details provided).
Remarks This value was derived by a liquid chromatographic technique with identification made from retention data only. Based on the solubility of UltiPro® 100 in octanol and water the following calculation was used to determine the octanol/water partition coefficient:

$P_{ow} = C_{octanol}/C_{water}$ where C = molar concentration
$C_{octanol}$ = 1.22 moles/litre
C_{water} = 0.0043 moles/litre
P_{OW} = 1.22 moles/litre/0.0043 moles/litre = 284

$\log P_{ow}$ = 2.45
TEST FACILITY INDSPEC Chemical Corporation (2004)

Adsorption/Desorption log K_{oc} = 2.8 ± 1.0 at pH 7 (estimated)

METHOD ACD/Adsorption Coeff. And BCFWin Service, 8.02
Remarks The notified chemical is expected to bind moderately strongly to organic matter in soil.

Dissociation Constant Not determined.

Remarks The apparent pH for a solution of Ulti-Pro™ 100 is reported to be in the range of 8.9 – 9.3.
TEST FACILITY INDSPEC Chemical Corporation (2002)

Particle Size Less than 0.1% of the material is smaller than 45 microns.

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Sieve No.	*Nominal Size (microns)*	*Weight% per Sieve*	*Weight % Cumulative*
3/8 in.	[9525]	29.5	29.5 (by hand)
5	4000	50.1	79.6 (by hand)
12	1700	17.2	96.8 (by hand)
20	850	2.0	98.8 (Ro-Tap)
50	300	0.8	99.6 (Ro-Tap)
100	150	0.2	99.8 (Ro-Tap)
140	106	0.1	99.9 (Ro-Tap)
200	75	0.0	99.9 (Ro-Tap)
325	45	Pan	

Remarks In the above table "by hand" refers to sieved by hand and Ro-Tap refers to a mechanical shaker.

TEST FACILITY INDSPEC (2006)

Viscosity

Temperature °C	*Viscosity, centipose*
70	Solid
78	70
80	60
100	25

METHOD Haake Rorovisco RV100; System: MV400; Rotor: MV 1

Remarks Viscosity measurements were made at a single shear rate until equilibrium was achieved.

The melt was first at 100°C and then gradually cooled. Viscosity was then measured at 80°C. As expected, the notified chemical solidified in the low 70°C's. Upon reheating, the rotor became somewhat free at about 75-70°C and a reading was taken at 78°C. The melt was then adjusted to 80°C for another measurement. The viscosities at 80°C – that upon cooling and that upon reheating – were the same.

TEST FACILITY INDSPEC (2002)

Flash Point > 99°C (Flash point by Pensky-Martens Closed Tester)
198°C (ASTM D92, Flash & Fire Points by Cleveland Open Cup)

METHOD Flash point by Pensky-Martens Closed Tester and ASTM D92, Flash & Fire Points by Cleveland Open Cup

Remarks Due to an uncertainty in the value obtained for the closed cup, a value was obtained using the open cup procedure.

TEST FACILITY INDSPEC (2002)

Flammability Limits Not determined.

Remarks Not expected to be flammable based on flash point.

Autoignition Temperature Not determined

Remarks Appears to be thermally stable up to 198°C and 358°C in measurements of vapour pressure and flash point.

Explosive Properties The notified chemical has strong dust explosion characteristics.

METHOD According to – International standardization Organization (1995) Explosion Protection systems. Part 1: Determination of Explosion Indices of Combustible Dusts in Air USO 6184/1, ISO Geneva.

Remarks The test substance was ground and sieved to a particle size of < 75 μm.

Maximum Explosion Pressure (Pmax):	8.8 bar
Max. Rate of Pressure Rise (dP/dt) max:	794 bar/s
Kst Value:	216 bar. m/s

RESULTS

Remarks – Results

TEST FACILITY Chilworth Technology Inc (2005)

Reactivity

Remarks Will not undergo hazardous polymerisation. Incompatible to strong oxidisers. Decomposition products are: toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral toxicity	Low to moderate toxicity, LD50 > 550 mg/kg bw
Rat, acute oral toxicity	Low toxicity, LD50 > 2010 mg/kg bw
Rat, acute dermal toxicity	Low toxicity, LD50 > 2010 mg/kg bw
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation	Severely irritating
Mouse, Local Lymph Node Assay (LLNA)	Evidence of sensitisation.
Repeat dose toxicity	No NOAEL was reported for an analogue in a 13 week feeding study. No significant organ damage was observed.
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	Non clastogenic

