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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C-3529

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FULL PUBLIC REPORT

C-3529

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188)
4th Floor, 969 Burke Road
Camberwell VIC 3124

Plastral Pty Ltd (ABN 68 00 144 132)
11B Lachlan Street
Waterloo NSW 2017

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
Molecular Formula
Structural Formula
Molecular Weight
CAS Number
Chemical Constituents
Identity of Non-hazardous Impurities
Details of Import Volume
Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour pressure
Water solubility
Hydrolysis as a function of pH
Partition co-efficient
Absorption/Desorption
Dissociation constant
Flash point
Toxicity information
Ecotoxicity information

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (1998)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
C-3529 (contain >95% of notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHOD IR and NMR
Remarks The notified chemical is a complex reaction product and there are no specific methods relating to its detection and determination. However, diagnostic IR and NMR data were provided.

3. COMPOSITION

DEGREE OF PURITY
The composition is variable and the purity is not defined.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

A mixture of two impurities at < 2% total

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as 100% in 200 L closed head steel drums.

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

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

USE
The notified chemical is to be used as a stabiliser in PVC (polyvinyl chloride) products for the construction industry, including pipe, fittings, siding, window profiles and other articles manufactured by extrusion or injection moulding of PVC.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified chemical will be imported by ship (Brisbane) and transported by road to the warehouse of Plastral Pty. Ltd and subsequently to one or more customers.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be used by one or more plastics processing companies.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 200 L closed head steel drums and transported from the wharf by road to the importer's warehouse and subsequently by road to customer sites.

5.2. Operation description

At the customer site, mixing plant operators transfer the notified chemical into a weighing container. Transfer is accomplished by inserting a pump spear into the drum and pumping the contents to the weighing vessel. The contents of the weighing container is added to an enclosed 1000 L mixing vessel containing PVC powder and other ingredients. After mixing the notified chemical is adsorbed into the porous PVC particles at a concentration of 1% (w/w) to produce a coarse free-flowing powder (97% of particles of between 61 and 425 microns in size). This powder is transferred via an enclosed chute to a

cooling vessel and subsequently via chute or auger-fed line to 500 L woven polypropylene bags until required for further processing.

The PVC compound is transferred from the 500 L storage bags into hoppers from which it is fed to moulding and extrusion machines.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport workers	5	1-2 hours/day	10 days/year
Warehouse workers	5-10	1-2 hours/day	20 days/year
Mixing plant operators	2-7	8 hours/day	30 days/year
Moulding and extrusion plant operators	10-15	8 hours/day	20-50 days/year

Exposure Details

Transport and warehouse workers would only be exposed to the notified chemical in the unlikely event of a spillage.

Inhalation exposure to mixing plant operators and moulding and extrusion plant operators is unlikely as the concentrated liquid form of notified chemical has low vapour pressure but dermal exposure to the 100% chemical is possible from drips and spills. However, after blending with PVC resin, inhalation of dust particles containing adsorbed notified chemical is possible. To control exposure workers wear goggles, respirator, nitrile gloves and overalls. The mixing vessel is fitted with local exhaust ventilation and is enclosed so that exposure of workers is unlikely during high-speed mixing. Local exhaust ventilation is employed during packing and some dermal contact may be possible from spillage.

There is potential for inhalation of the PVC particles which the notified chemical is adsorbed into during transfer and cleaning operations and this is controlled by the use of respirators and local exhaust ventilation. Once the moulding or extruded articles are produced the notified chemical should not be bioavailable and worker exposure should be nil.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Approximately 1% of import quantities (up to 300 kg per annum) of the notified chemical would be left in drums after emptying. The emptied drum contents are either incinerated or placed in landfill.

A further 0.5% (up to 150 kg per annum) may be lost to leaks and spills in the factory, and should be contained by appropriate bunding, absorbed onto sawdust or other absorbent materials and incinerated or placed into landfill.

Particulate material collected in vacuum equipment (stated to account for release of 0.5% of the chemical, up to 150 kg per annum), would also be placed in landfill.

Invariably some scrap PVC is generated during production as off cuts and tail end residues. This was stated to be a maximum of 1% of the PVC, and would account for a further release of up to 300 kg of notified chemical each year. Scrap could conceivably be recycled to the start of the extrusion process, but is more likely to be placed into landfill.

Overall release of the notified chemical during the PVC manufacturing process is estimated at a maximum of 3% of the import volume, amounting up to 900 kg each year. Most is expected to be placed in landfill although some may be incinerated.

RELEASE OF CHEMICAL FROM USE

Although the notified chemical is bound within the polymer matrix there may be some release from the surface of PVC pipes and other articles via slow diffusion, and loss via abrasion or slow dissolution in water (eg rain, drainage).

Although no specific information on the leaching of the chemical (or its possible degradation products) from construction materials under typical conditions was provided, a report was submitted by the notifier on the leaching of typical organic tin stabilisers from PVC into a fluid designed to simulate food (TNO Nutrition and Food Research, 1995). The fluid was composed of 3% acetic acid, 15% ethanol and 82% olive oil/water. A typical piece of PVC weighing 20 - 23 g and containing 0.7% of Sn stabiliser was immersed at 40°C in the simulation fluid for 10 days, after which the level of Sn in the fluid was determined using atomic adsorption spectroscopy (AAS). The broad conclusion was that the level of Sn migrating from the PVC to the food medium was very low, ranging from non detectable to around 14 µg Sn/kg of food. Results indicate that tin stabilisers are not very mobile in the PVC and that loss through leaching would be low.

The notifier indicated that some European authorities had concluded that the major Sn containing species that migrate from PVC stabilised with tin containing stabilisers are methyl tin chlorides (eg CH_3SnCl_3, $(CH_3)_2SnCl_2$). No supporting data were submitted but the conclusion is plausible given what is known of the new chemical's mechanism in stabilising PVC.

At the end of their service, most PVC pipes and other construction materials are expected to be placed into landfill. The PVC matrix would be slowly broken down through biological and abiotic processes and release the notified chemical or its degradation products.

5.5. Disposal

Overall release of the notified chemical during the PVC manufacturing process is estimated at a maximum of 3% of the import volume or up to 900 kg each year. Most is expected to be placed in landfill although some may be incinerated.

At the end of their service, most PVC pipes and other construction materials containing the notified chemical are expected to be placed into landfill.

5.6. Public exposure

Once the moulded and extruded articles are produced, the notified chemical will be bound within the PVC matrix, and will not be biologically available. The public will only come into contact with the encapsulated form of the notified chemical. Hence the potential for public exposure is considered to be low.

6. PHYSICAL AND CHEMICAL PROPERTIES

A closely related chemical, Advastab TM-950F, was previously notified as NA/883 and some of the physico-chemical data was provided for this chemical as indicated. Water solubility was determined for another analogue, ADVASTABTM-599D.

Appearance at 20ºC and 101.3 kPa Light yellow liquid

Melting Point/Freezing Point Not determined. The notified chemical is a liquid under temperatures encountered during normal use and handling.

Boiling Point ~216.2 ºC at 101.3 kPa

METHOD	Morton International test method 81.
Remarks	Determined for analogue chemical notified as NA/883.
TEST FACILITY	Morton International

Density 1130 kg/m^3 (Temperature unknown)

METHOD	Morton International test method 41.
TEST FACILITY	Morton International

Vapour Pressure < 1.1 kPa at 25ºC

Remarks Determined for analogue chemical notified as NA/883..

