File No: NA/686

June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Cyasorb ®UV-3529

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 Aged Care.

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 this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9514 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Cyasorb ®UV-3529

1. APPLICANT

Cytec Australia Holdings Pty Ltd of 7-11 Railway Street BAULKHAM HILLS NSW has submitted a limited notification statement in support of their application for an assessment certificate for Cyasorb ®UV-3529.

2. IDENTITY OF THE CHEMICAL

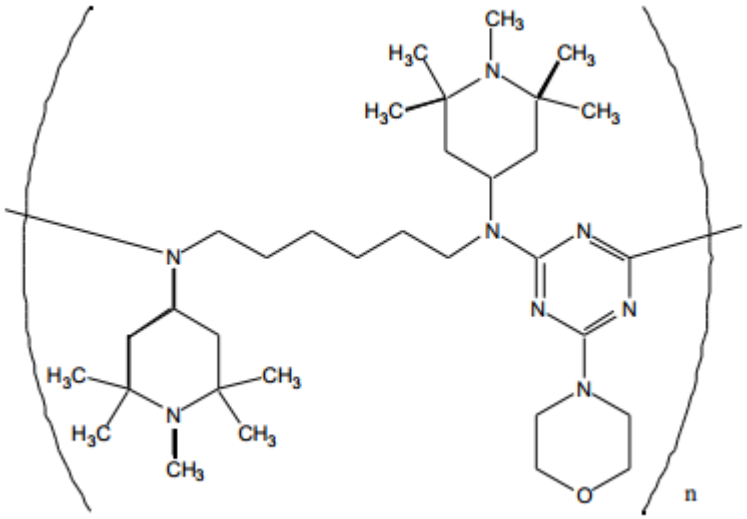
Chemical Name: 1,6-Hexanediamine, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated

Chemical Abstracts Service (CAS) Registry No.: 193098-40-7

Trade Name: Cyasorb® UV-3529 Light Stabiliser (contains approximately 95% Cyasorb ®UV-3529)

Molecular Formula: $(C_{33}H_{58}N_8O)_n$

Structural Formula:



Number-Average Molecular Weight (NAMW): 1 750

Weight-Average Molecular Weight: 3 120

Polydispersity: 1.8

Maximum Percentage of Low Molecular Weight Species
Molecular Weight < 500: 1.7%
Molecular Weight < 1 000: 14.7%

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
Monomer A:		
2,4,6-Trichloro-1,3,5-triazine	108-77-0	36
Morpholine	110-91-8	30
Monomer B:		
N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)-1,6-hexanediamine	61260-55-7	68
Post reactants:		
Paraformaldehyde	30525-89-4	16
Formic acid	64-18-6	23

Method of Detection and Determination: Infrared (IR) specturm; Nuclear Magnetic Resonance (NMR)

Spectral Data: an IR spectrum with major absorbance peaks at 2 965, 2 370, 1 541, 1 475, 1 428, 1 363, 1 320, 1 261, 1 217 and 1 118/cm and NMR data were provided for the characterisation and identification of the notified polymer

Comments on Chemical Identity

A proton NMR spectrum, an infrared spectrum and a GPC trace were submitted for the identification of the notified substance.

The formation of Cyasorb UV-3529 involves a three-step process. This involves the reaction of oligomers to form the unmethylated polymer chain, UV-3346 (the structural analogue of the notified polymer) and the methylation of secondary amine groups in a reaction involving paraformaldehyde and formic acid. The notifier claims that there is no more than 0.06wt% of un-methylated amine groups in the final product.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	pale amber solid pastilles, odourless
Melting Point:	91 - 115°C
Specific Gravity:	1.096
Particle size:	99.6% >500 μm
Vapour Pressure:	5.5×10^{-12} kPa at 20°C
Water Solubility:	0.61 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 4.49 at 21.5°C
Hydrolysis as a Function of pH:	half life > 1 year
Adsorption/Desorption:	not determined – see comments below
Dissociation Constant:	not determined – see comments below
Flammability Limits:	non flammable
Autoignition Temperature:	non self-igniting
Explosive Properties:	non explosive
Reactivity/Stability:	non oxidising

Comments on Physico-Chemical Properties

The above tests were conducted according to the EEC Methods for the Determination of Physico-Chemical Properties (European Economic Community (EEC), 1992) and the OECD Guidelines for Testing of Chemicals (Organisation for Economic Co-operation and

Development, 1992). The tests were performed on Cyasorb UV-3529 Light Stabiliser which contains 95% Cyasorb UV-3529.

The polymer exhibits a glass transition from 91-115°C, with decomposition above 235°C. According to the measured vapour pressure, the chemical was slightly volatile based on the Mensinck scale (Mensinck et al, 1995).

The results of the extended test for hydrolysis as a function of pH indicated that at both pH 4 and 7 at 25°C the polymer will possess a half-life of greater than 1 year.

Results for adsorption/desorption and dissociation constant were not determined because of the low water solubility. The notifier expects the polymer to adsorb strongly to organic matter in the soil because of the relatively high log P_{ow}.

