File No: NA/613

October 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Cyasorb UV-1164

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday – Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of the full public report may also be requested, free of charge, by contacting the Administration Coordinator.

Please direct enquiries or requests for full public reports to the Administration Coordinator at:

Street Address:	92 Parramatta Road, CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone:	(61) (02) 9577 9514
Facsimile:	(61) (02) 9577 9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Cyasorb UV-1164

1. APPLICANT

Cytec Australia Holdings Pty Ltd of Suite 1, 7 – 11 Railway Street BAULKHAM HILLS NSW 2153 has submitted a standard notification statement in support of their application for an assessment certificate for Cyasorb UV-1164.

2. IDENTITY OF THE CHEMICAL

Trade Name:	Cyagard UV-1164 UV-1164 CT-375-88 CT-483-91
Marketing Name:	Cyasorb UV-1164

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	pale yellow powder
Melting Point:	91.6 ± 0.2°C
Density:	1 150.9 ± 0.25 kg/m^3
Vapour Pressure:	8.44 x 10^{-2} kPa at 40°C
Water Solubility:	0.04 to 0.07 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	not determined, see comments below

Hydrolysis as a Function of pH:	not determined, see comments below
Adsorption/Desorption:	K_{oc} = 9.7 x 10^8 (calculated)
Dissociation Constant:	not determined, see comments below
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	> 350°C
Explosive Properties:	not explosive
Reactivity/Stability:	not reactive
Particle Size:	4.4 ± 3.9 µm

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

No studies on the hydrolytic stability of the notified chemical were supplied. This is acceptable as the notified substance contains no readily hydrolysable groups and has very low solubility in water (0.04 to 0.07 ppm). Therefore, hydrolysis is unlikely under environmental conditions.

The partition coefficient of the notified chemical has not been determined. Based on the low water solubility it is expected that the chemical will have a high partition coefficient and adsorb strongly to soils and sediments. The strong binding to soils is confirmed by the calculated K_{OC} using the atom/fragment contribution method developed by Syracuse Research Corporation. The K_{OC} was calculated for the electrically neutral (non-dissociated) molecule. As the chemical contains groups which are expected to dissociate and associate at various pHs (see below) the K_{OC} of the chemical is expected to show a pH dependence. However, given the magnitude of the calculated K_{OC} this variation is expected to have little effect on the behaviour of the chemical in the environment where it is expected to be tightly bound to soils and sediment.

Dissociation tests were not conducted due to the low water solubility and relatively high molecular weight of the notified chemical. The weak acidity of the phenolic functionality of the notified chemical would suggest some solubility in highly basic media (pKa phenol 9.89), while the weak basicity of the triazine nitrogens may impart solubility at low pH (pKa of azine conjugate acid 5.18).

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Toxic or Hazardous Impurities: none known

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported in powder form, and will be used as a light stabiliser for applications involving high temperature processed polymers and industrial baked coating systems. The current use will be in the area of engineering resin manufacture and later for the automotive top coat market and exterior building applications.

It is estimated that 500 to 1 000 kg per annum of the notified chemical will be imported in the first three years. However, there is the possibility that it may exceed 1 000 kg, depending on market demand.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 20 or 57 kg plastic bags packed in fibreboard cartons. The total import volume will be transported by road to United Transport Services warehouse at Arndell Park NSW for storage prior to transportation to the customer site. The following categories and number of workers may be exposed to the notified chemical during importation, reformulation and application.

Category of workers	Number	Hours/day	days/year
Waterside workers	5-10	2-3	10-20
Transport drivers	5-10	2-3	10-20
Plant operators	4-20	2	10
Laboratory technicians	2-4	1	10

Waterside Transport and Storage
For waterside, transport and warehouse workers, there is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

Manufacture-Masterbatch
A master batch is a solid mixture consisting of the notified chemical and other components in a suitable carrier polymer. The masterbatch is either extruded into pellets (~ 5 mm width) or will form the first stage of plastic bag manufacture. The process for formulating a master batch consists of weighing and blending of the notified chemical with other ingredients to produce resin solids.

