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August 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ADVASTAB TM-950 F

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FULL PUBLIC REPORT

ADVASTAB TM-950 F

1. APPLICANT

Rohm and Haas Australia Pty Ltd (ACN 004 513 188) of 969 Burke Rd CAMBERWELL VIC 3124 and Plastral Fidene Australia Pty Ltd (ABN 68 000 144 132) of 11b Lachlan St WATERLOO NSW 2017 have submitted a standard notification statement in support of their application for an assessment certificate for ADVASTAB TM-950 F.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, spectral data, details of the reaction components and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	C-3530
Marketing Name:	ADVASTAB TM-950F
Molecular Weight:	Unspecified.
Method of Detection and Determination:	Infrared (IR) spectroscopy.
Spectral Data:	An IR spectrum was provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Light yellow liquid.
Boiling Point:	216.2°C
Specific Gravity:	1.13
Vapour Pressure:	< 1.1 kPa at 25°C
Water Solubility:	32.6 mg/L at 22°C – see notes below.
Partition Co-efficient (n-octanol/water):	log P_{ow} of the analogue ADVASTAB TM-599 was 1.47

	– see notes below.
Hydrolysis as a Function of pH:	No data provided – see notes below.
Adsorption/Desorption:	No data provided – see notes below.
Dissociation Constant:	The notified chemical does not contain any dissociable groups.
Particle Size:	Not applicable. Chemical is a liquid.
Flash Point:	> 180°C
Flammability Limits:	Not expected to be flammable.
Autoignition Temperature:	Not expected to autoignite.
Explosive Properties:	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 sulfur, oxides of tin and organotin compounds.
Reactivity/Stability:	The notified chemical is stable under normal conditions of use. It is incompatible with oxidisers. Contact with acid can generate hydrogen sulfide.

3.1 Comments on Physico-Chemical Properties

The water solubility of the notified chemical was not provided, but a summary report on the water solubility of an analogue, ADVASTAB TM-599D was submitted (Rohm and Haas, 2001). The solubility of ADVASTAB TM-599D was determined at 22°C and pH 5 by stirring an excess of the compound in the 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 dissolved 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% Sn. The results for the samples taken at 24, 48 and 72 hours were 29.73, 34.96 and 33.08 mg/L, respectively, (mean 32.59 mg/L), and indicate that saturation is attained within at least 24 hours.

The n-octanol/water partition coefficient was estimated (no reference provided – summary report only submitted) by stirring one gram of the test material with a mixture of 50 mL water and 50 mL n-octanol for 2 minutes. The aqueous and n-octanol phases were allowed to separate by standing for 96 hours, and the tin content in each phase determined using atomic adsorption spectroscopy. Approximately 96.7% of the Sn was found in the n-octanol phase and 3.3% in the water phase, and the ratio Sn (octanol)/Sn (water) of 29.3 taken as an estimate of Kow ie. log Kow = 1.47). Since the test material is a complex mixture of organo

tin compounds 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 value of 1.47 is likely to be significantly smaller than true values for components containing substantial acid moieties which tend to have much higher values for log Kow concomitant with the high hydrocarbon content. The determined log Kow of 1.47 probably reflects a significant presence of lower molecular weight species with low hydrocarbon contents.

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.

No data on adsorption/desorption to soils were provided. The low log Kow suggests that the lower molecular weight components containing a low level of hydrocarbon have little tendency to associate with the organic component of soils and sediments and may be appreciably mobile. The fatty acid 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.

The various molecular species contained within the notified chemical do not contain either acidic or basic functional groups, so dissociation constant data is not appropriate.

4. PURITY OF THE CHEMICAL

Degree of Purity:	The composition is variable and the purity is not defined.
Hazardous Impurities:	None.
Non-hazardous Impurities (> 1% by weight):	A single impurity at less than 2%.
Additives/Adjuvants:	None.

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a heat stabiliser in PVC (polyvinylchloride) products for the construction industry, including pipe, fittings, siding, window profiles and other articles manufactured by extrusion or injection moulding of PVC. Five tonnes of the notified chemical is to be imported at 100% in 200 L closed head steel drums in the first year increasing to 20 tonnes per year by the fifth year.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

The notified chemical will be imported by ship and transported by road to the Plastral-Fidene warehouse and subsequently to a single customer. Fifteen transport and warehouse workers can be exposed to the notified chemical in the event of accidental spillage. Work duration is expected to be 1 to 2 hours per days, 10 days per year.