Water Solubility 32.6 mg/L at 22ºC

Remarks Determined for analogue chemical, ADVASTAB TM-599D.
The solubility of ADVASTAB TM-599D was determined at 22°C and pH 5 by stirring an excess of the compound in water for 72 hours, with samples taken at 24, 48, and 72 hours. The samples were analysed using an in-house method whereby the aqueous samples were acidified and treated with sodium borohydride to convert the dissolve test material to volatile alkyl tin hydrides which were then quantitatively analysed for the various tin alkyl hydrides using gas chromatography. The results were converted to total tin and back to the original concentration of the dissolved test compound ADVASTAB TM-599D on the assumption that this contains 19.7% tin. The results for the samples taken at 24, 48 and 72 hours we are 29.73, 34.96 and 33.08 mg per litre respectively, (mean 32.59 mg per litre), and indicate that saturation is attained within at least 24 hours.

TEST FACILITY Rohm and Haas (2001)

Hydrolysis as a Function of pH Not Determined

Remarks No data on hydrolytic decomposition of the notified chemical were provided. Nevertheless since the compound contains Sn-C and Sn-S bonds some hydrolytic attack could be expected under elevated pH, but without further data it is not possible to comment on hydrolysis at environmental pH 4 - 9. Ultimately the tin component is expected to be converted to SnO_2.

Partition Coefficient (n-octanol/water) log Pow = 1.47 at 20ºC
Determined for analogue chemical notified as NA/883.

METHOD The n-octanol/water partition coefficient was estimated (no reference provided, summary report only submitted) by stirring 1 g of the test material with a mixture of 50 mL of water and 50 mL n-octanol for two minutes. The aqueous and n-octanol phases were allowed to separate by standing for 96 hours, and then the tin content in each phase determined using atomic adsorption spectroscopy. Approximately 96.7% of the tin was found in the n-octanol phase and 3.3% in the water phase, and the ratio Sn(water)/Sn (water) of 29.3 taken as an estimate of Kow ie. Log Kow = 1.47.

Remarks Since the test material is a complex mixture of organo tin compound derived from derivatives of fatty acids this procedure effectively provides some mean estimate of the partitioning of all species present in the test material. The derived log Kow of 1.47 is likely to be significantly smaller than the true values for components containing substantial long chain acid moieties which tend to have much higher values for log Kow consistent with the high hydrocarbon content. The determined log Kow of 1.47 was obtained for a lower molecular weight species with smaller hydrocarbon content.

Adsorption/Desorption Not Determined

Remarks No data on an adsorption/desorption to soils were provided. The low log Kow suggests that the lower molecular weight components containing a smaller level of hydrocarbon are water soluble, and have little tendency to associate with the organic component of soils and sediments and may therefore be appreciably mobile. The higher molecular weight fatty acid-containing moieties are expected to be less mobile because of their higher hydrocarbon content, which would lower the water solubility and increase affinity for soil associated organic matter.

Dissociation Constant Not Determined

Remarks The notified chemical does not contain any (acidic or basic) dissociable groups. .

Particle Size Not applicable. The chemical is a liquid over the normal environmental temperature range.

Flash Point > 180 ºC

Remarks Determined for analogue chemical notified as NA/883.

Flammability Limits Not determined.

Remarks The notified chemical has a low vapour pressure and a flash point > 180 ºC and hence not expected to form flammable mixtures with air under normal conditions of use and handling.

Autoignition Temperature Not determined.

Remarks Not determined. The notified chemical has a low vapour pressure and a flash point > 180 ºC and hence not expected to autoignite under normal conditions of use and handling.

Explosive Properties

Remarks During a fire, irritating and toxic gases may be generated during combustion or decomposition. Combustion and decomposition products include smoke, soot, oxides of carbon, oxides of sulphur, oxides of tin and organotin compounds.

Reactivity The notified chemical is stable under normal conditions of use. It is incompatible with oxidisers. Contact with acid can generate hydrogen sulphide.

7. TOXICOLOGICAL INVESTIGATIONS

A closely related chemical, Advastab TM-950F, was previously notified as NA/883 and some of the toxicological data was provided for this chemical as indicated. Only the 4-week oral repeated dose study was conducted with the notified chemical in NA/883, ADVASTAB TM-950F (C-3530). Nine acceptable analogues, namely, Product 9286, TM-592, C-2533 (an unspecified mixture of 2 analogues), C-3530, TM-599, TM-599D, and three different formulations of TM-592 and Product 9286, were used to generate the other toxicological data.

Endpoint and Result	*Analogue*	*Assessment Conclusion*
Rat, acute oral LD50 > 5000 mg/kg bw	Product 9286	low toxicity
Rat, acute oral LD50 = 4687 mg/kg bw	TM-592	low toxicity
Rat, acute dermal LD50 > 4.64 mL/kg bw	TM-692 (TM-592 formulation)	low toxicity
Rat, acute inhalation 2.09 < LC50 < 5.45 mg/L/4 hour	TM-694 (Product 9286 formulation)	harmful
Rabbit, skin irritation	TM-592	slightly irritating
Rabbit, eye irritation	TM-592	non-irritating
Guinea pig, skin sensitisation – non-adjuvant test.	C-2533	no evidence of sensitisation
Rat, repeat dose <oral gavage> toxicity – 28 days.	C3530	NOAEL = 50 mg/kg/day
Rat, repeat dose <dietary> toxicity – 90 days.	TM-592	NOAEL = 15 mg/kg/day
Genotoxicity – bacterial reverse mutation	TM-592	non mutagenic

Genotoxicity – bacterial reverse mutation	TM-599	non mutagenic
Genotoxicity – bacterial reverse mutation	TM-599	non mutagenic
Genotoxicity – bacterial reverse mutation	TM-599-D	non mutagenic
Genotoxicity – bacterial reverse mutation	TM-599-D	non mutagenic
Genotoxicity – bacterial reverse mutation	(1:1) TM-592 and 2-mercaptoethyl oleate	non mutagenic
Genotoxicity – bacterial reverse mutation	(1:1) TM-592 and 2-mercaptoethyl oleate	non mutagenic
Genotoxicity – in vivo <Mammalian Erythrocyte Micronucleus Test>	(1:1) TM-592 and 2-mercaptoethyl oleate	non genotoxic

7.1.1 Acute toxicity – oral

TEST SUBSTANCE Product 9286

METHOD OECD TG 401 Acute Oral Toxicity.
Species/Strain Rat/Sprague-Dawley.
Vehicle Test substance administered as supplied
Remarks - Method No significant protocol deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	3 F, 1M

LD50 > 5000 mg/kg bw
Signs of Toxicity Non-specific signs, mainly on day 1, including piloerection, hunched posture, appearing depressed, urine stains and reddish stains on muzzle.
Effects in Organs No findings specific to treatment amongst decedents.
Remarks - Results 3 females and 1 male died between days 2 and 3.