Blending and encapsulation
Dermal, ocular and inhalation exposure is expected during blending operations as workers empty bags of the notified chemical into the feed hopper of the blending vessel and during changing of filter bags of the dust extraction system of the two hoppers. The loading area is subject to general ventilation with local exhaust ventilation in place over the hoppers to capture airborne particles. The hopper also has a door which is kept closed, except when loading. During loading operations the plant operators will be attired with overalls, gloves, a head covering, half-face respirator and safety glasses.

From the hopper the notified chemical drops via gravity to the blending vessel where blending is carried out in closed/sealed mixers. The mixed product containing the notified chemical is then fed into an extruder where it is completely dissolved and encapsulates the polymer. Exposure to the notified chemical may occur following extrusion of the notified chemical into its encapsulated form, either as pellets or as the final product (eg bag). If the final product is in pellet form the product will be extruded in spaghetti-like strings. These are passed through a water bath into a pelletiser, a classifier and finally a hopper for storage before being bagged. Alternatively, the product may be extruded as a bubble-type, cylinderical tube, which is air blown and cooled, and cut into lengths to form plastic bags.

Laboratory analysis
A laboratory technician will be exposed to the notified chemical during sample collection. Up to 3 samples per five tonne per batch are collected by scooping the notified chemical into a container which is then subjected to a series of quality control tests in the laboratory. The notifier states laboratory technicians are required to wear appropriate laboratory coats, safety glasses and gloves, during sampling and analysis.

No details were provided on the end use of the pellets

7. PUBLIC EXPOSURE

The notified chemical is for industrial use only. The potential for public exposure to the notified chemical during transport and industrial use or from disposal is assessed as negligible. Although the public will make dermal contact with the final products (eg plastic mulded forms; paintd surface on automotive) containing the notified chemical (approximately 1 to

5%), exposure will be negligible since the notified chemical (at a low concentrtion) will be in an encapsulated form, will not leach out and hence will not be bioavailable.

8. ENVIRONMENTAL EXPOSURE

Release

Under normal conditions it is not expected that the chemical would be released during storage and transportation. The Material Safety Data Sheet (MSDS) contains adequate instructions for handling a spill should one occur.

Empty containers used to hold the notified substance will be disposed of to landfill. The notifier has estimated that there will be 400 to 1 100 g of residual chemical left in these containers. This would correspond to a maximum of approximately 20 kg of the notified substance per annum at the maximum rate of import.

Release of the notified substance to the environment as a result of manufacture into masterbatches and final products is expected to be minimal.

A master batch is a solid mixture of one or more compounds in a suitable carrier polymer. The process for formulating a master batch consists of weighing and blending of the notified chemical, polymer and other compounding ingredients. The blending is carried out in closed/sealed mixers. This pre-blending process is followed by a melting and extrusion process that completely dissolves and encapsulates the notified chemical into the polymer. Wastes from master batch formulation, consisting of dirty spilt material or purging material, are recycled.

Manufacturing of the final product takes place in a closed system. The master batches will be fed automatically into extrusion or moulding machinery from a hopper. Off spec material will be sold at cheaper prices and waste is expected to be minimal.

The notifier estimates that up to 2 to 3% waste may be generated by the manufacturing process as a result of spills and production startup and shutdown. This corresponds to a maximum of approximately 30 kg of the notified chemical per annum at the maximum rate of import. This material bound within a polymer matrix, will be disposed of to landfill.

Fate

The biodegradation of the notified chemical was investigated by exposing activated sludge (30 mg/L) to 100 mg/L of the notified chemical and measuring both the biological oxygen demand (BOD) and the amount of chemical remaining in the test media after 28 days, by high pressure liquid chromatography (HPLC). No biodegradation was observed according to the BOD measurements and only a 2% loss of the chemical was found by HPLC, indicating that it is not readily biodegradable under the conditions of the test. The activity of the sludge was checked by examining the biodegradation of aniline (83% and 93% from BOD after 7 and 14 days, respectively).