PVC Manufacture and Processing

At the customer site, mixing plant operators transfer the notified chemical into a weighing container working 8 hours per day, 10 to 30 days per year. Transfer is accomplished by inserting a pump spear into the drum and pumping the contents to the weighing vessel. Inhalation exposure is unlikely as the notified chemical is not volatile but dermal exposure to 100% chemical is possible from drips and spills. To control exposure workers wear goggles, respirator, nitrile gloves and overalls. The contents of the weighing container is added to a 1000 L mixing vessel containing PVC powder and other ingredients. The mixing vessel is fitted with local exhaust ventilation and is enclosed so that exposure of workers is unlikely during high speed mixing. After mixing the notified chemical is absorbed into the porous PVC particles at a concentration of 1% (w/w) to produce a coarse free-flowing powder (97% of particles with a size between 61 and 425 micron). This powder is transferred via an enclosed chute to a cooling vessel and subsequently via chute or augur-fed line to 500 L woven polypropylene bags until required for further processing. Local exhaust ventilation is employed during packing and some dermal contact may be possible from spillage.

The PVC compound is transferred from the 500 L storage bags into hoppers from which it is fed to moulding or extrusion machines. There is potential for inhalation of the PVC particles during transfer and cleaning operations and this is controlled by the use of respirators and local exhaust ventilation. Once the moulded or extruded articles are produced the notified chemical should not be bioavailable and worker exposure should be nil. The total number of mixing plant and moulding/extrusion operators is between 5 and 10.

7. PUBLIC EXPOSURE

Once the moulded or 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 to the notified chemical is considered to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

8.1.1 Release during PVC manufacture

The notifier indicated that approximately 1% of import quantities (50 - 200 kg per annum, depending on import volume) of the notified chemical would be left in the drums after

emptying. The emptied drum contents are collected by an approved waste contractor and are either incinerated or placed into landfill.

A further 0.5% (25 - 100 kg per annum) may be lost due to leaks and spills in the factory, and should be contained within appropriate bunding, absorbed onto sawdust or other materials and incinerated or placed into landfill.

Particulate material collected in vacuum equipment (stated to account for release of 0.5% of the chemical, 25 - 100 kg each year, would also be placed into landfill.

Invariably some scrap PVC is generated during production as off cuts and tail end residuals. This was stated to be a maximum of 1% of the PVC, and would account for a further release of 50 - 200 kg 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 PVC manufacturing is estimated at a maximum of 3% of imports or between 150 and 600 kg each year. Most is expected to be placed into landfill although some may be incinerated.

8.1.2 Release through service life of PVC articles

Although the notified chemical is bound within the polymer matrix there may be some release from the surface of the 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 grams 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. 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 microgram Sn/kg of food. Results suggest that the 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 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 new chemical or its degradation products.

8.2 Fate

In landfill, the notified chemical is expected to eventually leach into the clay and soil. The measured value of log Kow indicates a weak affinity for the organic component of soils and sediments, and it is likely that the lower molecular weight components would be appreciably mobile and eventually reach the wider water compartment.

8.2.1 Biodegradation

The ready biodegradation of the notified chemical (called C-3530 in this study, and stated to contain 15.2% tin) was determined using the CO_2 evolution test of OECD TG 301 B (T R Wilbury, 1999a). The degree of biodegradation was determined by measuring the amount of carbon dioxide evolved over a 28-day period from a quantity of test material when incubated with sewage sludge bacteria. The concentration of the test material was nominally 35.1 mg/L (corresponding to 20 mg/L of organic carbon), and 71% degradation was observed after 28 days incubation. However, the results also indicated that 10% degradation had been achieved on day 2, increasing to approximately 64% by day 12 and this rate of degradation qualified the compound to be described as readily biodegradable.

Biodegradation of a close structural analogue of the notified chemical was also conducted according to the procedures of the OECD Expert Group on Degradation and Bioaccumulation pre test guideline 1979, C-80/113 (the Japanese Ministry of International Trade and Industry test). The oxygen consumption of the compound incubated with sewage sludge is measured weekly over a 4 week period and compared with the theoretical maximum oxygen demand which is either calculated from the chemical's stoichiometry or determined directly through an oxidative titration with acidified dichromate. The compound used in the biodegradation test was an organo thiostannate derivative of a C13 - 23 unsaturated carboxylic acid, judged to be sufficiently similar to "read across" biodegradation properties to the notified chemical.