7.1. Acute toxicity – oral

7.1.1 Limit Test - Dose: 550 mg/kg bw

TEST SUBSTANCE	Notified chemical
METHOD	United States Environmental Protection Agency, OPPTS Health Effects Test Guideline 870.1100.
Species/Strain	Rat/ Sprague-Dawley Crl:CD®(SD)(IGS)BR
Vehicle	Ethanol and PEG 400
Remarks – Method	Five male and five female rats were given a single gavage dose at a maximum level of 550 mg/kg bw. The animals were observed at 1, 2.5 and 4 hours and daily for 14 days following dosing for signs of toxicity. Animals were euthanised and subjected to necropsy following 14 days of observation.
RESULTS	
LD50	> 550 mg/kg bw
Signs of Toxicity	No animals died during the course of the study. Clinical findings noted during the study for males were limited to anogenital staining on all five animals on day 1 post dose. No other clinical findings were noted. On the day of dosing, all five females were noted with decreased activity, four animals had excessive salivation, two had lacrimation and three were noted with hunched posture. One female was noted with anogenital staining on day 1 post dose. No other clinical findings were noted. All five males and four females gained weight over the course of the study. The remaining female gained weight during the first week after dosing, but lost weight prior to termination.
Effects in Organs	One male was noted with mottled kidneys. One male (slight) and one female (moderate) were noted with dilated renal pelvis of the right kidney. All other tissues examined at necropsy were found to be grossly normal.
Remarks – Results	None.
CONCLUSION	The notified chemical is of low to moderate toxicity via the oral route.
TEST FACILITY	Ricerca Biosciences (2003a)

7.1.2 Limit Test - Dose 2010 mg/kg bw

TEST SUBSTANCE	Notified chemical
METHOD	United States Environmental Protection Agency, OPPTS Health Effects Test Guideline 870.1100.
Species/Strain	Sprague-Dawley/Crl:CD®(SD)
Vehicle	Ethanol and PEG 400
Remarks – Method	The test material was not GLP characterised. There were no analyses of the dose preparations performed.
RESULTS	
LD50	> 2010 mg/kg bw
Signs of Toxicity	No animals died during the course of the study. Clinical findings noted during the study for males and females in the vehicle control group were limited to soft faeces in each of the 10 animals on day 1 post dose. No other clinical findings were noted in this group. In group dosed with 2010 mg/kg bw, clinical signs included a decrease in activity and ataxia in most of the males and females at the 1-hour observation. Ataxia persisted in one female rat through the 4-hour interval. Soft faeces and dark faeces were noted in males on Day 1. The males were all normal by day 2 except for one with ventral hair loss and another with anogenital staining, few or no feaces and soiled coat. Soft faeces and dark urine were observed in most female rats on day 1 and green or dark urine was noted in the five female rats on days 2 and 3. Females were all normal by day 4. All 10 males and 10 females in both groups gained weight over the course of the study.
Effects in Organs	One male in the vehicle control (0 mg/kg bw) group was noted with a dilated renal pelvis of the right kidney. One female in the 2010 mg/kg bw group had slight hair loss on the left dorsal shoulder and another female had both ovaries discoloured red. All other tissues examined at necropsy were found to be grossly normal.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Ricerca Biosciences (2006)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	United States Environmental Protection Agency, OPPTS Health Effects Test Guideline 870.1200.
Species/Strain	Rat/Sprague-Dawley (Crl:CD®(SD)(IGS)BR)
Vehicle	Test substance moistened with water.
Type of dressing	Semi-occlusive.
Remarks – Method	One day prior to dermal application of the test material, the backs of the rats were clipped free of hair with electric clippers. An area starting at the scapulae (shoulder) to the wing of the ilium (hip bone) and half way down the flank of the animal was clipped. The clipped area allowed an adjacent area of untreated skin to serve as a control site. Care was taken to avoid abrading the skin during the clipping of the backs.

	The area of application was approximately 10% of the total body surface area. A porous gauze patch was used to maintain the test material in contact with the skin. The material was moistened with distilled water to ensure good contact with the skin. The patch was secured in place with Johnson and Johnson hypoallergenic tape. To further secure the patch, bandaging was wrapped around the trunk of the animal and taped in place. This procedure was repeated for each animal. An Elizabethan collar was worn by the animal during the exposure period. After 24 hours, the bandaging, patch and collar were removed and the skin was gently wiped with disposable paper towels wetted with tap water to remove any test material still remaining.
RESULTS	
LD50	> 2010 mg/kg bw
Signs of Toxicity - Local	None reported.
Signs of Toxicity - Systemic	No animals died during the course of the study. All five males and four females gained weight over the course of the study. The remaining female gained weight during the first week after dosing, but lost weight prior to termination. Clinical findings noted during the study for males included coloured material around the nose for all animals and around one or both eyes for four animals on the day of dosing. Two males were also noted with anogenital staining on the day of dosing. On day 1 post dose, one male had coloured material around both eyes, and on day 2, one male had few or no faeces. No other clinical findings were noted. Three females were noted with colored material around the nose, two females had coloured material around both eyes, and one female had anogenital staining on the day of dosing. Two females had few or no faeces (one on day 2 and one on days 5 and 12 post dose). One female was noted as dehydrated on days 5 and 6. No other clinical findings were noted.
Effects in Organs	The tissues of all animals used in the study were found to be grossly normal at necropsy.
Remarks – Results	No animals died during the course of the study. The LD50 of Ulti-Pro®100 was greater than 2010 mg/kg bw when administered as a single dermal dose to rats under the conditions of this study.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Ricerca Biosciences (2003b)

7.3. Acute toxicity – inhalation

Not determined.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	United States Environmental Protection Agency, OPPTS Health Effects Test Guideline 870.2500.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Vehicle	Test substance moistened with water.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks – Method	One day prior to dermal application of the test material, the backs of the

rabbits were clipped free of hair with electric clippers. An area starting at the scapulae (shoulder) to the wing of the ilium (hip bone) and half way down the flank on one side of the animal was clipped. The clipped area allowed an adjacent area of untreated skin to serve as a control site. Care was taken to avoid abrading the skin during the clipping of the backs.