Presumably at least some of the neutral amine groups would be protonated when in water. A polycationic charged species would then be expected to predominate leading to an increase in the water solubility and decrease of the log P_{ow}.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 95%

Toxic or Hazardous Impurities:

Chemical Name	*CAS No.*	*Weight %*
Toluene	108-88-3	0.5
Sodium hydroxide	1310-73-2	0.3
Methanol	67-56-1	0.2

Non-hazardous Impurities:

Chemical Name	*CAS No.*	*Weight %*
2,4,6-Tri-4-morpholinyl-1,3,5-triazine	16303-23-4	3
Sodium formate	141-53-7	0.3
2,4-Dichloro-6(4-morpholinyl)-1,3,5-triazine	6601-22-5	0.1
Sodium chloride	7647-14-5	0.3

Additives/Adjuvants: none

Loss of Monomers, Additives, Impurities: none expected

5. USE, VOLUME AND FORMULATION

The notified polymer, Cyasorb UV-3529, will not be manufactured in Australia. It will be imported in 20 kg packs of plastic liners within a fibreboard carton, as a component of Cyasorb UV-3529 Light Stabiliser containing 95% of the notified polymer. The notified polymer will be used in film or laminated woven products for agricultural greenhouse covers. The end use products will contain approximately 0.5 – 1.0% of the notified polymer.

Approximately 20 tonnes of the notified polymer will be imported per year in the first five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer, Cyasorb®UV-3529, will be imported as a component of a product called Cyasorb®UV-3529 Light Stabiliser. Cyasorb®UV-3529 Light Stabiliser will contain 95% of the notified polymer. The product comes in a solid pastille anti-dusting form in 20 kg packs in plastic liners within a fibreboard carton. The product will be compounded with other ingredients in an extrusion process to form compounded plastic pellets containing 10 to 20 % of the notified polymer. The plastic pellets will be sold to customers for the production of plastic products such as greenhouse covers. The plastic products would contain approximately 0.5 to 1.0 % by weight of the notified polymer.

During importation and reformulation of the pastilles containing the notified polymer, the number and categories of workers with potential exposure to the notified are as follows: waterside, transport and warehouse (5-10 personnel) and production (5-10 personnel). Waterside, transport and warehouse workers would not be exposed to the notified polymer under normal circumstances, as they will be handling only the sealed packages.

Formulation of masterbatch pellet

During reformulation, the pastilles containing the notified polymer will be compounded with other raw materials to form compounded plastic pellets known as masterbatch. The compounding process involves weighing of the notified polymer using an aluminum scoop and transferring the requisite amount into plastic bags. The plastic pellets and other ingredients are transferred into a mixer. The mixer is sealed during mixing. After mixing, the extruder operator releases the mixture from the sealed dispenser into the extruder. In the extruder, the mixture is melted and mixed further. The melted mixture is extruded through die holes in long spaghetti-like strings, and passes through a cooling water bath into a pelletiser and classifier. The masterbatch pellets are stored in a hopper ready for bagging. A quality control technician scoops a portion of the masterbatch pellets into a sample container and tests the quality of the pellets. Following quality control testing, a packaging operator will bag the masterbatch into a 25 kg capacity woven laminated plastic bags, ready for distribution to customers.

All of the workers involved in the production of masterbatch pellets will wear personal protective equipment including dust masks, gloves and overalls to minimise potential dermal and inhalation exposure to the notified polymer. Workers involved in weighing will also wear safety glasses in addition to the above protective equipment, to prevent eye contact. Dust extraction is employed at the weighing area to minimise inhalation exposure to the notified polymer. The extruder loading area is also fitted with local exhaust ventilation. The laboratory technician will wear protective clothing such as laboratory coat, safety glasses and gloves when carrying quality control tests.

Formulation of plastic products

At the customer site, the masterbatch pellet will be re-extruded using similar extrusion processes described above, to form plastic products, such as agricultural greenhouse covers. The notifier provided no other details on the mechanisms involved in incorporating the masterbatch pellets into the plastic products. Since the notified polymer is encapsulated in the masterbatch pellets, it is expected that worker exposure to the notified polymer during incorporation with plastic products will be unlikely.

7. PUBLIC EXPOSURE

The exposure of the general public to the notified polymer during transport, storage, processing and use is expected to be low. Although the public will make dermal contact with plastic products containing the notified polymer, exposure is expected to be negligible because of the low concentration of the notified polymer in the plastic products. In addition, the notified polymer is encapsulated and is not expected to leach from the plastic products. Plastic products containing the notified polymer will not be used in food and water containers.

If accident occurs, spills are to be swept up and disposed of according to state and local regulations and should not be allowed to enter waterways. Thermal decomposition may release carbon and nitrogen oxides and the use of self-contained breathing apparatus is recommended.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier estimates that during compounding of the masterbatch pellets, up to 5% of the product containing the notified polymer will be wasted (approximately 2% residual water in containers and 3% lost in spills and production waste). Spilled material (in a pellet form) can be collected and disposed of to landfill as industrial waste. Hence, up to 1 tonne will be disposed to landfill from this type of release.