In the test report provided (Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, 1981) the test chemical at 35 mg/L was incubated at 25°C with sewage bacteria over a 28-day period. Degradation determined from the amount of O_2 consumed found to be 1.6, 7.2, 11.7 and 15.5% of the theoretical maximum after 7, 14, 21 and 28 days respectively. In contrast aniline used as the reference material was degraded 58.3% after 7 days and 69.3% after 28 days, which established the viability of the bacterial culture.

Results indicate that the stannane test compound cannot be regarded as readily biodegradable but is nevertheless slowly degraded by sewage bacteria. Although the notified chemical is not identical to that used in the biodegradation test it is very likely to exhibit similar degradation behaviour.

8.2.2 Bioaccumulation

No bioaccumulation data were provided, but the rapid biodegradation reported above indicates that bioaccumulation would be unlikely. Also, the moderate water solubility (32.6 mg/L), low log Kow (1.47) and large molecular weight (around 1000 g/mol) indicate low potential for bioaccumulation (Connell, 1989).

A bioaccumulation test in carp using a much simpler organotin compound (dimethyltin thioglycolate with formula $(CH_3)_2Sn[SCH_2CO_2]$) was also provided (Mitsubishi-Kasei

Institute of Toxicological and Environmental Sciences, 1981). This compound does not contain a large hydrocarbon component and is likely to be have significantly less potential for bioaccumulation than the notified chemical. The results are not described, but the determined bioaccumulation factors (BCF) were always less than 8 over the 8 week test period, indicating that the compound has little tendency for bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

Only the 4-week oral repeated dose study was conducted with the notified chemical. Five acceptable analogues, namely, Product 9286, TM-592, C-2533 (a mixture of 2 analogues) and formulations, were used to generate the other toxicological data.

Test	*Formulation*
acute oral toxicity	1. Product 9286 2. TM-592
acute dermal toxicity	TM-692 = TM-592 formulation
acute inhalation toxicity	TM-694 = Product 9286 formulation
skin irritation	TM-592
eye irritation	TM-592
skin sensitisation	C-2533
28-day oral (gavage) study	C-3530 (the notified chemical)
90-day feeding study	TM-592
Ames test	1. TM-592 2. Product 9286 3. 50% TM-592 in 50% 2-mercaptoethyl oleate
mouse micronucleus test	50% TM-592 in 50% 2-mercaptoethyl oleate

For the 90-day feeding study only a summary of the data was available.

9.1 Acute Toxicity

Summary of the acute toxicity of analogues of ADVASTAB TM-950 F

Test	*Species*	*Outcome*	Reference
acute oral toxicity	rat	$LD_{50} > 5000$ mg/kg $LD_{50} = 4687$ mg/kg	(Hill Top Biolabs,1994; IBR-US, 1974)
acute dermal toxicity	rat	$LD_{50} > 4.64$ mL/kg	(Hill Top Research, 1978)
acute inhalation toxicity	rat	$2.09 < LC_{50} < 5.45$ mg/L	(Tox Monitor Laboratories, 1994)
skin irritation	rabbit	slight irritant	(IBR-US, 1974)
eye irritation	rabbit	not irritant	(IBR-US, 1974)
skin sensitisation	guinea pig	not sensitising	(Hill Top Biolabs, 1989)

9.1.1 Oral Toxicity

9.1.1.1 Product 9286 (Hill Top Biolabs, 1994)

Species/strain:	rat/Sprague-Dawley.
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	Oral (gavage); dose, 5000 mg/kg.
Test method:	OECD TG 401.
Mortality:	3 females and 1 male died between days 2 and 3.
Clinical observations:	Non-specific signs, mainly on day 1, including piloerection, hunched posture, appearing depressed, urine stains and reddish stains on muzzle.
Morphological findings:	No findings specific to treatment amongst decedents.
LD_{50}:	> 5000 mg/kg.
Result:	The test substance was of very low acute oral toxicity in rats.