Approximately 0.5 g of test material was applied to an approximately 1 x 1 in. (6 cm^2) test site on the side of each animal's back and was covered with a 1 x 1 in. gauze patch. The solid test material was moistened with water to aid in the application. The test sites were marked using a black marking pen. The patch was held in place with Johnson and Johnson hypoallergenic tape. In order to further secure the patch, bandaging was wrapped around the trunk of the animal and taped in place.

This procedure was repeated for each animal. The animals were maintained such that access to the test site was prevented. The exposure duration was 4 hours. After 4 hours, the bandaging and patch were removed, and the skin was gently wiped with disposable paper towels wetted with tap water to remove any test material that remained.

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	2	2	2	2	Day 14	1
Oedema	0	0	0	0	-	0

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

Remarks – Results

At the 1 hour scoring interval 2 of the 3 rabbits had well defined erythema scores and one animal had a very slight erythema score. From 24 hours through 72 hours all animals had well defined erythema. At day 7 the scores were decreased to very slight erythema in 2 rabbits and no erythema in one rabbit. By day 14 one animal had very slight erythema. One animal had desquamation at 72 hours, this finding was not present at the day 7 scoring interval. No oedema was seen during the observation and scoring period. The study was terminated on day 14.

CONCLUSION

The notified chemical is moderately irritating to skin.

TEST FACILITY

Ricerca Biosciences (2003c)

7.5. Irritation – eye

TEST SUBSTANCE

Notified chemical

METHOD

United States Environmental Protection Agency, OPPTS Health Effects Test Guideline 870.2400.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 3 Females (the rabbits were nulliparous and non-pregnant)

Observation Period: 8 days

Remarks – Method: Each of the rabbits received 0.1 g of the test material instilled into the conjunctival sac of one eye. After instillation of the test material, the upper and lower lids were closed for approximately one second to minimise loss material. All animals were maintained on the study for 8 days following test material administration.

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	2	2	2	2	Day 8	2
Conjunctiva: chemosis	3	3	3	3	Day 8	3
Conjunctiva: discharge	2.3	2.3	2.3	3	Day 8	2
Corneal opacity	2	2	2.3	4	Day 8	4
Iridial inflammation	1	1	1	1	Day 8	1

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

Remarks – Results: Opacities were seen in all 3 rabbits at the 1 hour scoring interval and continued through day 8. These opacities ranged from a score of 2 to 4 density with involvement of the entire cornea. The iris has a score of 1 from 24 hours through day 8 with swelling and congestion. Redness, chemosis and discharge of the conjunctivae were seen from the 1 hour score through day 8. Additional findings included blisters, purulent discharge, petechial haemorrhage, vascularization and epithelial lesions. Because of the severe effects seen in the eyes the study was terminated on day 8.

CONCLUSION: The notified chemical is severely irritating to the eye.

TEST FACILITY: Ricerca Biosciences (2003d)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD Guidelines for Testing of Chemicals, Updated Guideline 429: Skin Sensitisation: Local Lymph Node Assay (adopted 24 April 2002)

Species/Strain: Mice, CBA/CaOlaHsd

Number of Animals: Test Group: 3 Control Group: 1

Vehicle: acetone:olive oil (4 +1)

The animals where distributed as follows:

Group	*Concentration[b] (%)*	*No. of animals per group*
1 (Control Group[a])	-	4
2 (Low Dose)	12.5	4
3 (Mid Dose)	25	4
4 (High Dose)	50	4

[a]) – vehicle

[b]) – In a non-GLP pre-test in 2 mice, test item concentrations of 6.25, 12.5, 25 and 50% were tested on one ear each. No irritation effects were observed at these concentrations after a single application.

Remarks – Method: The test substance (25 µL) was administered topically to the dorsal surface of each ear lobe once daily for 3 consecutive days.

RESULTS

Test item concentration % (w/v)	*Group*	*Measurement DPM*	DPM-BG [a)]	*Calculation* number of lymph nodes	DPM per lymph node [b)]	*Result* Stimulation Index
	BG I	49.69	---	---	---	---
	BG II	17.06	---	---	---	---
	CG 1	5507.13	5473.8	8	684.2	

12.5	TG 1	40769.10	40735.7	8	5092.0	**7.44**
25	TG 2	56510.60	56477.2	8	7059.7	**10.32**
50	TG 3	69322.00	69288.6	8	8661.1	**12.66**

BG= Background (1 ml 5% trichloroacetic acid) in duplicate
CG= Control Group
TG = Test Group

a) = The mean value was taken from the figures BG I and BG II
b) = Since the lymph nodes of the animals of a dose group were pooled, DPM/node was determined by dividing the measured value by the number of lymph nodes pooled

Remarks – Results

The EC3 value could not be calculated, since all SIs were above 3.

No deaths occurred during the study period.

The animals did not show any clinical signs of toxicity after the first application. After the second application the highest dose (50 %) induced slight reddening of the ear skin of all 4 animals of the group. After the last application the reddening was not observed.

The body weight of the animals, recorded prior to the first application and prior to treatment with ^{3}HTdR, was within the range commonly recorded for animals of this strain and age.