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

TEST FACILITY Hill Top Biolabs (1994)

7.1.2 Acute toxicity – oral

TEST SUBSTANCE TM-592

METHOD Specified in the Regulations for the Enforcement of the Federal Hazardous Substances Act.
Species/Strain Rat/Sprague-Dawley.
Vehicle Test substance administered as supplied
Remarks - Method No significant protocol deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mL/kg bw*	*Mortality*
1	5 M	0.464	0
2	5 M	1.00	0
3	5 M	2.15	0
4	5 M	4.64	3/5

5	5 M	10.0	5/5

LD50	4.30 mL/kg bw = 4687 mg/kg bw
Signs of Toxicity	Group 1: Two rats exhibited diarrhoea on days 1 or 2. Group 2: 3 rats had diarrhoea on day 1, 4 on day 2 and all exhibited depression on day 2. Group 3: 2 rats on day 1 and 3 on day 2 exhibited mucoid diarrhoea; 1 rat exhibited excessive salivation on day 1; on day 2 all rats exhibited depression and 3 exhibited depressed righting and placement. Group 4: 3 rats on day 1 and 2 on day 2 (the two surviving rats) exhibited mucoid diarrhoea; 1 rat on day 1 exhibited excessive salivation and stains; on day 2 the 2 surviving rats exhibited depression and depressed righting and placement reflexes. Group 5: All rats exhibited depression, depressed righting and placement reflexes, excessive salivation and stains and mucoid diarrhoea.
Effects in Organs	Necropsy findings in the rats which died included congested lungs, kidneys and adrenals, mottled livers, diffuse irritation of the intestines, irritated and wrinkled peritoneal walls and fluid-filled stomachs.
Remarks - Results	Mortality was observed in the dose groups 4 and 5.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	IBR-US (1974)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	TM-692 = TM-592 formulation
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	rabbit/New Zealand White (NZW)
Vehicle	Test substance administered as supplied
Type of dressing	Occlusive
Remarks - Method	The skin from 2 rabbits out of each group was abraded with a hypodermic syringe needle. The test substance was placed in contact with the skin for 24 hours.

RESULTS

Group	*Number and Sex of Animals*	*Dose mL/kg bw*	*Mortality*
1	2F, 2M	0.464	0
2	1F, 3M	1.00	0
3	3F, 1M	2.15	0
4	1F, 3M	4.64	0

LD50	> 4.64 mL/kg bw
Signs of Toxicity - Local	Slight diarrhoea and emaciation in one rabbit in the 4.64 mL/kg dose group; irritative effects (erythema, oedema, desquamation and necrosis) were noted during the study at all doses in a dose-related manner. Desquamation occurred mainly following erythema; necrosis was observed in one rabbit receiving a dose of 2.15 mL/kg.
Signs of Toxicity - Systemic	There are no deaths or test-substance related clinical signs.
Effects in Organs	One rabbit in the 2.15 mL/kg dose group had pitted kidneys.
Remarks - Results	There were no deaths during the studies at any dosage level.

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Hill Top Research (1978)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	TM-694 = Product 9286 formulation
METHOD	OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	rat/Sprague-Dawley
Vehicle	Test substance administered as supplied
Method of Exposure	Whole-body exposure
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	> 10 microns 22.58 - 23.37 %
Remarks - Method	An aerosol was produced using an atomising system in a 100 L clear plastic chamber.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <mg/L>*		*Mortality*
		Nominal	*Actual*	
1	5/sex	2.0	2.09	2/10
2	5/sex	5.0	5.45	10/10

LC50	Between 2.09 and 5.45 mg/L 4 hours
Signs of Toxicity	5.45 mg/L group: hypoactivity, wet fur in all animals, uncoordinated movement in 2 males until time of death. 2.09 mg/L group: uncoordinated movement in 1 male until time of death; piloerection and hypoactivity in 1 male which died and 1 male which did not; also hypoactivity only in 1 female.
Effects in Organs	5.45 mg/L group: lungs red and mottled, G.I. tract distended. 2.09 mg/L group: as above in 2 males but less severe.
Remarks - Results	Complete mortality by day 3 in the 5.45 mg/L exposure group. Mortality of 20% by day 4 in the 2.09 mg/L exposure group. There were no further deaths for the 14 day period.
CONCLUSION	The notified chemical was harmful via inhalation.
TEST FACILITY	Tox Monitor Laboratories (1994)

7.4. Irritation – skin

TEST SUBSTANCE	TM-592
METHOD	Specified in the Regulations for the Enforcement of the Federal Hazardous Substances Act.
Species/Strain	rabbit/albino
Number of Animals	6/sex unspecified
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	0.5 mL under occlusive dressing for 24 hours on abraded and unabraded skin.

RESULTS

Draize scores (Intact skin):

Time after treatment (days)	*Animal #*					
	1	*2*	*3*	*4*	*5*	*6*
Erythema						

1	1[a]	1	1	1	0	1
3	1	1	1	1	0	1
Oedema						
1	0	0	0	1	0	0
3	0	0	0	0	0	0

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	***Rating***	***Oedema Formation***	***Rating***
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

Remarks - Results: Results were similar on abraded or non-abraded skin.

CONCLUSION: The notified chemical was slightly irritating to the skin.

TEST FACILITY: IBR-US (1974)

7.5. Irritation – eye

TEST SUBSTANCE: TM-592

METHOD: Specified in the Regulations for the Enforcement of the Federal Hazardous Substances Act.

Species/Strain: rabbit/albino
Number of Animals: 6/sex unspecified
Observation Period: 72 hours
Remarks - Method: 0.1 mL into the left eye of each rabbit. The untreated eye served as control.

RESULTS

No corneal, iridal or conjunctival effects were observed in any animal at 24, 48 and 72 hours post-instillation.

CONCLUSION: The notified chemical was non-irritating to the eye.

TEST FACILITY: IBR-US (1974)

7.6. Skin sensitisation

TEST SUBSTANCE: C-2533

METHOD: Buehler method

Species/Strain: guinea pig/Dunkin-Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration: 50%
topical: 0, 0.5, 1, 2.5, 5, 10, 25, 50% (w/v) in acetone

MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE	Test group: Three applications of 50% (w/v) test substance in acetone under occlusive dressing for 6 hours. Applications at weekly (varying between 5 and 9 days) intervals. Control group: Naive control - no exposure to the test substance.
Signs of Irritation	No erythema was observed in test or control animals following topical induction.
CHALLENGE PHASE	Approximately 2 weeks after the last induction exposure, with the same protocol used for induction, animals were treated at a site different from the induction site with 1% (w/v) test substance in acetone.
Remarks - Method	

RESULTS

Remarks - Results	Following primary challenge there were no grade of 1 produced in the test or control animals. The incidence of grade ± response in the test group (10 of 20) was comparable to that of the naïve control group (6 of 10). The incidence and severity of these responses in the test group were essentially comparable to those produced by the naïve group indicating that sensitisation had not been induced.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hill Top Biolabs (1989)

7.7.1 Repeat dose toxicity

TEST SUBSTANCE	C-3530
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 1 hour
Vehicle	Corn oil
Remarks - Method	The study was conducted in two parts. In part A rats were administered doses of 0, 10, 50, 150 and 300 mg/kg/day for 28 consecutive days. In part B the doses were 0 and 500 mg/kg/day.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (very low dose)	5/sex	10	0
III (low dose)	5/sex	50	0
IV (low-mid dose)	5/sex	150	0
V (high-mid dose)	5/sex	300	0
VI (control)	5/sex	0	0
VII (high dose)	5/sex	500	1

Mortality and Time to Death

One 500 mg/kg/day male died from a dosing error.

Clinical Observations

Statistically significant reductions in bodyweight gain occurred in the 500 mg/kg/day dose group for both males and females after one week of treatment and statistically significant increases occurred in these groups during the second week of treatment and in males during the third week. This effect was considered to indicate

tolerance.

Sporadic clinical signs were observed and considered to be incidental and unrelated to treatment with the test substance.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Male rats in the 150, 300 and 500 mg/kg/day dose groups exhibited elevated glucose, total protein, albumin and calcium and lower chloride. In the 500 mg/kg/day dose group males exhibited elevated creatinine, alkaline phosphatase, blood urea nitrogen, albumin/globulin ratio and total bilirubin and lower potassium. In the 300 mg/kg/day dose group but not in the 500 mg/kg/day dose group males exhibited elevated globulin. Female rats in the 300 and 500 mg/kg/day dose groups exhibited elevated phosphorus and lower chloride. In the 500 mg/kg/day dose group females exhibited elevated alkaline phosphatase, alanine aminotransferase, total protein, albumin, calcium and triglyceride and lower potassium. In the 300 mg/kg/day dose group but not in the 500 mg/kg/day dose group females exhibited elevated glucose.