9.1.1.2 TM-592 (IBR-US, 1974)

Species/strain:	rat/Sprague-Dawley.
Number/sex of animals:	5 males/dose group.
Dose groups:	0, 0.464, 1.00, 2.15, 4.64 and 10.0 mL/kg.
Observation period:	14 days.
Method of administration:	Oral (gavage).
Test method:	Specified in the Regulations for the Enforcement of the Federal Hazardous Substances Act.
Mortality:	Mortality was observed in the 4.64 (3/5) and 10.0 (5/5) mL/kg dose groups.

Clinical observations:

Dose (mL/kg)	Observations
0.464	Two rats exhibited diarrhoea on days 1 or 2.
1.00	3 rats had diarrhoea on day 1, 4 on day 2 and all exhibited depression on day 2.
2.15	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.
4.64	3 animals 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.
10.0	all rats exhibited depression, depressed righting and placement reflexes, excessive salivation and stains and mucoid diarrhoea.

Morphological findings: 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.

LD_{50}: 4.30 mL/kg (equivalent dose 4687 mg/kg).

Result: The test substance was of low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (TM-692) (Hill Top Research, 1978)

Species/strain: rabbit/New Zealand White (NZW).

Number/sex of animals: 7 males/9 females.

Dose groups: 0.464, 1.00, 2.15 and 4.64 mL/kg.

Observation period: 14 days.

Method of administration: 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 under an occlusive dressing.

Test method: OECD TG 402

Mortality: Not indicated.

Clinical observations:	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.
Morphological findings:	One rabbit in the 2.15 mL/kg dose group had pitted kidneys.
LD_{50}:	> 4.64 mL/kg.
Result:	The test substance was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity (TM-694) (Tox Monitor Laboratories, 1994)

Species/strain:	rat/Sprague-Dawley.
Number/sex of animals:	5/sex/dose group.
Dose groups:	2.09 and 5.45 mg/L for 4 hours.
Observation period:	14 days.
Method of administration:	An aerosol was produced using an atomising system in a 100 L clear plastic chamber.
Test method:	OECD TG 403
Mortality:	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.
Clinical observations:	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.
Morphological findings:	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.
LC_{50}:	Between 2.09 and 5.45 mg/L.
Result:	The notified chemical was of low acute inhalational toxicity in rats.

9.1.4 Skin Irritation (TM-592) (IBR-US, 1974)

Species/strain: rabbit/albino.

Number/sex of animals: 6/sex unspecified.

Observation period: 72 hours.

Method of administration: 0.5 mL under occlusive dressing for 24 hours on abraded and unabraded skin.

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

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

[a] see Attachment 1 for Draize scales

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

Result: The test substance was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation (TM-592) (IBR-US, 1974)

Species/strain: rabbit/albino.

Number/sex of animals: 6/ sex unspecified.

Observation period: 72 hours.

Method of administration: 0.1 mL into the left eye of each rabbit. The untreated eye served as control.

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

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

Result: The notified chemical was not irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (C-2533) (Hill Top Biolabs, 1989)

Species/strain: guinea pig/Dunkin-Hartley.

Number of animals: 20 test/ 10 control.

Induction procedure:

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: Naïve control - no exposure to the test substance.

Challenge procedure: 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/w) test substance in acetone.

Test method: Buehler method.

Challenge outcome:

Challenge concentration	• *Test animals* • *Control animals*			
	• *24 hours**	• *48 hours**	• *24 hours*	• *48 hours*
1%	0/20**	0/20	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response (ie Draize score equal to or greater than 1)

Result: The test substance was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity

9.2.1 28-Day Oral Study with C-3530 (Chrysalis, 1999)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex/dose group.

Method of administration: Oral (gavage).

Dose/Study duration: The study was conducted in two parts. In part A rats were administered doses of 0, 10, 50, 150 or 300 mg/kg/day for 28 consecutive days. In part B the doses were 0 or 500

mg/kg/day.

Test method: OECD TG 407

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

Body weight
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.

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

Clinical chemistry/Haematology/Urinalysis
Clinical chemistry
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.

Haematology
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.

Urinalysis
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.

Macroscopic findings and organ weights:
Macroscopic findings
In the 500 mg/kg/day dose group one male and five females exhibited pale livers and all but one female exhibited mottled livers.

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

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

Comment
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.

Result
The NOAEL for the test substance was found to be 50 mg/kg/day on the basis of diuretic effects seen primarily in males at higher doses.