CONCLUSION

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

TEST FACILITY

RCC (2007)

7.7. Repeat dose toxicity

TEST SUBSTANCE

Analogue.

METHOD

Not specified

Species/Strain: Rat/ Sprague-Dawley
Route of Administration: Oral – diet.
Exposure Information: Total exposure days: 90 days
Remarks – Method: Groups of 30 male and 35 female rats received 0%, 0.1%, 0.25% or 1.00% analogue in the diet for 13 weeks.

RESULTS

Mortality and Time to Death

No visible signs of toxicity related to treatment were noted during the course of the study. No deaths occurred.

Clinical Observations

Significant decreases in body weights and feed consumption were noted in the males and females of the high dose group over 13 weeks. A significant decrease in body weights of the females of the middle dose group was observed during weeks 3-13, whereas sporadic decreases were noted in the males of both the low and mid dose groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

The results of the clinical chemistry testing were that no significant differences occurred in the females, whereas the high dose males had a decreased triglyceride level, considered related to the extreme decrease in body weights. No significant differences were noted in haematological values of the males; the high dose females had significant changes in erythrocyte count (decrease), haemoglobin (decrease) and mean corpuscular volume (increase), although these were within normal limits for the rats of this strain and age. No significant differences were noted in the methemoglobin concentrations of the high dose and control animals.

Effects in Organs

At necropsy, no abnormalities that could be related to treatment were noted. Significant increases in the relative liver and kidney weights of the high dose males and females were considered to be compound-induced hypertrophy, a normal response to xenobiotics. Significant changes in other organ weights of the high dose group were considered related to the decrease in body weights. Significant decreases in the thyroid gland weight and relative thyroid weight for males and females occurred at the low and intermediate doses. An increase in relative thyroid gland weight was noted in the high dose females. The following two findings were considered to be related to treatment with the analogue:

1. Deposition of iron-positive pigment in the spleen, liver and kidneys; and
2. Evidence of increased thyroid gland activity.

The pigmentation in the spleen ranged from slight to moderate in the controls to moderately to severe to severe in the treated group. A significant increase in pigmentation in the liver and renal tubes was also noted. An increase in the epithelial cell height and a decrease in the follicular size of the thyroid gland alveoli of the rats of the mid and high dose groups were taken as evidence of an increased activity.

Remarks – Results	The full study report was not available so a NOAEL could not be established.

CONCLUSION

No NOAEL was reported.

TEST FACILITY	Published report in Journal of the American College of Toxicology.

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	Preincubation
Species/Strain	*S. typhimurium*: TA1535, TA98, TA100, TA97.
Metabolic Activation System	RLI – induced male Sprague Dawley rat liver S9 HLI – induced male Syrian hamster liver S9
Concentration Range in Main Test	a) With metabolic activation: 0 - 1000 μg/plate b) Without metabolic activation: 0 - 1000 μg/plate
Vehicle	DMSO
Remarks – Method	For each strain the negative control without activation was repeated, 10% or 30% S9 was used either derived from rat (RLI) or hamster (HLI) liver.

RESULTS

Remarks – Results	Toxicity as indicated by a reduction in the number of revertants below that of the negative control was observed at 333 μg/plate –S9 and at 1000 μg/plate +S9.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NTP (1984)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain	SPF ARC(S) Swiss mouse
Route of Administration	Oral – gavage; i.p. injection for positive control.
Vehicle	Ethanol : PEG 300 (20 : 80) (notified chemical); corn oil: positive control.
Remarks – Method	No deviations from standard protocol.

Group	*Number and Sex of Animals*	*Treatment*	*Dose (concentration)*	*Route of administration*	*Sacrifice Time Hours (Time post-dosing)*
1	1M – 5M 6F – 10F	Vehicle (negative control)	10 mL/kg	Oral	24 hours
2	11M – 15M 16F – 20F	Vehicle (negative control)	10 mL/kg	Oral	48 hours
3	21M – 25M 26F – 30F	DMBA (positive control)	40 mg/kg (8.8 mg/ml)	IP	48 hours
4	31M – 35M 36F – 40F	Notified chemical (test item)	2000 mg/kg (20% w/w)	Oral	24 hours
5	41M – 45M 46F – 50F	Notified chemical (test item)	2000 mg/kg (20% w/w)	Oral	48 hours

DMBA 9,10-dimethyl-1,2-benzanthracene

RESULTS

Doses Producing Toxicity

In the control (Group 1) and the test item (Group 4) treated groups both males and females showed reduced weight gains at the 24-hours sacrifice time (male -1.35 ± 1.24% and -1.81 ± 1.56%; female -2.13 ± 1.31% and –2.19 ± 1.73%, respectively). At the 48-hour sacrifice time only females in the control (Group 2) and test item (Group 5) treated groups showed reduced weight gain (-0.97 ± 3.19% and -0.59 ± 8.23%, respectively). The 48-hour DMBA treated group (Group 3) exhibited a statistically significant weight loss following treatment in the males and females ($P = 0.0001$ and $P = 0.0003$).

In the test item treated groups (Groups 4 and 5) all animals were subdued and showed a decrease in activity 20 – 30 minutes after injection. Mouse 43M also showed laboured breathing and was found dead after 2 hours. All other mice returned to normal after 4 – 5 hours. No other clinical abnormalities were observed in any treated animals throughout the 24 and 48 hour observation periods.