The notified polymer will be fully encapsulated within the masterbatch pellets so environmental exposure will be minimal. For each use of masterbatch (containing 0.5-1.0% Cyasorb UV-3529 Light Stabiliser), it is estimated that 1-2 % (380 kg) will be wasted in spills or production loss. Again, spilled material should easily be swept up and disposed of to landfill.

Fate

It is expected that agricultural greenhouse covers may be re-used on the agricultural property for other applications. Alternatively, they may be disposed of to commercial plastic recyclers. The notified polymer is expected not to be degraded during the recycling process and may be used to manufacture items such as plastic pallets or outdoor furniture. Since there are no recycling centres in rural areas, the notifier expects that eventually most of the agricultural greenhouse covers will be disposed of to landfill in rural and metropolitan areas.

In the event of accidental spillage of the chemical into waterways, the chemical is not expected to disperse into the water, but will settle out onto sediments. If the chemical is spilt on land, either during usage or transport, it is expected that the chemical would become immobilised in the soil layer. The chemical and any contaminated soil can be collected and disposed to landfill.

The degree of biodegradability of the product containing the notified polymer was determined by a CO_2 Evolution Test (Organisation for Economic Co-operation and Development, 1992). Cyasorb UV-3529 Light Stabiliser was added to two cultures of sewage sludge to give nominal concentrations of 10 mg carbon/L and assessed for the evolution of CO_2 over a 29 day period. There was no CO_2 released over the test period and no significant degradation of Cyasorb UV-3529 occurred. Hence, under the conditions of the study, Cyasorb UV-3529 was not readily biodegradable. Based on these studies, it is expected that the chemical will be stable within the landfill environment and it is not expected to leach into groundwater.

The low biodegradability of the polymer would suggest potential for bioaccumulation. However, the notified polymer has a large molecular size and low water solubility. These properties together with the relatively low exposure due to its incorporation in the plastic products will reduce the quantity of notified substance eventually released to the aquatic environment and will limit the potential for bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The tests were conducted in compliance with the EEC Methods for the Determination of Toxicity (European Economic Community, 1992) and the OECD Guidelines for Testing of Chemicals (Organisation for Economic Co-operation and Development, 1992). Unless otherwise indicated, the studies have been conducted on Cyasorb UV-3529 Light Stabiliser containing 95% of the notified polymer.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >500 mg/kg	(McRae, 1996b)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(McRae, 1996a)
acute inhalation toxicity*	rat (males) (females)	LC_{50} 2.91 mg/L LC_{50} 2.79 mg/L	(Biesemeier, 1982)
skin irritation	rabbit	non-irritant	(Parcell, 1996b)
eye irritation	rabbit	slight irritant	(Parcell, 1996a)
skin sensitisation	guinea pig	non-sensitiser	(Liggett, 1996)

*data from analogue chemical - UV-3346

9.1.1 Oral Toxicity (McRae, 1996b)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Dose:	500 mg/kg
Method of administration:	10 mL/kg of 5% w/v test material in 1% w/v aqueous methylcellulose administered by gavage
Test method:	OECD TG 401
Clinical observations:	all animals had piloerection, hunched posture and soft to liquid faeces; in addition, one female was walking on toes and had a waddling gait; all animals recovered by day 4
Mortality:	nil
Morphological findings:	none
LD_{50}:	> 500 mg/kg
Result:	the notified polymer was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (McRae, 1996a)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 g/kg of test substance at 77.77% w/v in physiological saline administered by topical application and held under semi-occlusive dressing; after 24 hours, the treated area was washed with warm water and blotted dry with absorbent paper
Test method:	OECD TG 402
Clinical observations:	no signs of systemic toxicity; slightly lower body weight gain was noted in all males and 2 females compared with historical control data at the end of the study
Dermal response:	transient slight dermal irritation (erythema only) in one female on removal of dressing; dermal irritation resolved by day 3
Mortality:	nil
Morphological findings:	none
LD_{50}:	> 2 000 mg/kg
Result:	the notified polymer was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity (Biesemeier, 1982)

Species/strain:	rat/Sprague-Dawley CD

	Test material (analogue)	
	UV-3346 Lot R9860-89	**UV-3346 Lot R9860-90**
Number/sex of animals:		
test group:	5/sex/group	5/sex/group
control group:	5/sex	5/sex

Dose:		
actual mean achieved:	0.0, 1.83 and 5.14 mg/L	0.0, 2.04 and 3.94 mg/L
nominal concentration:	0.0, 7.22 and 19.55 mg/L	0.0, 7.53 and 14.30 mg/L

Particle size distribution:

10.1 – 4.1μ = 4.87% ± 2.35
4.0 – 2.6μ = 7.00% ± 2.02
2.5 – 0.6μ = 6.47% ± 0.89
0.5 – 0.28μ = 5.23% ± 0.59
<0.28μ = 5.66% ± 1.05

Observation period: 14 days

Method of administration: whole body exposure for 4 hours by NBS Dust Feeder

Test method: OECD TG 403

Clinical observations:

UV-3346 Lot R9860-89
animals exposed at 1.83 mg/L of air showed occasional shallow and rapid respirations, blood coloured nasal discharge, lacrimation and piloerection during exposure; moderate eye and nasal irritation, in addition to exophthalmos were observed towards the end of exposure period; physical condition of animals was evaluated as poor at the end of the study

similar effects as above were observed in animals exposed at 5.14 mg/L of air except that earlier onset and longer duration of effects were observed; laboured respirations with gasping, oedematous and closed eye with blood coloured lacrimation, inflamed facial areas and extremities and excessive salivation and nasal discharge were observed post exposure; in addition, hypersensitive to touch, unkempt and anorexia were observed 24 hours post exposure

	UV-3346 Lot R9860-89	**UV-3346 Lot R9860-90**
Mortality	0.0 mg/L = nil 1.83 mg/L = 1 (Male,M); 2 (Females, F) 2.04 mg/L = 2 (M); 2 (F) 3.94 mg/L = 4 (M); 3 (F) 5.14 mg/L = 4 (M); 4 (F)	0.0 mg/L = nil 2.62 mg/L = 2 (M); 2(F) 3.89 mg/L = 3 (M); 3 (F)

Morphological findings:	animals found dead during study typically exhibited congested lungs; no treatment related findings observed in terminally sacrificed animals.
Comment:	dose-related mortality was observed
LC_{50}:	2.79 mg/L/4 hr (F); 2.91 mg/L/4hr (M)
Result:	the notified polymer was of low acute inhalation toxicity in rats

9.1.4 Skin Irritation (Parcell, 1996b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/females
Observation period:	4 days
Method of administration:	0.5 g of test substance moistened with 0.5 mL saline was applied to shaved test site and held under semi-occlusive dressing; after 4 hours the treatment site was washed with warm water; test sites were examined for evidence of irritation and graded at approximately 1, 24, 48 and 72 hours after treatment
Test method:	OECD TG 404; Annex 5 92/69/EEC

9.1.5 Eye Irritation (Parcell, 1996a)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	4/males
Observation period:	7 days
Method of administration:	all animals received 75 mg (equivalent to 0.1 mL) of test substance as supplied instilled into the lower everted lid of one eye, eyelids were held together for one second; the contralateral eye served as the control; treated eyes were examined for irritation and graded after 1, 24, 48 and 72 hours, and 4 and 7 days after instillation

Study design: the study was conducted in two stages as follows:

preliminary investigation:
one animal was treated in advance and the treated eye was rinsed with water 30 second after instillation (screen animal)

main investigation:
another animal was treated in advance without rinsing the treated eye after instillation (pilot animal); the remaining two animals were treated identically

Test method: OECD TG 405; Annex 5 92/69/EEC

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***		***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea[(1)]	***o***		***o***		***o***		***o***		***o***		***o***	
1*	0		0		0		0		0		0	
2#	0		0		0		0		0		0	
3	0		0		0		0		0		0	
4	0		0		0		0		0		0	
Iris												
1*	0		0		0		0		0		0	
2#	0		0		0		0		0		0	
3	0		0		0		0		0		0	
4	0		0		0		0		0		0	
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1*	1	0	1	0	0	0	0	0	0	0	0	0
2#	1	1	2	0	1	0	1	0	0	0	0	0
3	1	1	0	0	0	0	0	0	0	0	0	0
4	1	0	1	0	1	0	0	0	0	0	0	0

(1) see Attachment 1 for Draize scales
o = opacity r = redness c = chemosis D = dulling of the cornea
* screen animal (irrigated eyes)
# pilot animal

Comments:	no corneal opacity or iris inflammation observed; slight to diffuse reddening of the conjunctiva observed in 3 animals; all animals recovered by day 4
Result:	the notified polymer was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Liggett, 1996)

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	30 males: 20 test, 10 control

Induction procedure:

test group: day 0	*Intradermal induction* 3 pairs of intradermal injection (0.1 mL) into the scapular region of 20 animals: a) Freund's complete adjuvant (FCA) and water for irrigation (50:50) b) 0.5% (w/v) test substance in Alembicol D c) 0.5% (w/v) test substance in a 50:50 mix of FCA and Alembicol D injection sites were examined at 24 and 48 hours post injection
day 7	*Topical induction* filter paper saturated with 0.4 mL of 70% test substance (w/v) in Alembicol D was applied to the treated area and held under occlusive dressing for 48 hours test sites were examined at 24 and 48 hours after removal of occlusive dressing
control group:	control animals were treated identically to the test animals but omitting the test substance from the intradermal injection and topical application