The bioaccumulation of the notified chemical was investigated in carp (*Cyprinus carpio*) according to "Concentration Test of Chemical Substances in Fish Body" described in "On Test Methods of New Chemical Substances" in Regulations (Kanpogyo No. 5, Yakuhatsu No. 615, 49 kikyoku No. 392) issued on July 13, 1974. The test was conducted in a flow-through system for a period of 8 weeks and HCO-40 was used as a dispersing agent. Fish were exposed to two concentrations (0.5 and 0.05 mg/L). Calculated concentration factors ranged between 0.3-15 times for 0.5 mg/L and 2.5 to 5.1 times for 0.05 mg/L, indicating that the chemical does not significantly bioaccumulate.

The notified chemical is intended for use as a light stabiliser in plastics. As such, the fate of the majority of the chemical will share the fate of the plastic articles (eg plastic bags) into which it is incorporated. These will be disposal to landfill or incineration at the end of their useful lifetimes. Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon and nitrogen.

A small amount (approximately 20 kg per year) will be disposed of to landfill as waste from empty containers. The low water solubility of the chemical would indicate that it is unlikely to leach from landfill. Additionally, once bound within the polymer matrix the chemical is also not expected to be mobile.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Cyasorb UV-1164

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(1)
acute dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	(2)
acute inhalation toxicity	rat	LC_{50} > 0.377 mg/L	(3)
skin irritation	rabbit	non-irritant	(4)
eye irritation	rabbit	slight to moderate irritant	(5)
skin sensitisation	guinea pig	non-sensitiser	(6)

9.1.1 Oral Toxicity – Limit Test(1)

Species/strain: rat/Sprague Dawley

Number/sex of animals: 5/sex

Observation period: 15 days

Method of administration:	a single dose of 5 000 mg/kg administered by gavage; vehicle was 25% (w/w) corn oil
Clinical observations:	decreased activity and diarrhoea was noted in one male on day one of dose administration
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	similar to OECD guidelines – limit test (7)
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (2)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a dose of 2 000 mg/kg was applied to an intact skin site and covered with semi-occlusive dressing; after 24 hours the dressing and residual test material were removed
Clinical observations:	one male had soft stools on days 2 and 3; and one female had anorexia from days 2 to 6
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	similar to OECD guidelines (7)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rabbits

9.1.3 Inhalation Toxicity (3)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of exposure:	whole body exposure to a maximum attainable dust aerosol concentration of 377 mg/m^3 (standard deviation of 14.5 mg/m^3 and coefficient of variation of 3.85%) for 4 hours; aerosol concentration was relatively stable throughout the exposure; the total respirable concentration (penetration past the terminal bronchioles) was 152 mg/m^3, (mass median equivalent aerodynamic diameter of particles = 4.4 µm with a geometric standard deviation of 3.9 µm)
Clinical observations:	some animals had an accumulation of yellow material in their eye and fur; irregular breathing; clear ocular discharge; soft stools; brown ano-genital staining; and dry red nasal discharge;
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	similar to OECD guidelines (7)
LC_{50}:	>0.377 mg/L
Result:	there was no mortality in the study therefore an LC_{50} value could not be determined; the study authors consider the LC_{50} to be greater than the maximum attainable dust aerosol concentration of 0.377 mg/L

9.1.4 Skin Irritation (4)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Method of administration:	a dose of 2 000 mg/kg was applied to an intact skin site; the site was covered with occlusive dressing; after 24 hours the dressing and residual test

	material were removed
Observation period:	24, 48 and 72 hours after dose administration
Test method:	similar to OECD guidelines (7) except the test substance was applied to the intact skin for a period of 24 hours instead of 4 hours
Comment:	none of the animals showed any erythema or oedema;
Result:	the notified chemical was non irritating to the skin of rabbits

9.1.5 Eye Irritation (5)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	9 males
Method of administration:	100 mg of the test substance was placed in the conjunctival sac of one eye of each rabbit whilst the contralateral eye of each rabbit served as the control; the treated eye of each rabbit was irrigated with physiological saline 30 seconds post treatment
Observation period:	1, 24, 48 and 72 hours after dose administration