9.2.2 90-Day Oral Study with ADVASTAB TM-592 (Central Institute for Nutrition and Food Research, 1975)

Species/strain:	rat/Wistar.
Number/sex of animals:	5/sex/dose group.
Method of administration:	Dietary.
Dose/Study duration:	The test substance was mixed into stock diet at levels of 0, 30, 100, 300 or 1000 ppm.
Test method:	Not specified.

Mortality
None.

Body weight
No statistically significant differences were observed.

Clinical observations
None.

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.

Macroscopic findings and organ weights
Macroscopic findings
No findings.

Organ weights
Some changes in intermediate dose groups were not considered to be toxicologically significant.

Histopathology
No treatment-related changes.

Result
The NOAEL was considered to be 300 ppm (equivalent to 15 mg/kg/day) on the basis of low urine specific gravity in 1000 ppm males.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays

9.3.1.1 TM-592 (SRI International, 1996)

Strains:	*S. typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100 and *E. coli* WP2*uvrA*
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate.
Test method:	OECD TG 471
Comment:	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.
Result:	The test substance was non mutagenic under the conditions

of the test and no increase in the mean number of revertants above background occurred.

9.3.1.2 TM-599 (SRI International, 1993a)

Strains:	*E. coli* WP2*uvrA*
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate (maximum of 2500 μg/plate in the duplicate assay).
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.1.3 TM-599 (SRI International, 1993b)

Strains:	*S. typhimurium* TA 1535, TA 1537, TA 98, TA 100
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate (maximum of 2500 μg/plate in the duplicate assay).
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine and 2-nitrofluorene. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.1.4 TM-599D (SRI International, 1993c)

Strains:	*E. coli* WP2*uvrA*
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate (maximum of 2500 μg/plate in the duplicate assay).
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.1.5 TM-599D (SRI International, 1993d)

Strains:	*S. typhimurium* TA 1535, TA 1537, TA 98, TA 100
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate (maximum of 2500 μg/plate in the duplicate assay).
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine and 2-nitrofluorene. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.1.6 TM-592 and 2-mercaptoethyl oleate (1:1) (SRI International, 1990a)

Strains:	*E. coli* WP2*uvrA*
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.

Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate.
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system and N-ethyl-N'-nitro-N-nitrosoguanidine. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.1.7 TM-592 and 2-mercaptoethyl oleate (1:1) (SRI International, 1990b)

Strains:	*S. typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100
Metabolic activation:	Microsomal fraction (S9) from Aroclor 1254-induced rat liver homogenate.
Concentration range:	0, 10, 50, 100, 500, 1000 or 5000 μg/plate.
Test method:	OECD TG 471
Comment:	Positive controls used were 2-anthramine to test the efficacy of the metabolic activation system, sodium azide, 9-aminoacridine and 2-nitrofluorene. Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.
Result:	The test substance was non mutagenic under the conditions of the test and no increase in the mean number of revertants above background occurred.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse using TM 592 and 2-mercaptoethyl oleate (1:1) (SRI International, 1990c)

Species/strain:	mouse/Swiss-Webster.
Number and sex of animals:	5/sex/dose.
Doses:	0, 600, 1200 and 2500 mg/kg in males; 0, 450, 900 and 1800 mg/kg in females.
Method of administration:	Oral (gavage).
Test method:	OECD TG 474

Comment:	Sampling times were 24, 48 or 72 hours post-treatment. Treatment with benzene (500 mg/kg) as positive control demonstrated the test sensitivity. Negative control (vehicle) gave the expected response.
Result:	The test substance was non clastogenic under the conditions of the test and no increase in the frequency of micronucleated polychromatic erythrocytes occurred.

9.4 Overall Assessment of Toxicological Data

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

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

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. A 90-day feeding study in rats was conducted on an analogue of the notified chemical. The NOAEL was 15 mg/kg/day on the basis of lower urine specific gravity in males, also an indicator of diuresis in the 28-day study with the notified chemical.

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

The test substance used to measure acute inhalation toxicity is determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and is assigned the risk phrase R20: Harmful by inhalation. Therefore, the notified chemical is assigned the risk phrase R20.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

A number of tests of the toxicity of the notified chemical or of a chemical analogue were provided, and the results of these test summarised below.