Male rats in the 150, 300 and 500 mg/kg/day dose groups exhibited elevated red blood cell count, haemoglobin and haematocrit. Neutrophils were elevated and lymphocytes were reduced in the 500 mg/kg/day dose group. Female rats in the 300 and 500 mg/kg/day dose groups exhibited elevated red blood cell count, haemoglobin and haematocrit. Elevated lymphocyte and white blood cell counts occurred solely in the 300 mg/kg/day dose group and elevated mean corpuscular volume occurred solely in the 500 mg/kg/day dose group. No changes were observed in erythrocyte morphology.

Males exhibited elevated pH and urine volume in the 150, 300 and 500 mg/kg/day dose groups and lower specific gravity in the 150 and 300 mg/kg/day dose groups. Females exhibited elevated urine volume and lower specific gravity in the 300 and 500 mg/kg/day dose groups and elevated pH in the 500 mg/kg/day dose group.

Effects in Organs
In the 500 mg/kg/day dose group one male and five females exhibited pale livers and all but one female exhibited mottled livers.

The only significant differences were decreased absolute and relative spleen to body weights.

The only significant finding was increased severity of hepatocyte microvacuolation in rats of the 500 mg/kg/day dose group.

Remarks – Results
Lower body weight gain observed in males and females of the 500 mg/kg/day dose group and males of the 300 mg/kg/day dose group in the first week correlated with lower food consumption in the former group. Adaptation to the test substance in the second week was indicated by a recovery in body weight gain and food consumption.

Polycythaemia indicated by increases in erythrocyte count, haemoglobin and haematocrit, a secondary effect of diuresis, correlated with increased urine volume and pH and decreased urine specific gravity. Clinical chemistry parameters associated with diuresis were increased glucose, albumin (and total protein values), blood urea nitrogen and calcium and decreases in electrolytes potassium and chloride. These effects were observed to a greater extent in males with a low effect level of 150 mg/kg/day.

Gross findings of mottled and/or pale livers in the 500 mg/kg/day dose group, primarily in females, were not correlated with microscopic findings.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 50 mg/kg/day on the basis of diuretic effects seen primarily in males at higher doses.

TEST FACILITY Chrysalis (1999)

7.7.2 Repeat dose toxicity

TEST SUBSTANCE TM-592

METHOD	Not specified.
Species/Strain	rat/Wistar
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: unspecified
Vehicle	Test substance administered as supplied.
Remarks - Method	The test substance was mixed into stock diet at levels of 0, 30, 100, 300 and 1000 ppm.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration <ppm>*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	30	0
III (low-mid dose)	5/sex	100	0
IV (high-mid dose)	5/sex	300	0
IV (high dose)	5/sex	1000	0

Mortality and Time to Death
None.

Clinical Observations
Body weight: no statistically significant differences were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry: slight increase in alanine aminotransferase in 1000 ppm males.
Haematology: no consistent findings.
Urinalysis: lower urine specific gravity in 1000 ppm males. Urine volume unaffected.

Effects in Organs
Macroscopic findings: no findings.
Organ weights: some changes in intermediate dose groups were not considered to be toxicologically significant.
Histopathology: no treatment-related changes.

Remarks – Results
Only a summary of the data was available.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 300 ppm (equivalent to 15 mg/kg/day) on the basis of low urine specific gravity in 1000 ppm males.

TEST FACILITY Central Institute for Nutrition and Food Research (1975)

7.8.1 Genotoxicity – bacteria

TEST SUBSTANCE	TM-592
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000

	µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.
TEST FACILITY	SRI International (1996)

7.8.2 Genotoxicity – bacteria

TEST SUBSTANCE	TM-599
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*E. coli*: WP2uvrA
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.
TEST FACILITY	SRI International (1993a)

7.8.3 Genotoxicity – bacteria

TEST SUBSTANCE	TM-599
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate

Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.
TEST FACILITY	SRI International (1993b)

7.8.4 Genotoxicity – bacteria

TEST SUBSTANCE	TM-599D
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*E. coli*: WP2uvrA
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.
TEST FACILITY	SRI International (1993c)

7.8.5 Genotoxicity – bacteria

TEST SUBSTANCE	TM-599D
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

TEST FACILITY SRI International (1993d)

7.8.6 Genotoxicity – bacteria

TEST SUBSTANCE TM-592 and 2-mercaptoethyl oleate (1:1)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*E. coli*: WP2uvrA
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

CONCLUSION The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

TEST FACILITY SRI International (1990a)

7.8.7 Genotoxicity – bacteria

TEST SUBSTANCE TM-592 and 2-mercaptoethyl oleate (1:1)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate b) Without metabolic activation: 0, 10, 50, 100, 500, 1000 and 5000 µg/plate
Vehicle	acetone
Remarks - Method	No significant protocol deviation.

RESULTS

Remarks - Results	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine, 2-nitrofluorene and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
CONCLUSION	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.
TEST FACILITY	SRI International (1990b)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	TM 592 and 2-mercaptoethyl oleate (1:1)
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	mouse/Swiss-Webster
Route of Administration	Oral – gavage
Vehicle	Corn oil
Remarks - Method	0, 600, 1200 and 2500 mg/kg in males; 0, 450, 900 and 1800 mg/kg in females.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 M	0	24, 48, 72
II (low dose)	5 M	450	24, 48, 72
III (mid dose)	5 M	900	24, 48, 72
IV (high dose)	5 M	1800	24, 48, 72
V (positive control, benzene)	5 M	500	24, 48, 72

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 F	0	24, 48, 72
II (low dose)	5 F	600	24, 48, 72
III (mid dose)	5 F	1200	24, 48, 72
IV (high dose)	5 F	2500	24, 48, 72

RESULTS

Doses Producing Toxicity	There were no statistically significant changes.
Genotoxic Effects	None.
Remarks - Results	Treatment with benzene (500 mg/kg) as positive control demonstrated the test sensitivity. Negative control (vehicle) gave the expected response.
CONCLUSION	The test substance was non clastogenic under the conditions of the test and no increase in the frequency of micronucleated polychromatic erythrocytes occurred.
TEST FACILITY	SRI International (1990c)

8. ENVIRONMENT

Data for the notified chemical was not provided. However, data for analogues have been provided and are presented in the following sections. The acceptable analogue, C-3530 (ADVASTAB TM-950F), has been assessed previously as NA/883. In the assessment of NA/883, Alkytin ME (ADVASTAB TM-599D) was accepted as an analogue and is again accepted for this assessment.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Acceptable analogue - C-3530.
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm).
Inoculum	Sewage Sludge Bacteria treating predominantly domestic waste.
Exposure Period	28 Days
Auxiliary Solvent	None specified
Analytical Monitoring	CO_2 detection using $Ba(OH)_2$ (back titration)
Remarks - Method	Duplicate tests were performed by adding 35.1 mg/L (corresponding to 20 mg/L of carbon) of test material to the inoculum. An inoculum blank was run as well as a positive control using sodium benzoate. A toxicity control was also conducted by adding 52.8 mg of test substance and 51.2 mg of sodium benzoate to the inoculum. Dilution water: KH_2PO_4 85 mg/L, Na_2HPO_4 21.8 mg/L, NH_4Cl 5.016 mg/L, 27.5 mg/L $CaCl_2$, 22.5 mg/L $MgSO_4.7H_2O$, 0.25 mg/L $FeCl_3.6H_2O$. pH = 7.4