In the DMBA treated group (Group 3) all male and all female mice (except 27F) exhibited piloerection during the first 24 hours. At the 48-hour observation period four mice (23M, 24M, 25M and 26F) still had piloerection, other mice showed no other clinical abnormalities.

Genotoxic Effects

The test procedure was considered valid since a statistically significant increase ($P = 0.0017$ and $P = 0.0005$) in the frequency of micronucleated polychromatic erythrocytes (MPCE) was seen in both sexes treated with the positive control DMBA (Group 3), when compared with the negative vehicle control group (Group 2). There was also a statistically significant depression ($P < 0.0001$) of PCE and PCE + NCE ratio in the positive control groups indicating toxicity of DMBA.

In both test item treated groups (Groups 4 and 5), there was no significant increase in the frequency of MPCE when compared with negative control groups (Groups 1 and 2) at 24 and 48 hour sampling

tines. There was no statistically significant depression of PCE and PCE + NCE ratio in the test item treated groups in either sex when compared with the vehicle control groups.

Remarks – Results

CONCLUSION The notified chemical was not clastogenic in this in vivo mouse micronucleus test under the conditions of the test.

TEST FACILITY ICP Firefly Pty Ltd (2006)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical

METHOD
- Inoculum: Inoculums from activated sludge (domestic waste)
- Exposure Period: 28 d
- Auxiliary Solvent: Deionised Water
- Remarks - Method: The following deviations were made from the protocol:

Benzoic acid was used for the Process Control rather than aniline. The testing guidelines indicate that either of these chemicals may be used for this purpose.

100 mL rather than 50 mL of 0.0125 mol/L $Ba(OH)_2$ was used in the bottles used to trap CO_2 evolved from the biodegradation. The calculation in section 10.5 was therefore revised compared with that given in the protocol to adjust for the larger volume.

There was an error in the formula given in section 10.3.1 of the protocol. The term mg/mg was not required.

There were errors in the formula given in section 10.4 of the protocol. There was a multiplication symbol before "mg test substances added" which was not required and the % degradation presented was calculated by subtracting the mean IC results from the mean test substance or mean Process Control results.

The TOC and TC were not determined at the end of the test. These determinations were not required as the experimental procedures used were identical for all samples prepared (Inoculum Controls, Process Controls and test substance).

None of these deviations had any effect on the integrity or validity of this study.

RESULTS

Test substance		*Benzoic Acid*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0.629	1	17.5
3	-1.28	3	53.6
8	-0.580	8	79.3
12	-2.27	12	82.5
20	-1.73	20	86.7

28	-3.987	28	86.89

Remarks - Results: Ten percent degradation had not been reached and the test substance, ULTI-PRO® 100 did not reach the pass level of 60%. The validation criteria were satisfied.

CONCLUSION: The test substance is not readily biodegradable.

TEST FACILITY: Supervision and Test Center for Pesticide Safety Evaluation and Quality Control (2006a)

8.1.2. Bioaccumulation

No study is available on the notified chemical. A BCF of 49.4 (pH = 7) is estimated for the notified chemical using ACD Laboratories Software. This indicates a low potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – Semi – static condition.
Species: *Brachydanio rerio* (Zebra fish)
Exposure Period: 96 hours
Auxiliary Solvent: Dimethylformamide (DMF)
Water Hardness: 88 mg $CaCO_3$/L
Remarks – Method: 1.0 g of test substance was dissolved in 20 mL DMF, and then aliquots of this stock solution were added to water to produce the test concentrations. No deviations from the standard protocol.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*						*Abnormalities*
Nominal	*Actual*		*3 h*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*	
2.0		10	0	0	0	0	0	0	No observed toxic effects
2.5		10	0	0	0	0	0	0	No observed toxic effects
3.2		10	0	0	0	0	0	3	Loss of equilibrium, haemorrhaging of opercula
3.5		10	0	0	1	1	1	8	Loss of equilibrium, haemorrhaging of opercula
4.0		10	0	0	2	2	4	6	Loss of equilibrium, haemorrhaging of opercula, curved spine
4.5		10	0	0	1	2	5	8	Loss of equilibrium, haemorrhaging of opercula, curved spine
5.0		10	0	0	5	9	10	10	Loss of equilibrium, haemorrhaging of opercula, curved spine
Control		10	0	0	0	0	0	0	No observed toxic effects
Solvent Control		10	0	0	0	0	0	0	No observed toxic effects

LC50: 3.4 mg/L at 96 hours (95% confidence limit was 3.1 – 3.8 mg/L)
NOEC: 2.5 mg/L at 96 hours.