Test	*Species*	*Results*
Acute Toxicity OECD TG 203	Rainbow trout *Oncorhynchus mykiss*	LC50 (96 h) > 4.4 mg/L (measured) NOEC (96 h) < 0.56 mg/L (measured)
Acute Toxicity OECD TG 203	Fathead minnow *Pimephales promelas*	LC50 (96 h) > 1000 mg/L (nominal WAF) NOEC (96 h) > 1000 mg/L (nominal WAF)
Acute Toxicity OECD TG 203	Sheepshead minnow *Cyprinodon variegatus*	LC50 (96 h) > 1000 mg/L (nominal WAF) NOEL (96 h) > 1000 mg/L (nominal WAF)
Acute Immobilisation OECD TG 202	*Daphnia magna*	LC50 (48 h) = 0.27 mg/L (measured) NOEC (48 h) < 0.14 mg/L (measured)
Acute Immobilisation OECD TG 202	*Daphnia magna*	LC50 (96 h) = 130 mg/L (nominal WAF) NOEL (96 h) = 10 mg/L (nominal WAF)
Acute Toxicity OECD TG 203	Mysid shrimp *Mysidopsis bahia*	LC50 (96 h) = 250 mg/L (nominal WAF) NOEL (96 h) = 100 mg/L (nominal WAF)
Algal reproduction OECD TG 201	Green algae *Selenastrum capricornutum*	EC50 (96 h) = 0.64 mg/L (measured) NOEL (96 h) = 0.28 mg/L (measured)
Algal reproduction OECD TG 201	Green algae *Selenastrum capricornutum*	E_bC50 (96 h) = 10 mg/L (nominal WAF) NOEL (96 h) = 1.0 mg/L (nominal WAF)
Algal reproduction OECD TG 201	Marine algae *Skeletonema costatum*	E_bC50 (96 h) = 24 mg/L (nominal WAF) NOEL (96 h) = 0.1 mg/L (nominal WAF)

* NOEC - no observable effect concentration

Fish

The test on rainbow trout (Wilbury, 1999a) was conducted at 12 ± 2°C over a 96-hour period using flow through methodology. The test compound used was C-3530, the notified chemical, and was stated to contain 15.2% tin.

The test media were prepared and maintained by continuously adding metered quantities of a stock solution of the test material prepared at (nominally) 50 g/L in dimethylformamide

(DMF) to the dilution water with a hardness of 44 mg/L as $CaCO_3$. The tests were performed in duplicate with 10 fish per test chamber with a water control, a solvent control (nominally 0.1 mL/L of DMF) and at five nominal concentrations of the test material of 0.05, 0.1, 0.5, 1.0 and 5.0 mg/L which were measured (through analysis of the Sn concentration) to give concentrations of 0.56, 0.99, 1.6, 2.8 and 4.4 mg/L respectively. Throughout the tests the pH and dissolved oxygen content of the water were always 7.4 - 7.6 and between 8.9 and 10.6 mg/L, respectively.

After 96 hours, one (of 20) fish in the water control had died although all 20 in the solvent control were alive. A small percentage of deaths (never exceeding 3 of 20 or 15%) was observed in all the test solutions, with the largest effect at the highest concentration (nominally 5.0 mg/L of test substance) where 1 fish had died after 24 hours exposure and 3 had died after 96 hours. Some sub lethal effects (lethargy, discolouration and/or loss of equilibrium) were also observed, but with low frequency (maximum 10%) and at all concentrations.

The results were analysed using accepted statistical methods to provide a 96-hour LC50 of > 4.4 mg/L and a 96-hour No Observed Effect Concentration (NOEC) of < 0.56 mg/L, based on the measured concentrations of test substance.

This result indicates that the notified chemical is likely to be moderately toxic to this species of freshwater fish (Mensink, 1995).

Two other tests reports on the toxicity of alkyl tin compounds to fish were provided, although these tests were performed with a compound described as Alkyltin ME, which has the same CAS No. as the compound called ADVASTAB TM-599D and may therefore be considered to be chemically very similar – see notes on water solubility above. The first of these (Wilbury, 1995a) was conducted over 96 hours against fathead minnow (a freshwater fish) using Water Accommodation Fractions (WAF) prepared at nominal test concentrations between 0.1 and 1000 mg/L at 22±1°C under static conditions. The water hardness was 40 mg/L as $CaCO_3$, the pH of the water was 7.3 - 7.6 while dissolved oxygen levels were always between 6.3 and 8.6 mg/L. Ten fish were tested at each nominal WAF and no deaths or sub lethal abnormalities were observed over the 96-hour test period. Accordingly both the 96-hour LC50 and 96-hour NOEC were determined as > 1,000 mg/L WAF.