Challenge procedure:

day 21 (first challenge)	0.2 mL of 25 and 50% (w/v) test substance in Alembicol D was applied to the posterior and anterior site of the treated animal, respectively; the filter paper containing the test substance was held in place by occlusive dressing for 24 hours; test sites were examined at 24, 48 and 72 hours after test substance application
day 28 (second challenge)	same as above, except 5 and 10% (w/v) test substance in Alembicol D was applied to the right flank

Test method:	OECD TG 406; Annex 5 92/69/EEC ; Magnusson and Kligman-Guinea Pig Maximisation Test
Comments: Induction	*Intradermal induction:* necrosis was recorded in test and control animals receiving FCA; slight irritation was observed in test animals receiving 0.5% (w/v) test substance in Alembicol D and control animals receiving only Alembicol D *Topical application* moderate erythema was observed in test animals receiving 70% (w/v) test substance in Alembicol D; slight erythema was observed in control animals;
1st challenge	irritation observed in animals treated with 25 and 50% (w/v) test substances in Alembicol D precluded meaningful assessment of evidence of sensitisation;
2nd challenge	no dermal reactions were noted following the second challenge using lower concentrations (5 and 10% (w/v)) of test substance in Alembicol D.
Result:	the notified polymer was not sensitising to guinea pig skin

9.2 Repeated Dose Toxicity (Chambers, 1998)

28 day Repeat-Dose Study

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex/dose group
Method of administration:	gavage; vehicle was 1% methylcellulose
Dose/Study design:	10 ml of test substance administered daily for 28 consecutive days (20 consecutive days for group receiving 300 mg/kg/day) 0 mg/kg/day (vehicle control) 0 mg/kg/day (recovery vehicle control) 15 mg/kg/day (low dose) 150 mg/kg/day (mid dose) 300 mg/kg/day (high dose) 300 mg/kg/day (high dose recovery)

recovery group animals were maintained for a further 14 days untreated and then killed

Test method: OECD TG 407

Mortality:

Because of clinical signs (see below), one male of the high dose group was euthanised on day 18. On day 20 all remaining animals of the high dose group were also euthanised and blood samples taken.

All the animals allocated to the high dose and control recovery groups commenced their 14 day recovery period from this point, in order to allow the recovery from treatment to be investigated among the surviving high dose recovery animals.

Clinical observations:

<u>High and Mid dose animals</u>
In the high dose group, salivation occurred in most animals from week one of dosing. One male was terminated on day 18 and all remaining animals were terminated on day 20 due to poor and deteriorating clinical condition. The animals showed piloerection, poor grooming, lack of muscle tone, hunched posture, swollen abdomen, prominent vertebrae, partially closed eyes, urogenital staining and walking on toes. Behavioural changes associated with systemic toxicity, such as altered appearance, staining, hair loss and low activity counts, were also observed.

Similar effects were observed in the mid dose group. Brown staining around the mouth and a wet coat were also noted in most animals after dosing.

The body weight gain and the mean food consumption of animals in the high and mid dose group were significantly reduced compared with the control group. These reductions were associated with impaired food utilisation.

<u>Low dose animals</u>
No treatment-related toxicity was observed. The body weight gain, food consumption and food utilisation was comparable with the control group.

<u>Recovery animals</u>
During recovery, body weight gain increased compared with the control group. However, the actual body weights were lower compared with the control body weights over the recovery period.

Haematology:

High dose animals

Early kill of the high dose animals precluded statistical assessment of haematology data. A general assessment of the parameters compared with historical control data showed increases in all white blood cell (WBC) parameters (eosinophils, basophils, neutrophils and large unstained cells), except lymphocytes and platelets. Total WBC values were decreased in males but not in females. The packed cell volume (PCV) was raised, accompanied by a lowering of the mean corpuscular haemoglobin concentration (MCHC) in both sexes and raising of mean corpuscular volume (MCV) in females only.

Low and Mid dose animals

The PCV of animals in the mid dose group was slightly increased while the activated partial thrombin time (APTT) was significantly decreased in males and females but of statistical significance in male animals only. The WBC parameters were generally increased except for lymphocytes and basophils when compared with the control group.

Recovery animals

After the recovery period (day 15), significantly reduced PCV values and hemoglobin were recorded. In males, the red blood cell count was also significantly reduced. Eosinophil and lymphocyte levels of both sexes were comparable with controls, indicating recovery.

Clinical chemistry:

High dose animals

Early kill of the high dose animals precluded statistical assessment of clinical chemistry data. In general, the chemistry parameters when compared with historical control data, revealed higher alanine amino-transferase (ALT), aspartate amino-transferase (AST), glucose, potassium and phosphorus levels in both sexes. Increased, although slight, sodium, calcium, creatinine and trigycerides levels were also observed. Total protein, albumin and cholesterol levels were slightly reduced for both sexes.

Low and Mid dose animals

Lower total protein and albumin levels were recorded for both sexes of the mid dose group. The albumin/globulin ratio and cholesterol levels were slightly reduced and in females, phosphorus levels were slightly higher, however, all values were within the historical control data.