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0.5	1	19.2
3	21.9	3	53.9
9	56.8	9	67.0
14	63.5	14	70.3
19	65.4	19	73.1
27	70.2	27	73.7
28	70.5	28	74.4

Remarks - Results	The toxicity control showed 79.2% biodegradation, demonstrating that the test substance was not toxic to the activated sludge at the tested concentration. The 10 day window criteria (60% degradation reached within the following 10 day period after 10% reached) was just satisfied (10% on day 2 and approximately 64% on day 12).
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	T R Wilbury Laboratories (1999d)

8.1.1.a Ready biodegradability

TEST SUBSTANCE	Unclear analogue - Fraction No.4 of the biodegraded product of the biodegraded product of 1,1,3,3-tetramethyl-1,3-bis{[2-alkenyl(C=13–23)-carbonyloxyethyl]thio}distannathiane.
METHOD	MITI method “Chemical Control Law” (Japanese Law No. 117, 1974) in accordance with C-80/113 OECD Test Guideline
Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Oxygen Meter, Coulometer.
Remarks - Method	Triplicate tests were performed by subjecting nominal concentration of 100 ppm of test chemical to 30 ppm of inoculum. An inoculum blank was run as well as a positive control using aniline. A test only containing the chemical and no sludge was also run to test for abiotic decomposition.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	1.6	7	58.3
14	7.2	14	65.5
21	11.7	21	67.5
28	15.5	28	69.3

Remarks - Results: The chemical is not completely soluble in water. Biodegradation could not be determined by dissolved organic carbon (DOC) as the amount of DOC would be in equilibrium with the undissolved carbon until it was consumed. The test blank containing only the notified chemical had a measured concentration of 93 ppm. This showed no significant difference from the measured test concentrations.

CONCLUSION: The test substance is not readily biodegradable.

TEST FACILITY: Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, 1981

8.1.2. Bioaccumulation

TEST SUBSTANCE: Unacceptable analogue - Dimethyltin Thioglycolate (DTG). This chemical is expected to show a lower potential to bioaccumulate because it is a much simpler organotin compound.

METHOD: Japanese Industrial Standard Method "JIS K0102 (1974)"
Species: Carp *Cyprinus Carpio*
Exposure Period: Exposure: 56 days Depuration: Nil
Auxiliary Solvent: None Specified
Concentration Range: Nominal: 0.1 – 1.0 µg/L
Analytical Monitoring: Atomic Absorption Spectrometry (AAS)
Remarks - Method: An acute toxicity test was initially conducted on 10 fish (Japanese Rice Fish *Oryzias latipes*) of test concentration of 0.0 (control), 100, 300 and 500 mg/L at water temperature of 25 ± 1°C. No lethal effects were observed at all concentrations at 48 h.
Fifteen fish were subjected to continual flow of each test concentration of 0.0 (control), 0.1 and 1.0 mg/L with a flow rate of 400 L/day. The concentrations of the test solutions were monitored twice weekly. Two fish were removed for analysis every two weeks. Fish were spiked with 100 mg/L of DTG and water was spiked with 50 mg/L to check for recoveries of the chemical. The detection of DTG was not made directly but was made by using phenylfluorone probably as a "stain".
Temperature 25 ± 1°C.
Dissolved Oxygen 6 – 7 ppm

RESULTS

Week	Exposure µg/mL*	DTG Fish µg/g *	BF	Exposure µg/mL*	DTG Fish µg/g* #	BF
0		<0.3	<3			
2	0.111	<0.3	<3	1.18	0.53	0.5
4	0.112	<0.3	<3	1.16 **	0.74	0.6
6	0.113	<0.3	<3	1.16	0.75	0.7
8	0.112	<0.3	<3	1.14	1.2	1.1

BF = Bioaccumulation Factor
* Average of two results
# Corrected for recovery
** One result was recorded as 1.66 but appeared to be a typographical error and was ignored

Bioconcentration Factor: 0.3 – 1.1 for 1 mg/L of DTG over 8 weeks

	<3 for 0.1 mg/L of DTG over 8 weeks
Remarks - Results	Recovery of DTG from fish was 84% and 93% from water. The test solutions had overall mean values of 0.112 and 1.14 mg/L for the nominal 0.1 and 1.0 mg/L solutions. There were no mortalities or abnormal behaviour form any fish.
CONCLUSION	DTG is unlikely to bioaccumulate.
TEST FACILITY	Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, 1980

8.1.2.a Bioaccumulation

TEST SUBSTANCE	Not Tested
Remarks	No report of a bioaccumulation test of the notified chemical was provided, but the ready biodegradation reported above indicates that bioaccumulation would be unlikely. Also, the moderate water solubility (32.6 mg/L), relatively low value of Log Kow (1.47) and relatively large molecular weight (around 1000 g/mol) indicate low potential for bioaccumulation (Connell, 1989).

8.2. Ecotoxicological investigations

8.2.1. a Acute toxicity to fish

TEST SUBSTANCE	Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static.
Species	Fathead Minnow *Pimephales promelas*
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40 mg $CaCO_3$/L
Analytical Monitoring	Visual observation
Remarks – Method	A range finding test was conducted preparing Water Available Fractions (WAF) of 0 (control) 0.10, 1.0, 10, 100 and 1000 mg/L. A measured amount of test material (25 g) in 25 litres of dilution water were stirred for 24 hours and then allowed to stand for approximately 1 h, the WAF was extracted by mid-depth siphoning. The test concentrations were prepared by the combining of the appropriate volume of WAF (1000 mg/L) and dilution water. There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. Single treatments of 10 fish were subjected to each WAF concentration. Lighting 16 hour light, 8 hour dark with 15 minute transition Light intensity: 4µEin/m^2sec Dissolved Oxygen 6.3 – 8.9 mg/L Conductivity 130 – 140 µmhos/cm. Temperature 21.9 – 22.5 °C

RESULTS

Concentration(WAF) mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0
0.1		10	0	0	0	0
1.0		10	0	0	0	0
10		10	0	0	0	0
100		10	0	0	0	0

1000	10	0	0	0	0

LC50 >1000 mg/L (WAF) at 96 hours.
NOEC (or LOEC) 1000 mg/L (WAF) at 96 hours.
Remarks – Results No sublethal effects were noted during the test

CONCLUSION The test substance was non-toxic to Fathead Minnow up to the limit of its water solubility.

TEST FACILITY T R Wilbury Laboratories (1995a)

8.2.1.b Acute toxicity to fish

TEST SUBSTANCE Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.

METHOD OECD TG 203 Fish, Acute Toxicity Test - static.
Species Sheepshead minnow *Cyprinodon variegatus*
Exposure Period 96 h
Auxiliary Solvent None
Water Hardness 40 mg $CaCO_3$/L
Analytical Monitoring Visual observation
Remarks – Method A range finding test was conducted preparing Water Available Fractions (WAF) of 0 (control) 0.10, 1.0, 10, 100 and 1000 mg/L, prepared as in section 8.2.1 – acute toxicity to Fathead minnow (above). There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. Single treatments of 10 fish were subjected to each WAF concentration.
Lighting 16 hour light, 8 hour dark with 15 minute transition
Light intensity: 4µEin/m^2sec
Dissolved Oxygen 6.5 – 8.0 mg/L
Salinity 20 parts per thousand (ppt)
Temperature 22.1 – 22.8°C

RESULTS

Concentration (WAF) mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0
0.1		10	0	0	0	0
1.0		10	0	0	0	0
10		10	0	0	0	0
100		10	0	0	0	0
1000		10	0	0	0	0

LC50 >1000 mg/L (WAF) at 96 hours.
NOEC (or LOEC) 1000 mg/L (WAF) at 96 hours.
Remarks – Results No sublethal effects were noted during the test

CONCLUSION The test substance was non-toxic to Sheepshead Minnow up to the limit of its water solubility.