Remarks – Results	Analysis of test concentrations was not conducted, and results are based on the nominal concentrations only. The test report failed to indicate whether the notified chemical was fully dissolved.
CONCLUSION	The notified chemical is toxic to *Brachydanio rerio.*.
TEST FACILITY	Supervision and Test Center for Pesticide Safety Evaluation and Quality Control (2006b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Dimethylformamid (DMF)
Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	HPLC/UV
Remarks – Method	The study plan states (section 2.6, first paragraph) that twice a year, a 48 hour reference test will be conducted with daphnids from laboratory culture. Only once a year, a 48 hour reference test was conducted with daphnids from laboratory culture. This deviation does not affect the results of this study, since parallel to the definitive study reported here a 48 hour reference test was conducted. Solutions were prepared by first dissolving in the auxiliary solvent, and then diluting with water to produce the test concentrations. The test report failed to indicate whether the notified chemical was fully dissolved. However, daphnids were observed carrying material at their carapax and/or abdominal claws, which was presumably undissolved notified chemical. Analytical of test concentrations was done using HPLC and UV.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	0	20	0	0
Solvent Control	0	20	0	0
0.31	0.32	20	0	0
0.68	0.69	20	0	0
1.55	1.57	20	0	0
3.28	3.24	20[a]	0	1[b]
7.28	7.57	20[c]	11	20

[a] 7 out of 20 daphnids were swimming carrying material at their carapax and/or abdominal claws

[b] From the surviving daphnids, 1 out of 19 daphnids showed lethargic behaviour and were swimming carrying material at their carapax and/or abdominal claws.

[c] From the surviving daphnids, 9 out of 9 daphnids showed lethargic behaviour and were swimming carrying material at their carapax and/or abdominal claws at the same time.

EC50	4.68 mg/L at 48 hours (95% confidence interval: 3.24 to 7.57 mg/L)
NOEC	1.57 mg/L at 48 hours
Remarks – Results	The EC50 value and corresponding 95% confidence interval was determined using non-linear interpolation calculated by binomial probability. The validation criteria were satisfied.
CONCLUSION	The notified chemical is toxic to *Daphnia magna*.
TEST FACILITY	Springborn Smithers Laboratories (Europe) 2006

8.2.3 Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	In accordance with ESA Standard Operating Procedure 103, based on methods described by the USEPA (1994). Test type: Static, non-renewal
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	10, 5, 2.5, 1.25 and 0.625 mg/L
Auxiliary Solvent	Methanol carrier solvent
Analytical Monitoring	
Remarks – Method	No significant deviations from standard protocol were reported, other than the concentration of solvent exceeding guideline levels.

RESULTS

The cell density of *Selenastrum capricornutum* after 72-h exposure to Ulti-Pro® 100

Concentration (mg/L)	*Cell density at 72-h (x 1000) (Mean ± SD)*
0 (Control)	45.3 ± 2.1
Solvent control (0.1% vol/vol methanol)	45.3 ± 2.2
0.625	44.5 ± 3.0
1.25	44.5 ± 2.7
2.5	32.5 ± 1.3*
5	14.3 ± 1.7*
10	3.0 ± 0.8*

* Significantly reduced algal cell density compared with solvent control treatment (Dunnett's Test, P=0.05, 1-tailed, df = 5.18)

Remarks – Results	The 72-h IC50 (with 95% confidence limits) of Ulti-Pro® 100 in methanol carrier solvent to *Selenastrum capricornutum* was estimated to be 3.9 (3.6-4.1) mg/L. The NOEC and LOEC estimates were 1.25 and 2.5 mg/L, respectively. None of the test solutions exhibited any opaqueness, and therefore were unlikely to have affected light availability to the algal cells. The solvent control treatment was not significantly different to the control treatment, and the solvent control treatment was used for statistical comparison against the test treatments.
CONCLUSION	The notified chemical is toxic to *Selenastrum capricornutum.*
TEST FACILITY	Ecotox (2006)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported in 90 kg plastic lined fibre drums, and on arrival, will be transported to rubber product manufacturing facilities, where the notified chemical will be mixed with other rubber components and extruded to form the finished products. Up to 5% of the total annual import volume may be produced as waste during the manufacture of tyres, resulting from trimming during the process. This is expected to be disposed of to landfill. Residual within the import containers has been conservatively estimated to account for up to 0.5% of the total annual import volume, and is expected to be disposed of to landfill. Similarly, accidental spills have been estimated to account for a further 0.5% of the total annual import volume, and again, are expected to be disposed of to landfill.

Manufacture products containing the notified chemical are expected to include rubber tyres. As rubber tyres, containing the notified chemical, wear during normal use, it is expected that rubber containing the notified chemical will be released to the environment along roadsides, and that much of this, in an urban environment, will eventually enter storm water drains during rainfall events, thus entering the aquatic environment. This concentration within the sewer system is expected to be mitigated by the increased flow resulting from the corresponding rainfall event.

At the end of the useful life of the rubber products, it is expected that they will be disposed of to landfill, or to a lesser extent, by incineration.

9.1.2. Environment – effects assessment

The following Predicted No-Effect Concentration value has been derived using the most sensitive of the three trophic levels tested.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	3.40	mg/L
Assessment Factor	100.00	
PNEC:	34.00	µg/L

9.1.3. Environment – risk characterisation

As it is not possible to calculate a Predicted Environmental Concentration, it is therefore, not possible to determine a Risk Quotient (Q) value. While the notified chemical has been found to be toxic to aquatic organisms, and not to be readily biodegradable in sewer, direct release to the aquatic environment of the notified chemical, in isolation from rubber products is not anticipated throughout the proposed lifecycle of the notified chemical within Australia. While it is anticipated that a proportion of the total annual import volume of notified chemical in association with worn rubber from tyres, will eventually enter natural waters after been washed by precipitation into storm water systems, this is expected to occur when flows are higher than normal, thus significantly mitigating the concentration of notified chemical within the aquatic environment. Therefore, it is expected that the risk to the aquatic environment from the proposed use pattern and volume of the notified chemical will be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage workers will handle the 90 kg fibre drums in which the notified chemical is imported but the only potential for exposure would arise from cleaning up spillage from an accident involving rupture of the containers. In this case, the potential for dermal exposure would be expected to be controlled by the use of impervious gloves and protective clothing.