Draize scores (8) of unirrigated eyes:

Time after instillation

Animal	***1 hour***		***24 hour***		***48 hour***		***72 hour***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	0	0	1	2	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
Iris								
1	0		0		0		0	
2	0		0		0		0	
3	0		0		0		0	
4	0		0		0		0	
5	0		0		0		0	
6	0		0		0		0	

Conjunctiva[(1)]	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1[b]	3	2	1[b]	0	1	0[b]	0	0	0[b]	0
2	2	1[b]	1	2	0[b]	0	2	0[b]	0	0	0[b]	0
3	2	1[b]	1	1	0[b]	0	0	0[b]	0	0	0[b]	0
4	2	2[b]	3	2	1[b]	1	1	1[b]	1	0	0[b]	0
5	2	1[b]	2	2	0[b]	0	1	0[b]	0	0	0[b]	0
6	2	1[b]	2	1	0[b]	0	0	0[b]	0	0	0[b]	0

[(1)] see Attachment 1 for Draize scales o=opacity a=area
r= redness c= chemosis d= discharge
b=blistering of mucous membrane

Unirrigated eyes: conjunctival irritation (scores 1 to 2) with blistering was observed in all animals; one animal exhibited diffuse areas of corneal opacity at 24 hours post-treatment; all eyes appeared normal after 72 hours;

Irrigated eyes: conjunctival irritation (scores 1 to 2) was observed in all animals and blistering in 2 animals; all eyes appeared normal after 48 hours

Test method: according to OECD guidelines (7)

Result: the notified chemical was a slight to moderate eye irritant in rabbits

9.1.6 Skin Sensitisation – Buehler Method (6)

Species/strain: guinea pig/Hartley White

Number of animals: 5/sex (test group);
3/sex (positive and vehicle control groups);
2/sex (naïve group)

Induction procedure: test animals:
based on the results of a dose range study, each animal was topically induced with 0.5g of the test substance (at 100%) moistened with 0.5 ml of acetone for 6 hours, 3 times a week for 3 weeks (3 different sites were used for the first week and the same sites were used for the next 2 weeks);

positive and vehicle control groups:
positive control group was treated with DNCB and 70% ethanol and the vehicle control group was treated with acetone;

the sites were examined and evaluated for erythema 24 and 48 hours after each application

Challenge procedure: test animals:
two weeks after the last induction application each animal was topically challenged with 0.5g of the test substance moistened with 0.5 ml of acetone; the naïve animals were also challenged with 0.5 g of the test substance;

positive and vehicle control groups:
positive control group was challenged with DNCB in 70% ethanol and the vehicle control group was challenged with acetone;

Challenge outcome:

	Test animals		***Control animals (naïve)***	
Challenge concentration	***26 hours****	***48 hours****	***26 hours***	***48 hours***
100%	1**/10	1/10	4/4	1/4

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to OECD guidelines (7)

Comment: very faint to moderate erythema was observed at challenge in all animals of the naïve group; only one animal in the treated group exhibited erythema;
the skin reaction in the treated animals did not exceed the most severe naïve control reaction, the responses therefore were not considered to be positive for sensitisation

Result: the notified chemical was not a sensitiser to the skin of guinea pigs

9.2 Repeated Dose Toxicity (9)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 12/sex (control and high dose groups);
6/sex (low and mid dose groups);
6/sex of the control group and 6/sex of the high dose group were assigned to the 14 day recovery period

Method of administration: gavage: vehicle was medical grade olive oil

Dose/Study duration: dose levels were selected from the results of a range finding study in rats

test substance administered daily for a total of 28 consecutive days:

control	0 mg/kg/day
low dose	40 mg/kg/day
mid dose	200 mg/kg/day
high dose	1 000 mg/kg/day

all but the recovery group animals were sacrificed at the end of the treatment period; recovery group animals were sacrificed after a further 14 days