TEST FACILITY T R Wilbury Laboratories (1995b)

8.2.1.c Acute toxicity to fish

TEST SUBSTANCE Acceptable analogue - C-3530

METHOD U.S. EPA (1993 and 1996) – flow through.
Species Rainbow trout *Oncorhynchus Mykiss*

Exposure Period	96 h
Auxiliary Solvent	Dimethyl Formamide (DMF)
Water Hardness	44 mg $CaCO_3$/L
Analytical Monitoring	Visual observation; AAS for Sn
Remarks – Method	A range finding test was conducted under static conditions by subjecting an unspecified amount of fish to 0.050 mg/L, 0.10, 0.50, 1.0, and 5.0 mg/L of test substance. A control (0.0 mg/L) and a solvent control 0.1 mL/L of DMF and 0.0 mg/L of test substance were also run. After 96 h there was 60% survival in the control, 100% in the solvent control, 60% at 0.050 mg/L, 80% at 0.10 mg/L, 60% at 0.50 mg/L, 40% at 1.0 mg/L and 100% at 5.0 mg/L of test substance. Duplicate treatments of 10 fish each were subjected to a flow through test by an intermittent flow proportional diluter of measured concentrations of 0.56, 0.99, 1.6, 2.8, and 4.4 mg/L. A control containing no DMF nor test substance was conducted as well as a solvent control containing DMF 0.1 mL/L but no test substance. Lighting 16 hour light, 8 hour dark with 15 minute transition Light intensity: approximately 50 foot candles Conductivity 130 – 140 µmhos/cm Dissolved Oxygen 8.9 – 10.6 mg/L pH 7.3 – 7.6 Temperature 11.0 – 13.7°C

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3h*	*24 h*	*48 h*	*72 h*	*96 h*
0 (Control)	< 0.13	20	0	0	0	0	1
0 (Solvent Control)	NR	20	0	0	0	0	0
0.65	0.56	20	0	0	0	1	1
1.1	0.99	20	0	1	2	2	2
1.8	1.6	20	0	1	1	1	1
3.0	2.8	20	0	1	1	2	2
5.0	4.4	20	1	1	2	3	3

NR = Not Recorded

LC50	>4.4 mg/L at 96 hours.
NOEC	<0.56 mg/L at 96 hours.
Remarks – Results	One solvent fish exhibited loss of equilibrium, lethargy and change in colouration. Fish in treatments of 0.99, 2.8 and 4.4 mg/L of test concentration exhibited lethargy, discolouration and/or loss of equilibrium in 10% or less of test species. The treatments of 1.8 – 5.0 mg/L nominal concentrations showed cloudiness throughout the test.

CONCLUSION The test substance is likely to be moderately toxic to fish.

TEST FACILITY T R Wilbury Laboratories (1999c)

8.2.2.a Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	160 - 180 mg $CaCO_3$/L in dilution water

Analytical Monitoring	Visual Observation
Remarks - Method	A range finding test was conducted preparing Water Available Fractions (WAF) of 0 (control) 0.10, 1.0, 10, 100 and 1000 mg/L, prepared as in section 8.2.1 – acute toxicity to Fathead minnow (above). There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. Single treatments of 10 daphnia were subjected to each WAF concentration. Lighting 16 hour light, 8 hour dark with 15 minute transition Light intensity: 7 µEin/m^2sec Dissolved Oxygen 8.5 – 8.9 mg/L Temperature 19.6 – 20.6°C Conductivity 600 – 650 µmhos/cm

RESULTS

Concentration (WAF) mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		10	0	0
0.10		10	0	0
1.0		10	0	0
10		10	0	0
100		10	0	3
1000		10	6	10

LC50	130 mg/L WAF at 48 hours
NOEC	10 mg/L WAF at 48 hours
Remarks - Results	No insoluble material was noted during test. Sub lethal effects of immobilisation but presumably not mortality were observed in the 100 mg/L and 1000 mg/L treatments. One daphnid was affected in the 100 mg/L at 48 hours and four daphnia in the 1000 mg/L at 24 hours. Binomial/non-linear interpolation method was used to calculate the 48 hour EC50 and 95% confidence limits.

CONCLUSION The test substance was toxic to Daphnia below the limit of its water solubility.

TEST FACILITY T R Wilbury Laboratories (1995c)

8.2.2.b Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Acceptable analogue - C-3530.

METHOD U.S. EPA. Daphnid Acute Toxicity Test Final Rule 797.1300 Test – flow through.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	DMF
Water Hardness	44 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation; Test substance AAS for Sn
Remarks - Method	A range finding test was conducted under static conditions by subjecting an unspecified number (but probably 10) of daphnia to 0.050 mg/L, 0.10, 0.50, 1.0, and 5.0 mg/L of test substance. A control (0.0 mg/L) and a solvent control 0.1 mL/L of DMF and 0.0 mg/L of test substance were also run. After 48 h there was 100% survival in the control, 100% in the solvent control, 100% at 0.050 mg/L, 100% at 0.10 mg/L, 10% at 0.50 mg/L, 10% at 1.0 mg/L and 0% at 5.0 mg/L of test substance. Duplicate treatments of 10 daphnia each were subjected to a flow through test by an intermittent flow proportional diluter of measured concentrations of 0.13, 0.22, 0.36, 0.60, 1.0 mg/L. A control containing

no DMF nor test substance was conducted as well as a solvent control containing DMF 0.1 mL/L but no test substance.
Lighting 16 hour light, 8 hour dark with 15 minute transition
Light intensity: approximately 51 foot candles
Conductivity 550 - 580 µmhos/cm
Dissolved Oxygen 7.9 – 8.5 mg/L
pH 7.3 – 7.6
Temperature 20.0 – 21.4°C

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual**		*24 h*	*48 h*
0 (Control)	< 0.066	20	0	0
0 (Solvent Control)	< 0.066	20	0	0
0.13	0.14	20	0	1
0.22	0.23	20	6	9
0.36	0.36	20	10	16
0.60	0.59	20	10	16
1.0	0.99	20	11	20

* Average of two samples

LC50	0.27 mg/L at 48 hours. 0.22 – 0.33 mg/L with 95% confidence interval.
LOEC	0.14 mg/L at 48 hours
Remarks - Results	No insoluble material was noted during test. Lethargy was observed in 0.99 mg/L treatment at 24 h. EC50 calculated by the probit method

CONCLUSION The test substance is highly toxic to daphnia

TEST FACILITY T R Wilbury Laboratories (1999b)

8.2.2.c Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.

METHOD ASTM Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macro-invertebrates and Amphibians E-729-80 - static.

Species	Mysid shrimp *Mysidopsis bahia*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Visual Observation
Remarks - Method	A range finding test was conducted preparing Water Available Fractions (WAF) of 0 (control) 0.10, 1.0, 10, 100 and 1000 mg/L, prepared as in section 8.2.1 – acute toxicity to Fathead minnow (above). There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. Single treatments of 10 mysid were subjected to each WAF concentration. Lighting 16 hour light, 8 hour dark with 15 minute transition Light intensity: 22 µEin/m^2sec Dissolved Oxygen 6.6 – 7.3 mg/L Temperature 23.3 – 24.8°C Salinity 17 ppt.