For tyre manufacture the notified chemical in the form of large flakes is scooped manually to a weighing vessel and then to a mixer containing the rubber and other additions. Conveyor belt manufacture is initiated similarly except that EVA bags are used to receive the weighed chemical.

Exposure to the notified chemical in the form of solid flakes is likely to be mainly dermal and will be controlled by the use of impervious gloves. Given the physical nature of the notified chemical, any exposure to unprotected skin would be brief as the flakes should not be retained on the skin and if retained, the notified chemical is unlikely to be absorbed in this form due to the low likelihood of dissolution in, for example, perspiration. Accidental ocular exposure could occur during manual weighing and transfer can also occur. Inhalation exposure is low due to the fact that ~98% of particles have a size of 1 mm or above but, in any case, is also controlled by the use of local exhaust ventilation at the point of weighing an over the mixing vessels.

The notified chemical is added to the mixer at 2% and is no longer present following mixing as it is chemically reacted with the rubber and other components. Thus exposure of workers to the notified chemical following mixing will not occur.

9.2.2. Public health – exposure assessment

The public could potentially be exposed to the notified chemical in the event of a transport accident but in this case exposure can be predicted to be low given the physical form of the notified chemical. The public may be exposed to rubber tyres or tyre particles in the environment. However, the notified chemical in these instances, no longer exists in free form and therefore exposure is expected to be negligible.

9.2.3. Human health – effects assessment

The notified chemical is predicted to be of low acute oral and dermal toxicity, is likely to be a moderate skin and a severe eye irritant and a skin sensitiser and is not likely to be genotoxic. Although no NOAEL could be established from a 90-day oral repeat dose study on an analogue chemical no significant organ damage was observed.

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

R38 Irritating to skin.
R41 Risk of serious damage to eyes.
R43 May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

The form of the notified chemical (solid flakes with a low level of inspirable particles, which are slightly water soluble) suggests that exposure can be easily controlled. The main point at which workers can be exposed is when the flakes are manually scooped from the import containers to a weighing vessel and then to the mixer. Once in the mixer, exposure is not expected as the system is enclosed and subject to exposure controls such as local exhaust ventilation and the notified chemical becomes chemically bound in the rubber. Therefore, any fumes generated should not contain the notified chemical as such and no absorption should occur from handling the rubber in subsequent operations.

Given the hazardous nature of the notified chemical, particularly the potential to cause irreversible damage to eyes, mechanical aids for transfer operations should be employed in favour of reliance on personal protective equipment alone. This is despite the fact that the form of the notified chemical means it would be unlikely to be retained on the skin or solubilised appreciably in, for example, perspiration which could increase the likelihood of skin irritation or sensitisation. In addition absorption from the skin would also be expected to be minimal in these circumstances. Although there is some uncertainty in assessment of the effects of repeated or prolonged exposure, the likelihood of such exposure is low given the form of the notified chemical and the brief period required for addition to the mixer. Therefore, the risk of systemic effects is also low.

There is a low likelihood of transport or storage workers coming into contact with the notified chemical if import containers are accidentally ruptured and such exposure should be controlled by following recommendations for clean up of spillage as outlined in the MSDS.

9.2.5. Public health – risk characterisation

As negligible public exposure is expected there is no significant concern to public health when used as described.

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 *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R38 Irritating to skin.
R41 Risk of serious damage to eyes.
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 irritation	Category 3	Causes mild skin irritation
Eye irritation	Category 1	Causes severe eye damage
Sensitisation	Category 1	May cause an allergic skin reaction
Environment		
Acute	Category 2	Toxic to aquatic organisms
Chronic	Category 2	Toxic to aquatic organisms with long lasting effects

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be unacceptable due to the hazardous nature of the notified chemical and in particular it's potential to cause irreversible eye damage. As a result additions to the rubber mixer should only be conducted using mechanical aids (see recommendations section).

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 *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 *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:
  - R38 Irritating to skin.
  - R41 Risk of serious damage to eyes.
  - R43 May cause sensitisation by skin contact.
- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 1%, < 5% : R43
  - ≥ 5%, < 10%: R36 Irritating to eyes, R43
  - ≥ 10%, < 20%: R43, R41
  - ≥ 20%: R43, R41, R38
- The following safety phrases should appear on the MSDS and label for the notified chemical:
  - S24: Avoid contact with skin
  - S25: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S37: Wear suitable gloves
  - S39 Wear eye/face protection

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 sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - The notified chemical should be transferred from import containers to the mixer containing rubber and other components by mechanical means and specifically not by manual handling
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced when

transferring the notified chemical to a mixing vessel:
– Safety goggles or face shield, impervious gloves and protective clothing

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances*, 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 incineration or to landfill.

Emergency procedures

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

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.

13. BIBLIOGRAPHY

Ecotox (2006) Toxicity Assessment of Ulti-Pro 100 to the alga *Selenestrum capricornutum*. Study No. PR0208, May 2006, Ecotox Services Australasia Pty Ltd, Unit 27/2 Chaplin Drive, Lane Cove, NSW, Australia (unpublished report submitted by notifier).