Mortality: none

Food consumption/Body weight:

treatment:
a significant decrease in food consumption was observed in all dose group females; high and mid

	dose animals lost weight *recovery:* no significant changes in both males and female
Clinical observations:	no treatment related clinical signs of toxicity were noted in any of the animals throughout the study
Clinical chemistry:	*treatment:* low and mid dose males showed a decrease in alanine aminotransferase (ALT); low dose males also showed an increase in calcium whilst the mid and high dose females showed a decrease in calcium; *recovery:* high dose recovery group males showed a decrease in gamma-ALT, triglyceride and albumin
Haematology:	*treatment:* low dose group males showed an increase in the platelet count; high dose females showed a decrease in the reticulocyte ratio; *recovery:* high dose recovery group females showed a decrease in the lymphocytic ratio
Histopathology:	*treatment:* one high dose male showed a blackish area of the mucosa of the cardiac stomach and necrosis of the stomach mucosa; *recovery:* no abnormalities were noted in recovery group males
Organ weights:	in high and mid dose females a decrease in absolute kidney weights were noted after the treatment phase
Test method:	similar to OECD guidelines (7)
Result:	the notified chemical did not exhibit any significant organ toxicity in females and exhibited no signs of overt toxicity in males; in high dose recovery group males, haematology and clinical chemistry changes were not severe and not dose related; abnormalities observed in the cardiac stomach of one high dose male could be attributed to hypersensitivity in the

	absence of similar findings in any other animals
	the no-observable effect level (NOEL) for this 28-day rat study of the notified chemical in female rats is 40 mg/kg/day; a NOEL could not be determined for males

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (10)

Strains:	*Salmonella typhimurium* TA 1537, TA 1535, TA 1538, TA 100 and TA 98; (in the second experiment TA 1538 was substituted for *Escherichia coli* WP2 *uvrA*)
Metabolic activation system	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration range:	the assay was performed in two independent experiments with or without metabolic activation; the test substance and controls were tested in triplicate in the first experiment at concentrations of: 667, 1 000, 3 333, 6 667 and 10 000 µg/plate; in the second experiment at concentrations of 313, 625, 1 250, 2 500 and 5 000 µg/plate
Test method:	similar to OECD guidelines (7)
Comment:	there were no significant increases in revertant colony numbers at any dose level, with or without metabolic activation;
Result:	the notified chemical is not considered to be mutagenic in bacteria.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (11)

Species/strain:	mice/ICR
Number and sex of animals:	5/sex;13 groups
Doses:	1 250, 2 500, 5 000 mg/kg; cyclophosphamide as positive control and corn oil as negative control
Method of administration:	intraperitonal injection;

Test method:	similar to OECD guidelines (7)
Result:	no reduction in the ratio of polychromatic erythrocytes or significant increase in polychromatic erythrocytes were observed at any dose level when observed at 24, 48 and 72 hour time points

9.3.3 Chromosomal Aberration Assay in Chinese Hamster Lung Fibroblast Cells (12)

Cells:	Chinese Hamster Lung Fibroblast Cells
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Dosing schedule:	without metabolic activation: 1 250, 2 500 and 5 000 µg/mL treatment time = 24 or 48 hours, harvest time = 18 hours with metabolic activation: 1 250, 2 500 and 5 000 µg/mL treatment time = 6 hours, harvest time = 18 hours all tests carried out in triplicate
Test method:	similar to OECD guidelines (7)
Result:	the notified chemical was not considered to be clastogenic under the conditions of this chromosomal aberration test

9.4 Overall Assessment of Toxicological Data

The notified chemical had very low acute oral toxicity (LD_{50} > 5 000 mg/kg) and low dermal toxicity (LD_{50} = 2 000 mg/kg) in rats. In an acute inhalation study in rats, the LC_{50} was greater than 0.337 mg/L, the maximum attainable concentration in this test. In this study the particles were of respirable size (mass median equivalent aerodynamic diameter of 4.4 µm). The notified chemical was a slight to moderate eye irritant in rabbits and a non-irritant and non-sensitiser to skin of rabbits and guinea pigs, respectively.