The second test (Wilbury, 1995b) was conducted using the same test material (Alkyltin ME) and test methodology in salt water (salinity adjusted to 20 parts per thousand) against the saltwater fish, sheepshead minnow. The test was performed at 22±1°C under static conditions over a 96-hour period. The LC50 and NOEL were determined as > 1000 mg/L (nominal WAF).

The results of the latter two tests indicate that the test compound used (ie. ADVASTAB TM-599D) is not toxic to these two fish species up to the limits of its water solubility.

Invertebrates

Daphnia

The test on daphnia (Wilbury, 1999b) was conducted on C-3530 at 20±2°C over a 48-hour period using flow through methodology.

The test media were prepared and maintained by continuously adding metered quantities of a stock solution of the test material prepared at (nominally) 50 g/L in DMF to the dilution water which had a hardness of 160 - 180 mg/L as $CaCO_3$. The tests were performed in duplicate using 10 daphnia per test chamber with a water control, a solvent control (nominally 0.1 mL/L of DMF) and at five nominal concentrations of the test material of 0.13, 0.22, 0.36, 0.60 and 1.0 mg/L which were measured (through analysis of the Sn concentration) to give concentrations of 0.14, 0.23, 0.36, 0.59 and 0.99 mg/L, respectively. Throughout the tests the pH and dissolved oxygen content of the water were always 7.3 - 7.6 and between 7.9 and 8.5 mg/L respectively.

After 48 hours one (of 20) daphnia in the nominally 0.13 mg/L solution was immobile, and after 48 hours exposure to the most concentrated solution (nominally 1.0 mg/L), all animals were dead. The results were analysed to using accepted statistical methods to provide a 48-hour LC50 of 0.27 mg/L and a 48-hour No Observed Effect Concentration (NOEC) of < 0.14 mg/L, with results based on the measured concentrations of test substance.

This result indicates that the notified chemical is highly toxic to this species of invertebrate (Mensink, 1995).

A second daphnia toxicity test was performed with Alkyltin ME (Wilbury, 1995c). The test was conducted over 48 hours against daphnia using WAF prepared at nominal concentrations between 0.1 and 1000 mg/L of the test substance at 22±1°C under static conditions. The water hardness was 160 mg/L as CaCO3, the pH of the water was 8.2 - 8.5 while dissolved oxygen levels were always between 8.5 and 8.9 mg/L. Ten daphnia were tested at each nominal WAF and after 48 hours exposure to the nominally 100 mg/L WAF, 3 of the test animals were dead, and all had died after 48 hours exposure to the highest test substance loading of 1000 mg/L. The results were analysed to give a 48-hour LC50 of 130 mg/L WAF with corresponding NOEL of 10 mg/L nominal WAF, and indicate that the test compound is toxic to this species below its water solubility.

Mysid Shrimp

A test report on mysid shrimp (a saltwater invertebrate) toxicity was performed with Alkyltin ME (Wilbury, 1995d). The test was conducted over 96 hours against the mysid shrimp using WAF prepared at nominal concentrations between 0.1 and 1000 mg/L of the test substance at 25±2°C under static conditions in salt water (salinity adjusted to 20 parts per thousand).

The pH of the water was 7.2 - 8.0 while dissolved oxygen levels were always between 6.6 and 7.3 mg/L. Ten mysids were tested at each nominal WAF and after 48 hours exposure to the nominally 100 mg/L WAF one of the test animals was dead, and all had died after 48 hours exposure to the highest test substance loading of 1000 mg/L. The results were analysed to give a 96-hour LC50 of 250 mg/L WAF with corresponding NOEL of 100 mg/L nominal WAF, again indicating toxicity below the water solubility limit.

Algae

The test on green algae (Wilbury, 1999c) was conducted on C-3530 at 24±2°C over a 96-hour period using static methodology.

The test media were prepared and maintained by adding measured quantities of the test

material in DMF to the dilution water. The tests were performed in triplicate with a water control, a solvent control (nominally 0.1 mL/L of DMF) and at five nominal concentrations of the test material of 0.34, 0.66, 1.3, 2.5 and 5.0 mg/L which were measured (through analysis of the Sn concentration) to give concentrations of 0.28, 0.57, 1.3, 2.2 and 4.6 mg/L respectively.