In males, alkaline phosphatase (ALP) levels were decreased in the mid and low dose groups and the chloride levels were increased slightly in the mid dose group. However, these observations were not considered to be of toxicological significance, as all the values were within the historical control data and similar findings were not observed among females of these groups or in animals of the high dose group.

Recovery animals
A significant reduction in total protein and albumin values and a slight reduction in cholesterol levels was observed at the end of the recovery period.

Urinalysis:

High dose animals
No urinalysis performed due to early termination.

Mid dose animals
Decreased urinary volume was recorded in both sexes, although only obtaining statistical significance in males. This was associated with a decrease in the group mean urinary pH values and slight increase in urinary specific gravity (although only obtaining statistical significance in males) for both sexes.

Recovery animals
No remarkable differences.

Organ weights:

High dose animals
Early termination precluded statistical assessment of the organ weight data. In general, the group mean body weights were reduced (compared with historical control data and animals of the low and mid dose group after 4 weeks treatment) with a concomitant reduction of all organ weights, in particular, the thymus weights for both sexes and prostate, seminal vesicle and epididymides weights in males. In females a slight increase in adrenal weights was recorded.

Low and Mid dose animals
No treatment-related changes noted.

Recovery animals
No treatment-related changes noted.

Gross pathology:

High dose animals
Macroscopic examination revealed alopecia and stained fur in 90% of animals and enlarged mesenteric lymph nodes in 50% of animals. Watery contents, distention, and watery or gaseous distension within the various levels of the gastrointestinal tract (GIT) were also observed in 30% or less of animals.

Mid dose animals
Macroscopic examination of animals revealed alopecia in 50% of animals. Similar GIT findings as high dose animals was also observed in 30% or less of animals.

Low dose animals
No treatment-related findings were noted.

Recovery animals
Macroscopic examination of animals revealed alopecia in 90% of animals.

Histopathology:

High dose animals
Involution/atrophy of the thymus was observed and was considered to be associated with the low thymus weights recorded as well as the deteriorating condition of animals in this group.

A significant presence of minimal vacuolated macrophages was found in the paracortex of the mesenteric nodes and in the white pulp of the spleen. Granulomata with prominent neutrophils was also found in the mesenteric lymph nodes. The latter was considered to be associated with the enlarged mesenteric lymph nodes observed macroscopically.

Effects on the liver consisted of a significant presence of minimal vacuolated macrophages in the sinusoids, and swollen and vacuolated biliary epithelial cells.

Reduced colloid in both prostate and seminal vesicles was observed in males. These findings were considered to be associated with the reduced weights for these tissues in these animals.

Significant epithelial hyperplasia was observed in the small and large intestine and caecum; hyperplasia was also evident in the stomach and rectum but did not achieve statistical significance. The hyperplasia was associated with the distension, gaseous or watery, and watery contents in the GIT reported macroscopically for various levels of the GIT. A significant incidence of vacuolated macrophages was found in the lamina propia of the small intestine.

Skin changes were of low incidence and consisted of minimal epidermal hyperplasia.

Mid dose animals
A significant presence of minimal vacuolated macrophages was found in the paracortex of the mesenteric nodes and in the white pulp of the spleen. Granulomata with prominent neutrophils was also found in the mesenteric lymph nodes. The latter was considered to be associated with the enlarged mesenteric lymph nodes observed macroscopically.

Effects on the liver consisted of a significant presence of minimal vacuolated macrophages in the sinusoids, and swollen and vacuolated biliary epithelial cells.

Epithelial hyperplasia was observed in the small and large intestine (except rectum) and of significant incidence in the caecum. The hyperplasia was associated with the distension, gaseous or watery, and watery contents in the GIT reported macroscopically for various

levels of the GIT. Vacuolated macrophages were found in the lamina propia of the small intestine and of significant incidence in the ileum.

Skin changes were of low incidence and consisted of minimal epidermal hyperplasia and reduced number of hair follicles.

Low dose animals
Vacuolated macrophages were found in the lamina propia of the ileum.

Recovery animals
Cellular changes still present at the end of the recovery period consisted of minimal vacuolated macrophages in the paracortex of the mesenteric nodes, in the white pulp of the spleen and in the lamina propia of the small intestine (significant presence in the jejunum and ileum), swollen and vacuolated biliary epithelial cells and epithelial hyperplasia in the caecum.

Skin changes persisted with minimal levels of epidermal hyperplasia, folliculitis and focal scab noted.

Summary of microscopic findings

A dose related incidence and distribution of vacuolated macrophages seen in the lamina propia of the small intestine in rats from all treatment groups and recovery phase rats. Associated vacuolated macrophages were seen in mesenteric lymph nodes, spleen and liver in rats receiving 150 or 300 mg/kg/day. The study authors suggest these vacuolated macrophages probably represent uptake of the test material and are not considered to be an adverse finding.