In a 28 day repeat oral dose study, the notified chemical exhibited no signs of oral toxicity in males. Changes in haematology and clinical chemistry parameters were seen at all treatment doses in males. A NOEL was not achievable in males. A NOEL of 40 mg/kg/day for female rats was determined.

The notified chemical was not mutagenic *in vitro* in studies using bacteria or mammalian cell lines or *in vivo* in the mouse micronucleus assay.

Based on the data submitted the notified chemical would not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (13).

It should be noted that the LC_{50} value given for the acute inhalation study represents the maximum attainable aerosol concentration for this study. A true lethal concentration could not be determined because of constraints in generating a dust concentration greater than 0.377 mg/L. No systemic toxicity was observed at 0.377 mg/L, although it is unknown whether a higher concentration could have elicited toxic effects or mortality.

The LC_{50} value falls within the classification limits of the Approved Criteria for acute inhalation toxicity. However, these criteria are based on the tenet that lethality is required in 50% of animals during the test period. In the case of this study no mortality occurred, and in the absence of data to the contrary, for classification purposes the notified chemical cannot be classified hazardous for this toxicological end point.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD Test Methods.

Species	*Test*	*Concentrations[a] (mg/L)*	*Result (mg/L)*	*Reference*
Rainbow trout *(Oncorhynchus mykiss)*	96 h static acute	0, 0.32, 1.0, 3.2	LC_{50} > 3.2 NOEC = 3.2	(14)
Bluegill Sunfish (*Lepomis macrochirus*)	96 h static acute	0, 0.32, 1.0, 3.2	LC_{50} > 3.2 NOEC = 3.2	(15)
Water Flea (*Daphnia magna*)	48 h static acute	0, 0.1, 1.0, 10	EC_{50} > 10 NOEC = 1.0	(16)
Algae (*Selenastrum capricornutum*)	72 h growth	0, 100	$E_R C_{50} \geq 56^b$ $E_B C_{50} \geq 56^b$ NOEC $\geq 56^b$	(17)
Activated Sludge	3 h Respiration inhibition	0, 100	EC_{50} > 100 NOEC = 100	(18)

[a]Nominal concentrations. [b]Mean measured concentration.

In the fish studies, a small amount of dimethylformamide (DMF) was used to dissolve the test material initially. Over the course of the test, precipitate was observed in both the 1.0 and 3.2 mg/L test media in both studies. No mortalities or other sublethal effects were observed in either study.

In the daphnid study, the test concentrations were prepared by making standard solutions of the chemical in acetone and adding aliquots of the standard solutions to the test media to give the final concentrations. Precipitate was observed in all three test concentrations. A single mortality was observed at the highest concentration with no sublethal effects observed.

During the algal study, the concentration of the test material was measured for both filtered and unfiltered samples of the test media. For the unfiltered samples, the level of test material remained stable between 52-60% of the nominal concentrations, giving a mean measured concentration of 56 mg/L. The concentration of the chemical in the filtered samples was below the quantification limit of 0.05 mg/L. No significant reduction was found in either the average specific growth rates or the biomass values, compared to the solvent control.

The notified chemical had no inhibitory effect on the respiration rate of activated sludge at the concentration used in the study.

The ecotoxicity data for the notified chemical indicate that chemical is not toxic to aquatic organisms up to the limit of its water solubility and is practically non-toxic to activated sludge.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as a light stabiliser for plastics. Once incorporated into these products the notified chemical is expected to remain within the product matrix. Hence, the majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the product matrix.

Waste from empty containers (total 20 kg per annum) and product manufacturing processes (~30 kg per annum) will be disposed of to landfill. Waste is expected to be immobile, due to the chemical's low water solubility.

Hence, the overall environmental hazard of the chemical can be rated as low, given the low environmental exposure.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical had very low acute oral toxicity (LD_{50} > 5 000 mg/kg) and low dermal toxicity (LD_{50} = 2 000 mg/kg) in rats. In an acute inhalation study in rats, there was no mortality and the LC_{50} was greater than 0.337 mg/L, the maximum attainable concentration in this test. The notified chemical was a slight to moderate eye irritant in rabbits and a non-irritant and non-sensitiser to skin of rabbits and guinea pigs, respectively. In a 28 day repeat oral dose study, the notified chemical exhibited no signs of oral toxicity in males. Changes in haematology and clinical chemistry parameters were seen at all treatment doses in males. A NOEL was not achievable in males. A NOEL of 40 mg/kg/day for female rats was determined. The notified chemical was not mutagenic *in vitro* or *in vivo*. Based on the data submitted the notified chemical would not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (13).