ICP Firefly Pty Ltd (2006) In vivo Micronucleus Test of Ulti-Pro®100 in the Mouse. Study Number: ICPQN590.2 ICP Firefly Pty Ltd, 129 Queen Street, Beaconsfield NSW 2015, Australia (unpublished report submitted by notifier).

INDSPEC Chemical Corporation (2002) Ulti-Pro®100 Analysis of Softening Point (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2002) Ulti-Pro®100 Analysis of Apparent pH (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2002) Ulti-Pro®100 – Flash Point (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2002) Ulti-Pro®100 Test for Specific Gravity and Melt Viscosity (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2004) Ulti-Pro®100 – Octanol/Water Partition Coefficient (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2004) Solubility of Ulti-Pro®100 in Octanol and Water. (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2006) Ulti-Pro®100 – Sieve Analysis (3680) (*Interoffice memo)*. INDSPEC, 1010 William Pitt Way, Pittsburgh, PA 15238.

INDSPEC Chemical Corporation (2002) Interoffice Memo regarding pH.

INDSPEC Chemical Corporation (2004) Interoffice Memo regarding Solubilities.

INDSPEC Chemical Corporation (2006a) Biodegradation Test of Ulti-Pro 100, Study No. G0640A0090, 20 June 2006, Supervision and Test Center for Pesticide Safety Evaluation and Quality Control, 8 East Shenliao Road, Tiexi District, Shenyang 110021, Liaoning Province, P.R. China.

INDSPEC Chemical Corporation (2006b) Acute Toxicity Study of Ulti-Pro 100 to Zebra Fish (*Brachydanio rerio*), Study No. G0623J0090, 15 August 2006, Supervision and Test Center for Pesticide Safety Evaluation and Quality Control, 8 East Shenliao Road, Tiexi District, Shenyang 110021, Liaoning Province, P.R. China.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NTP (1984) National Toxicology Program: Salmonella Study Summary for Notified Chemical.

RCC Cytotest Cell Research GmbH (2006) Local Lymph Node Assay (LLNA) in Mice with Ulti-Pro® 100. Reference No. B00617. RCC Cytotest Cell Research GmbH (RCC-CCR), In den Leppsteinswiesen 19, 64380 Rossdorf (unpublished report submitted by notifier).

Ricerca Biosciences (2003a) Ulti-Pro®100: Acute Oral Toxicity Study in Sprague-Dawley Rats. Study Number: 015344. Toxicology and Pharmacology, Ricerca Biosciences, LLC, 7528 Auburn Road, Concord OH 44077-1000 (unpublished report submitted by notifier).

Ricerca Biosciences (2003b) Ulti-Pro®100: Acute Dermal Toxicity Study in Sprague-Dawley Rats. Study Number: 015433. Toxicology and Pharmacology, Ricerca Biosciences, LLC, 7528 Auburn Road, Concord OH 44077-1000 (unpublished report submitted by notifier).

Ricerca Biosciences (2003c) Ulti-Pro®100: Acute Dermal Irritation Study in New Zealand White Rabbits. Study Number: 015434. Toxicology and Pharmacology, Ricerca Biosciences, LLC, 7528 Auburn Road, Concord OH 44077-1000 (unpublished report submitted by notifier).

Ricerca Biosciences (2003d) Ulti-Pro®100: Acute Eye Irritation Study in New Zealand White Rabbits. Study Number: 015435. Toxicology and Pharmacology, Ricerca Biosciences, LLC, 7528 Auburn Road, Concord OH 44077-1000 (unpublished report submitted by notifier).

Ricerca Biosciences (2006) Acute Oral Toxicity Study in Sprague-Dawley Rats with Ulti-Pro®100. Study Number: 019296. Toxicology and Pharmacology, Ricerca Biosciences, LLC, 7528 Auburn Road, Concord OH 44077-1000 (unpublished report submitted by notifier).

Springborn Smithers Labs (2006) Ulti-Pro 100 – Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions, Study No. 1100.000.110 27 July 2006, Springborn Smithers Laboratories (Europe), Seestrasse 21, Postfach CH-9326 Horn, Swizterland (unpublished report submitted by notifier).

Supervision and Test Center for Pesticide Safety Evaluation and Quality Control (2006a) Degradation Test for Ulti-Pro®100. Study No.: G0640A0090. Supervision and Test Center for Pesticide Safety Evaluation and Quality Control, 8 East Shenliao Road, Tiexi District, Shenyang 110021, Liaoning Province, P.R. China (unpublished report submitted by notifier).

Supervision and Test Center for Pesticide Safety Evaluation and Quality Control (2006b) Acute Toxicity Study of Ulti-Pro® 100 to Zebra Fish *Brachydanio rerio.* Study No.: G0623J0090. Supervision and Test Center for Pesticide Safety Evaluation and Quality Control, 8 East Shenliao Road, Tiexi District, Shenyang 110021, Liaoning Province, P.R. China (unpublished report submitted by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

Wiltec (2004) Vapour Pressure Measurements on “Notified chemical” from 180 to 358 C. Wiltec Research Company Inc, UT, USA (unpublished report submitted by notifier).