The incidence and distribution of epithelial hyperplasia seen in mid and high dose groups was dose-related. This finding affected all levels of the GIT in rats receiving 300 mg/kg/day but was confined to the caecum in the majority of rats receiving 150 mg/kg/day. This finding was present at a minimal degree in the caecum only of a small number of rats of the recovery phase and the authors consider this evidence of reversibility in the absence of this finding elsewhere in the GIT.

Swollen and vacuolated biliary epithelial cells in the liver of rats receiving 150 or 300 mg/kg/day at the end of treatment and in rats after the recovery period.

Dose related alopecia reported in rats receiving 150 and 300 mg/kg/day was associated with microscopic changes (epidermal hyperplasia, folliculitis, focal scab and reduced number of hair follicles) at the end of treatment and after the recovery period.

Treatment related changes observed in rats receiving 300 mg/kg/day at the end of treatment but not after the recovery period included granulomata with prominent neutrophils in mesenteric lymph nodes, thymic involution/atrophy and in males reduced colloid in the prostate and seminal vesicles.

No treatment-related changes were found in animals receiving 15 mg/kg/day, except for the presence of vacuolated macrophages in the ileum. The study authors determined 15 mg/kg/day to be the no observed effect level (NOEL) for microscopic changes.

Summary of Overall Findings

One male of the 300 mg/kg/day dose group was sacrificed on day 18 and all remaining animals of this dose group were terminated on day 20 due to poor and declining clinical condition and the 2-week recovery period started from this day. Animals of the 15 and 150 mg/kg/day dose groups were able to tolerate the treatment for 28 days.

Administration of the test substance resulted in a disruption of GIT function. In animals receiving 300 mg/kg/day this was evident as a gaseous/watery distension in the GIT. The decrease in total protein, albumin and cholesterol values observed in these animals is suggested by the study authors as indicative of poor absorption across the GIT wall, resulting in the poor utilisation of ingested food and reduced body weight gain, and the rapid deterioration in the clinical condition of these animals.

Other findings at 300 mg/kg/day include a general increase in all WBC parameters, except lymphocytes, lower activity counts and enlarged mesenteric lymph nodes in the GIT.

Microscopic findings consisted of an increased incidence of vacuolated macrophages present in the GIT, mesenteric lymph nodes, spleen and liver, together with epithelial hyperplasia in the GIT and swollen/vacuolated biliary epithelial cells in the liver. Other findings included granulomata with prominent neutrophils in mesenteric lymph nodes, reduced colloid in the prostate and seminal vesicles and involution/atrophy of the thymus. Some evidence of recovery was shown by increased weight gains and reductions in the incidence of some treatment related findings; although other changes noted in the GIT and liver were still present after the recovery period.

Similar changes were observed in the GIT, associated with a slight reduction in bodyweight gain, slight increases in white cell parameters and decreases in total protein, albumin and cholesterol values at 150 mg/kg/day. The incidence and degree of these findings was reduced when compared to animals receiving 300 mg/kg/day.

No treatment-related changes were found in animals receiving 15 mg/kg/day, except for the presence of vacuolated macrophages in the ileum. The study authors considered this finding to be due to the uptake of test material from the gut and, in the absence of any other treatment-related findings at this dose level, this was not considered to be an adverse effect.

Result:

The No Observed Adverse Effect Level (NOAEL) was considered to be 15 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Kitching, 1996)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA98, TA100 and *Escherichia coli* WP2 *uvrA*
Metabolic activation system:	liver microsomal fraction (S9) from rats pretreated with Aroclor 1254 in Arachis oil
Test method:	OECD TG 471; Annex 5 92/69/EEC

Experimental design:

Mutation Test: two independent experiments were conducted, with and without metabolic activation; the test substance and controls were tested in triplicate as follows:

without metabolic activation (-S9)
0, 156.25, 312.50, 625.0, 1 250.0, 2 500.0 and 5 000 µg test substance/plate

solvent control: hexane

positive controls: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG)
9-Aminoanthracene (9AA)
2-Nitrofluorene

with metabolic activation (+S9)

0, 156.25, 312.50, 625.0, 1 250.0, 2 500.0 and 5 000 µg test substance/plate

solvent control: hexane

positive control: 9AA

	An additional dose of 78.13 µg test substance/plate was included in the second independent experiment, tested both with and without metabolic activation
Additional Test*:*	because of toxicity observed at higher doses, in particular with strains TA100 and WP2 *uvrA*, an additional mutation test was performed with these two strains at doses of 78.13, 156.25, 312.5, 625.0, 1 250.0 and 2 500 µg test substance/plate TA 100 was tested with and without S9 and WP2 *uvrA* was tested with S9 only
Comment:	1st independent experiment: toxicity was observed and sufficient, non-toxic concentrations were not achieved 2nd independent experiment: sufficient non-toxic concentrations were obtained Additional test: sufficient non-toxic dose levels were obtained from TA 100 and WP2 *uvrA* no evidence of mutagenic activity was observed with the solvent control in any of the three tests concurrent positive controls, tested with and without metabolic activation, induced marked increases in the frequency of revertant colonies in each of the three tests; the activity of the S9 fraction was found to be satisfactory following treatment with the notified polymer, no substantial increases in the frequency of revertant colonies in any of the tester strains, at any concentration, with or without S9, was observed
Result:	the notified polymer was not considered to be mutagenic in the bacterial strains tested with or without metabolic activation