Growth of the biomass was monitored over the test period and the results analysed using accepted statistical procedures to give a 96-hour E_bC50 of 0.64 mg/L and corresponding 96-hour NOEC of 0.28 mg/L, based on the measured concentrations. According to Mensink (1995) this result indicates that the new compound highly toxic to this species of green algae.

Two other toxicity reports on Alkyltin ME were also submitted, one for a freshwater algae (Wilbury, 1995e) and the other for a marine algae (Wilbury, 1995f). Toxicity of the material against the freshwater alga *Selenastrum capricornutum* was measured using five WAFs prepared at nominal loadings between 0.1 and 1000 mg/L. All WAFs were clear except for the highest loading which showed slight turbidity. The growth of the algal biomass was monitored over a 96-hour test period at 24±1°C. The results were analysed using accepted statistical methods to provide a 96-hour E_bC50 of 10 mg/L (nominal WAF) with corresponding 96 hour NOEL of 1.0 mg/L.

Toxicity of Alkyltin ME was tested against the marine alga *Skeletonema costatum* at 20±1°C using five WAFs prepared with nominal loadings between 0.1 and 1000 mg/L of test material. All WAF preparations were clear over the duration of the test period (96 hours), and the growth of the algal biomass monitored over this period. The results were analysed to provide a 96-hour E_bC50 of 24 mg/L (nominal WAF) with corresponding 96-hour NOEL of 0.1 mg/L, indicating that the chemical is toxic to this species at concentrations well below its limit of water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical is a tin compound to be used as a stabiliser for construction materials fabricated from PVC, and when used in the typical manner is not expected to present a large hazard to the environment.

Approximately 3% of annual imports (or a maximum of 600 kg each year) may be released during manufacture 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, is not anticipated to be large. Release may not be of the notified chemical but is more likely to be the methyl tin chlorides which are produced through reaction of the new chemical with PVC as a consequence of its action as a stabiliser.

At the end of their service lives most of the PVC products containing the chemical are likely to be disposed of into landfill where the PVC will be broken down through biological and abiotic processes and the chemical will be slowly released. The moderate water solubility and low log Kow (1.47) suggest weak affinity for the organic component of soils and sediments. It is likely that the chemical will be mobile and may reach the wider water compartment.

However, the notified chemical has been shown to be readily biodegradable and would not persist in the environment, or have high potential for bioaccumulation.

Incineration would destroy the notified chemical with production of water vapour and oxides of carbon and sulphur. The tin component would be converted to SnO_2 and become assimilated into ash. Biodegradation would also mineralise the compound to water, CO_2 and sulphate, while the tin component would be converted to SnO_2.

The notified chemical is highly toxic to freshwater invertebrates (daphnia) and algae, and has demonstrated toxicity to freshwater fish, marine shrimp and marine algae. Overall release to waterways will be low (except in the case of a transport accident) and the notified chemical is unlikely to reach the water compartment in quantities likely to exceed toxic levels. Potential toxicity would also be mitigated by the demonstrated rapid rate of biodegradation.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Analogues of the notified chemical were of very low acute oral toxicity (LD50 > 5000 mg/kg, low acute dermal toxicity (LD50 > 4.64 mL/kg) and low acute inhalation toxicity (LC50 between 2.09 and 5.45 mg/L) in rats. Analogues of the notified chemical were slightly irritating to rabbit skin, not irritating to rabbit eyes and not skin sensitising in guinea pigs.

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.

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

The test substance used to measure acute inhalation toxicity is determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and is assigned the risk phrase R20: Harmful by inhalation. Therefore, the notified chemical is assigned the risk phrase R20.

Occupational Health and Safety

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.

Public Health

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.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R20: Harmful by inhalation

- 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR 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

No additional secondary notification conditions are stipulated.

The Director will then decide whether secondary notification is required.

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T R Wilbury Laboratories (1999a) Determination of the Ready Biodegradability of C-3530 Using the CO2 Evolution Test (Modified Sturm). Study No. 1674-MO. T R Wilbury Laboratories Inc., Massachusetts, USA (unpublished report submitted by Rohm and Haas Australia Pty Ltd).

Attachment 1

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

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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