Occupational Health and Safety

During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

Exposure may occur to the notified chemical during initial blending and during masterbatching. There is potential for ocular contact and inhalation exposure to the dust form of the notified

chemical during loading of the feed hopper and changing of filter bags. Should dermal, ocular, contact or inhalation exposure occur, the notified chemical is unlikely to cause acute systemic toxicity. However, it may cause slight to moderate eye irritation. Of particular concern would be respiratory irritation, given the particle size of the notified chemical is within the respirable range, that is less than 7 µm. Therefore, respiratory and ocular exposure should be controlled and workers must be attired with safety glasses, gloves, head covering, respiratory protection and overalls as stipulated under Recommendations, see section 13.

General ventilation in the loading area, local exhaust ventilation over the hopper and the door to the hopper should control exposure to the notified chemical.

The notifier states that the workers will receive education and training on safe use of dust products and preventive controls. This in combination with engineering controls, a predominantly closed system, and personal protective equipment will control exposure to the notified chemical and consequently any adverse health effects.

Minimal exposure to the notified chemical may occur following extrusion of the notified chemical into its encapsulated form and workers must be attired with safety glasses, head covering, respiratory protection. However, the notified chemical is not likely to pose an occupational health risk to workers, because it is incorporated within the resin solids and unavailable for separate exposure and uptake through the skin.

The notified chemical is of respirable particle size. To avoid adverse health effects of high concentrations of dust in the workplace, good hygiene practices should be adopted to minimise airborne dust levels. Exposure to the dust in the workplace should be controlled below the NOHSC exposure standard for Dusts, not otherwise classified, 10 mg/m^3 TWA (measured as inspirable fraction)(19). Because of the respirable particle size of the notified chemical, the ACGIH respirable particulate threshold limit value (TLV) of 3 mg/m^3 can be used as guidance for the control of respirable dust in the workplace. Employers are responsible for ensuring the exposure standard is not exceeded. It is recommended that MSDS and labels for the notified chemical carry the safety phrase – avoid breathing dust.

It should also be noted that the potential for dust explosion exists when handling the notified chemical in the powdered form. The notifiers MSDS provides advice on safe storage and handling.

The notifier has not provided any details of the process involved during end use application of the resin solids containing the notified chemical. Limited exposure to the notified chemical is expected as it will be incorporated into the solids during these processes.

The notified chemical will not be sold to the general public. Although the members of the public will make dermal contact with products (eg plastic moulded forms; painted surface on automotives) containing the notified chemical, exposure will be negligible because of the low concentration (final concentration 1 to 5%), and the encapsulated form of the notified chemical in the final products from which the notified chemical is not expected to leach.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety glasses should be selected and fitted in accordance with Australian Standard (AS) 1336 (20) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (21);
- Respiratory protection should be selected and fitted in accordance with AS/NZS 1715 (22) to comply with AS/NZS 1716 (23);
- Industrial clothing should conform to the specifications detailed in AS 2919 (24) and AS 3765.1 (25);
- Impermeable gloves or mittens should conform to AS 2161 (26);
- All occupational footwear should conform to AS/NZS 2210 (27);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

Because the notified chemical is of respirable particle size, the MSDS and labels should carry the safety phrase – avoid breathing dust.

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* (28).

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

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Laveglia J. 1988, *Acute Oral Toxicity Study in the Rat with Cyosarb UV-1164,* Project no., 88.0079.017, Food and Drug Research Laboratories, New York, USA.

2. Lavegila J. 1988, *Acute Dermal Toxicity Study in the Rabbit with Cyosarb UV-1164,* Project no., 88.0079.018, Food and Drug Research Laboratories, New York, USA.