RESULTS

Concentration (WAF) mg/L		*Number of Mysid*	*Mortalities*	
Nominal	*Actual*		*48 h*	*96 h*
0		10	0	0

0.10	10	0	0
1.0	10	0	0
10	10	0	0
100	10	1	1
1000	10	10	10

LC50	250 mg/L (WAF) at 96 hours
LOEC	100 mg/L (WAF) at 96 hours
Remarks - Results	No insoluble material was noted during test. Sub lethal effects of lethargy and loss of equilibrium were observed in the 100 mg/L and 1000 mg/L treatments.
CONCLUSION	The test substance was toxic to mysid shrimp below its limit of water solubility.
TEST FACILITY	T R Wilbury Laboratories (1995d)

8.2.3.a Algal growth inhibition test

TEST SUBSTANCE	Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: 0.10 - 1000 mg/L
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Cell count by direct microscopic examination.
Remarks - Method	Duplicate treatments of approximately 1×10^4 cells were subjected to WAF of nominal concentrations of 0.0 (control) 0.10, 1.0, 10, 100, and 1000 mg/L, prepared as in section 8.2.1 – acute toxicity to Fathead minnow (above). There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. At the conclusion of the test a 0.5 mL sub-sample was extracted form each flask of the 1000 mg/L WAF and combined with 50 mL of fresh media for 216 h to test whether algicidal or algistatic effect had occurred. Light 24 hours at 306 µEin/m^2sec Temperature 24 ± 1°C pH initial 7.5; final 8.0 – 10.3

RESULTS

Biomass Cell Density		*Growth Rate*	
EbC50 mg/L (WAF) at 72 h	*EbC50 mg/L (WAF) at 96 h*	*ECr50 mg/L (WAF) at 72 h*	*ECr50 mg/L (WAF) at 96 h*
120	10	220	200

Remarks - Results	The 1000 mg/L treatment showed slight cloudiness throughout the test period and insoluble material was observed at 96 hours. No abnormal observations to size differences, unusual cell shapes, colours, flocculation or adherence to test containers were made. Binomial/non-linear interpolation method was used to calculate the 48 hour EC50 and 95% confidence limits. After 216 h examination of media from the flask containing the combined 0.5 mL sub-samples and 100 mL of fresh media contained 76000 algal cells/mL. This indicated that the effect of the test substance at this concentration was algistatic.
CONCLUSION	The test substance is toxic to algae below its limit of water solubility.

TEST FACILITY	T R Wilbury Laboratories (1995e)

8.2.3.b Algal growth inhibition test

TEST SUBSTANCE	Acceptable analogue - Alkytin ME (ADVASTAB TM-599D) chemically similar to the notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Marine Algae *Skeleonema costatum*
Exposure Period	96 hours
Concentration Range	Nominal: 0.10 - 1000 mg/L
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Cell count by direct microscopic examination.
Remarks - Method	Duplicate treatments of approximately 1×10^4 cells were subjected to WAF of nominal concentrations of 0.0 (control) 0.10, 1.0, 10, 100, and 1000 mg/L, prepared as in section 8.2.1 – acute toxicity to Fathead minnow (above). There was indication of precipitation in the preparation and apparently no analysis of the WAF was undertaken. At the conclusion of the test a 0.5 mL sub-sample was extracted form each flask of the 100 mg/L WAF and combined with 50 mL of fresh media for 144 h to test whether algicidal or algistatic effect had occurred. Light 14 hours light and 10 hours dark with intensity of 49 - 51 µEin/m^2sec. pH initial 8.1 – 8.3; final 8.5 – 9.6

RESULTS

Biomass Cell Density		*Growth Rate*	
EbC50 mg/L (WAF) at 72 h	*EbC50 mg/L (WAF) at 96 h*	*ECr50 mg/L (WAF) at 72 h*	*ECr50 mg/L (WAF) at 96 h*
22	24	28	29

Remarks - Results	No insoluble material was noted during test. No abnormal observations to size differences, unusual cell shapes, colours, flocculation or adherence to test containers were made. Binomial/non-linear interpolation method was used to calculate the 48 hour EC50. After 144 hours examination of media from the flask containing the combined 0.5 mL sub-samples and 100 mL of fresh media contained 886000 algal cells/mL. This indicated that the effect of the test substance at this concentration was algistatic.
CONCLUSION	The test substance is toxic to algae below its limit of water solubility.
TEST FACILITY	T R Wilbury Laboratories (1995f)

8.2.3.c Algal growth inhibition test

TEST SUBSTANCE	Acceptable analogue - C-3530.
METHOD	U.S EPA 1996 OPPTS 850.5400, Algal Toxicity, Tiers I and II. EPA 712-C-96-164
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: 0.34 – 5.0 mg/L Actual: 0.37 – 4.7 mg/L
Auxiliary Solvent	DMF
Water Hardness	Not specified
Analytical Monitoring	Cell count by direct microscopic examination.

Remarks - Method

A range finding test was conducted under static conditions by subjecting an unspecified concentration of algal cells for an unspecified length of time to 0.050 mg/L, 0.10, 0.50, 1.0, and 5.0 mg/L of test substance. A control (0.0 mg/L) and a solvent control 0.1 mL/L of DMF and 0.0 mg/L of test substance were also run. At the conclusion the cell counts relative to the control were 101% in the solvent control, 101% at 0.050 mg/L, 96% at 0.10 mg/L, 68% at 0.50 mg/L, 37% at 1.0 mg/L and 37% at 5.0 mg/L of test substance.

Triplicate treatments of approximately 1×10^4 cells were subjected to nominal concentrations of 0.0 (control) 0.34, 0.66, 1.3, 2.5, and 5.0 mg/L. A solvent control 0.1 mL/L of DMF and a stability control of 5.0 mg/L of test substance but no algae were also run. At the conclusion of the test a 0.5 mL sub-sample was extracted form each flask of the 4.6 mg/L and combined with 100 mL of fresh media and incubated for 72 h to test whether algicidal or algistatic effect had occurred.
Light 24 hours light at 370 to 380 foot candles.
Temperature 24 ± 2°C
pH initial 7.4 – 7.5; final 7.6 – 10.2

RESULTS

Nominal Conc. mg/L	Actual Conc. mg/L	% of control at 24 h	% of control at 48 h	% of control at 72 h	% of control at 96 h
0.0 (control)	<0.13	-	-	-	-
0.0 (solvent control)	<0.13	109	95	95	112
0.34	0.28	97	97	96	103
0.66	0.57	103	92	62	72
1.3	1.3	60	36	14	10
2.5	2.2	40	17	5	4
5.0	4.6	<29	<8	3	3

EC50 0.64 mg/L (algal growth)
NOEC 0.28 mg/L (algal growth)
Remarks - Results

The highest tested concentration of the range finding test showed slight cloudiness. The treatments of nominal concentration of 2.5 mg/L were observed to be slightly cloudy at 0 and 24 hours, whilst the treatments at 5.0 mg/L were cloudy throughout the test period. The blank algal population grew well with 3 647 000 ± 241 000 cells/mL. No abnormal observations to size differences, unusual cell shapes, colours, flocculation or adherence to test containers were made. The percent nominal recovery of the test substance in the stability control was 96%. Binomial/non-linear interpolation method was used to calculate the 48 hour EC50. After 72 hours examination of media from the flask containing the combined 0.5 mL sub-samples and 100 mL of fresh media contained 628 000 algal cells/mL in comparison with 1500 cells/mL at initiation. This indicated that the effect of the test substance at this concentration was algistatic.

CONCLUSION The test substance is highly toxic to algae.