3. Phillips R. 1992, *Acute Inhalation Toxicity Study in the Rat with Cyosarb UV-1164,* Project no., 104616, Exxon Biomedical Science Inc., New Jersey, USA.

4. Lavegila J. 1988, *Acute Dermal Irritation Study in the Rabbit with Cyosarb UV-1164,* Project no., 88.0079.018, Food and Drug Research Laboratories, New York, USA.

5. Lavegila J. 1988, *Acute Eye irritation Irritation Study in the Rabbit with Cyosarb UV-1164,* Project no., 88.0079.019, Food and Drug Research Laboratories, New York, USA.

6. Lavegila J. 1988, *Dermal Sensitisation in the Guines Pig with Cyosarb UV-1164,* Project no., 88.0079.020, Food and Drug Research Laboratories, New York, USA.

7. Organisation for Economic Co-operation and Development 1995-1996, OECD Guidelines for the Testing of Chemicals on CD-Rom, OECD, Paris.

8. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* 49.

9. Kenkyusho H. 1990, *Repeat Dose Oral Toxicity Study in the Rat with Cyosarb UV-1164,* Project no., 015038-01, Kagakuhin Anzen Center, Kagakuhin Kensa Kyokai Foundation, Japan.

10. Lawlor T.E. 1988*, Microbial Mutagenesis in Salmoella Mammalian Microsome Plate Incorporation Assay with Cyosarb UV-1164,* Project no., T5900.501015 Microbiological Associates, Inc. Rockville, MD. USA

11. Putman D.L. 1992*, Micronucleus Cytogenetic Assay in Mice with Cyosarb UV-1164,* Project no., T50590.122 Microbiological Associates, Inc. Rockville, MD. USA

12. Kajiwara Y. 1990, Chromosomal Aberration Assay in Chinese Hamster Lung Fibroblast Cells with Cyosarb UV-1164, Project no. K06-0149, Society for Tests on Chemicals, Center for Safety on Chemicals, Hida Laboratory, Japan

12. Edwards C.N. 1997, Cytogenetic Study in Cultured Chinese Hamster Lung Cells with Cerium sulphide, Project no., RNP505/970007, Huntingdon Life Sciences Ltd., Cambridgeshire England.

13. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)],* Australian Government Publishing Service, Canberra.

14. Sword (1991a) Acute toxicity of CT-483-91 to Rainbow Trout (*Oncorhynchus mykiss*). Report No. 39583, Aquatic Toxicology Division, ABC Laboratories, Colombia, Missouri, United States. Unpublished.

15. Sword (1991b) Acute toxicity of CT-483-91 to Bluegill (*Lepomis macrochirus*). Report No. 39584, Aquatic Toxicology Division, ABC Laboratories, Colombia, Missouri, United States. Unpublished.

16. England DC and Muckerman JG (1991) Acute toxicity of CT-483-91 to *Daphnia magna*. Report No. #39582, Aquatic Toxicology Division, ABC Laboratories, Colombia, Missouri, United States. Unpublished.

17. Jenkins CA (1996a) Cyagard® UV-1164: Determination of 72-hour EC50 to *Selenastrum capricornutum*. Report No. 96/CDU001/1025, Schedule No. CDU/001, Huntington Life Sciences Ltd, Eye, Suffolk, England. Unpublished.

18. Jenkins CA (1996b) Cyagard® UV-1164: Activated sludge – Respiration inhibition test. Report No. 96/CDU002/1006, Schedule No. CDU/002, Huntington Life Sciences Ltd, Eye, Suffolk, England. Unpublished.

19. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment', [NOHSC:1003(1995)], in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service Publ., Canberra.

20. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

21. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

22. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

23. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

24. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing,* Standards Association of Australia, Sydney.

25. Standards Australia 1990, Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals, Standards Association of Australia Publ., Sydney.

26. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia, Sydney.

27. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear,* Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

28. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)],* Australian Government Publishing Service, Canberra.

Attachment 1

The Draize Scale 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 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