TEST FACILITY T R Wilbury Laboratories (1999c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is a tin compound to be used as a stabiliser for construction materials fabricated from PVC.

Around 3% of annual imports (or a maximum of 900 kg each year) may be released during manufacturing of extruded/moulded PVC pipes and other construction materials. The majority of this would be placed into landfill although some may be incinerated.

Some slow and continuing release of the chemical from the surfaces of PVC pipes and other articles during their service lives is expected, and although this is difficult to quantify it is not anticipated to be large. However, it is to be noted that this release may not be of the notified compound itself but is more likely to be in the form of methyl tin chlorides which are produced through reaction of the new chemical with PVC as a consequence of its action as a stabiliser.

Nevertheless, at the end of their useful lives most of the PVC product containing the chemical is likely to be disposed of into landfill where the chemical will be slowly released as the PVC is broken down through biological and abiotic processes. The water solubility is moderate (32.6 mg/L) and the value of Log Kow modest (1.47) indicating only modest affinity for the organic component of soils and sediments and so it is likely that the chemical will be mobile in these media and may reach the wider water compartment. However, the chemical has been shown to be readily biodegradable and would therefore not be persistent in the environment, and it is not expected to have high potential for bioaccumulation.

Incineration would destroy the new compound with production of water vapour and oxides of carbon and sulphur while the tin component would be converted to SnO_2 and become assimilated into ash. Biodegradation would also decompose the compound to water, CO_2 and sulphate while the tin component would again be converted to SnO_2. The compound is not likely to decompose to form tri alkyl tin compounds.

9.1.2. Environment – effects assessment

The following table is a summary of the available data.

Test	Species	Results
Acute Toxicity Fish	Rainbow trout *Oncorhynchus mykiss*	LC50 (96 h) > 4.4 mg/L (measured)
Acute Toxicity Fish	Fathead minnow *Pimephales promelas*	LC50 (96 h) > 1000 mg/L (nominal WAF)
Acute Toxicity Fish	Sheepshead minnow *Cyprinodon variegatus*	LC50 (96 h) > 1000 mg/L (nominal WAF)
Acute Immobilisation Daphnia	*Daphnia magna*	LC50 (48 h) = 0.27 mg/L (measured)
Acute Immobilisation Daphnia	*Daphnia magna*	LC50 (96 h) = 130 mg/L (nominal WAF)
Acute Toxicity Shrimp	Mysid shrimp *Mysidopsis bahia*	LC50 (96 h) = 250 mg/L (nominal WAF)
Algal reproduction	Green algae *Selenastrum capricornutum*	EC50 (96 h) = 0.64 mg/L (measured)
Algal reproduction OECD TG 201	Green algae *Selenastrum capricornutum*	E_bC50 (96 h) = 10 mg/L (nominal WAF)
Algal reproduction OECD TG 201	Marine algae *Skeletonema costatum*	E_bC50 (96 h) = 24 mg/L (nominal WAF)

The notified chemical is highly toxic to fish and daphnia. The Predicted No Effect Concentration (PNEC) is derived from the LC50 of daphnia and divided by an uncertainty safety factor of 100 (as toxicity data exist for three trophic levels) and is calculated as 2.7 µg/L.

9.1.3. Environment – risk characterisation

The notified chemical being slowly release from PVC piping is expected to be rapidly biodegraded and not form any toxic biodegradation products. Although no Predicted Environmental Concentration can be calculated and hence no Risk Quotient, when used in the typical manner is not expected to present an unacceptable risk to the environment. The very low levels that may occur should result in an acceptable margin of safety.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage workers should only be exposed to the notified chemical in the event of accidental spillage and the risk of adverse health effects to these workers is assessed as low.

Transfer of the notified chemical to a 1000 L mixing vessel containing PVC powder may expose workers to drips and spills. However, inhalation exposure is unlikely given the low vapour pressure of the notified chemical and the fact that aerosols should not be created during transfer. Dermal and ocular exposure of workers is neither frequent nor high level. As workers wear goggles, respirator, nitrile gloves and overalls, there is little likelihood of the adverse health effects from inhalation indicated by the hazard assessment. After mixing, the PVC powder is coarse (less than 3% of particles below 61 micron, therefore, a low amount in the respirable range but likely a high proportion in the inspirable range), free-flowing and contains the notified chemical at a low concentration (1%). As local exhaust ventilation is employed during mixing, transfer to a cooling vessel and packing into bags and as the system in largely enclosed and workers are expected to wear personal protective equipment, worker exposure and consequent risk of adverse health effects is negligible. A similar conclusion can be drawn for transfer of the PVC powder to extrusion machines where exposure is controlled by the use of local exhaust ventilation and the wearing of respirators. Once the moulded or extruded articles are produced the notified chemical should not be bioavailable and worker exposure should be nil. Although methyl tin chlorides may be released from the extruded articles during their service lives from reaction of the notified chemical with PVC, the amounts should be low and no adverse health effects to workers would be expected.

9.2.2. Public health – exposure assessment

The notified chemical will not be available to the public. Members of the public will only come into contact with encapsulated form of the notified chemical. However, the risk to public health will be low because the notified chemical will not be biologically available and it is bound within a matrix.

9.2.3. Human health – effects assessment

Acute toxicity
Analogues of the notified chemical were of low acute oral toxicity (LD50 > 5000 mg/kg, low acute dermal toxicity (LD50 > 4.64 mL/kg) and harmful in inhalation toxicity (LC50 between 2.09 and 5.45 mg/L) in rats.

Irritation and Sensitisation
Analogues of the notified chemical were slightly irritating to rabbit skin, not irritating to rabbit eyes and not skin sensitising in guinea pigs.

Repeated Dose Toxicity
Analogue of the notified chemical exhibited diuretic effects in a 28-day oral repeated dose study in rats with a NOAEL of 50 mg/kg/day. Organ toxicity was limited to increased severity of hepatocyte microvacuolation at 500 mg/kg/day. The NOAEL in a 90-day feeding studies in rats conducted on an analogue of the notified chemical was 15 mg/kg/day on the basis of lower urine specific gravity in males.

Mutagenicity.
Analogues of the notified chemical were not mutagenic in bacteria and were not clastogenic in mouse bone marrow cells in vivo.

Based on the available data, the notified chemical is likely to be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The following risk phases for the notified chemical are recommended:
Xn: Harmful
R20: Harmful by inhalation

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, based on the minimal exposure to workers because of engineering control in place, such as personal protective equipment, local exhaust ventilation and the low concentration (1%) of the notified chemical in the PVC powder.

9.2.5. Public health – risk characterisation

The public will only come into contact with the encapsulated form of the notified chemical bound within a PVC matrix. Hence the potential for public exposure to the notified chemical is considered to be low, and its use pattern and low toxicity are unlikely to pose a significant risk to public health.

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

10.1. Hazard classification

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

Xn: Harmful
R20: Harmful by inhalation
S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
S51: Use only in well-ventilated areas

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***
Acute toxicity	4	Harmful if inhaled

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing 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 product containing 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:
  - Xn: Harmful
  - R20: Harmful by inhalation

- The following safety phases for the notified chemical are recommended:
  - S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)
  - S51: Use only in well-ventilated areas

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - At a concentration of the notified chemical greater than 25%, risk phrase R20.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Spillage should be avoided; spills should be should be cleaned up promptly with absorbents which should be put into containers for disposal

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Goggles, respirator, nitrile gloves and overalls

  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.

Disposal

- The notified chemical should be disposed of by authorised landfill or incineration.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment. Soak up using inert absorbent material (e.g. sand, acid binder, universal binder, saw dust etc) and transfer to suitable containers for 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.

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