9.3.2 Chromosome Aberration Assay in Human Lymphocytes (Akhurst, 1997)

Cells: peripheral blood lymphocytes from male donors

Metabolic activation system: liver microsomal fraction (S9) from rats pretreated with Aroclor 1254 in Arachis oil

Experimental design: two independent experiments were conducted:

Experiment 1: 3 hour culture treatment with or without metabolic activation, with a harvest at 24 hours; and

Experiment 2: 24 and 48 hour continuous treatment without metabolic activation

Experiment 1 was later repeated with narrower dose ranges.

The experimental design and concentrations tested are represented in the table below.

Metabolic Activation	Experiment	Test concentration (μg/mL)	Controls
-S9	Experiment 1	3 hour treatment with 24 hour harvest: 75, 150, 300, 350, 400, 450, 500, 550, 600 and 1 200	Positive: Mytomycin C (MMC) – 0.8 μg/mL
	Experiment 1 (repeated)	3 hour treatment with 24 hour harvest: 25, 50, 62.5, 75, 112.5, 150, 225, 300, 350 and 400	Negative: Sterile water
	Experiment 2	24 hour continuous treatment: 50, 100, 150, 200, 250, 300, 350, 400 and 450 48 hour continuous treatment 25, 50, 75, 100, 150, 200, 250, 300, 350 and 400	Positive: MMC – 0.4μg/mL Negative: Sterile water
+S9	Experiment 1	3 hour treatment with 24 hour harvest 75, 150, 300, 350, 400, 450, 500, 550 and 600	Positive: cyclophosphamide - 30 μg/mL
	Experiment 2	3 hour treatment with 24 hour harvest 50, 75, 112.5, 125, 150, 175, 225 and 300	Negative: Sterile water

Test method: OECD TG 473

Metaphase analyses and Mitotic index:

Experiment 1

with S9 mix:

3 hour treatment: due to cell death at concentrations of 300 µg/ml and above, and insufficient analysable metaphase spread at 225 µg/ml, the highest concentration selected for metaphase analysis was 150 µg/ml; 150 µg/ml reduced the mitotic index to 38% of the negative control value; 112.5 and 75 µg/ml were selected as lower dose levels for metaphase analysis

without S9 mix:

3 hour treatment: due to cell death at concentrations 625 and 1 250 µg/ml, the test was repeated and 400 µg/ml was selected for metaphase analysis; 400 µg/ml reduced the mitotic index to 49% of the negative control value; 300 and 150 µg/ml were selected as lower dose levels for metaphase analysis

Experiment 2

with S9 mix:

3 hour treatment: cell death occurred at 300 µg/ml; 200 µg/ml was selected for metaphase analysis; 200 µg/ml reduced the mitotic index to 47% of the negative control value; 175 and 150 µg/ml were also selected as lower dose levels for metaphase analysis

without S9 mix:

24-hour continuous treatment: 450 µg/ml reduced the mitotic index to 44% of the negative control and was selected for metaphase analysis; 350 and 200 µg/ml were selected as intermediate and lowest dose levels for metaphase analysis, respectively

48-hour continuous treatment: 250 µg/ml and above resulted in cell death; 220 µg/ml was selected for metaphase analysis; 220 µg/ml reduced the mitotic index to 28% of the negative control value; 75 and 50 µg/ml were also selected as lower dose levels for metaphase analysis

Comment:	there were no statistically significant increases in the frequency of chromosomal aberrations, or in the proportion of polyploid cells at any dose tested in both experiments compared with the negative control with or without metabolic activation all positive controls induced significant increases in the frequency of chromosomal aberrations
Result:	the test substance was not considered clastogenic to human lymphocytes *in vitro*

9.4 Overall Assessment of Toxicological Data

The notified polymer, Cyasorb UV-3529, exhibited low acute oral and dermal toxicity in rats with an LD_{50} > 500 mg/kg and LD_{50} > 2 000 mg/kg, respectively. The inhalation toxicity data were provided from an analogue chemical with a similar chemical structure to that of the notified polymer and are accepted as a representative of the notified polymer. The LC_{50} for male and female rats were 2.91 and 2.79 mg/L, respectively. It is not expected the LC_{50} for the notified polymer would be dissimilar to that of the analogue. Cyasorb UV-3529 was non-irritating to rabbit skin, non sensitising to guinea pig skin, but slightly irritating to rabbit eye.

Oral administration of 15, 150 or 300 mg/kg/day of the notified polymer for 28 consecutive days to rats was associated with severe signs of systemic toxicity at 300 mg/kg/day. This group was terminated on day 20, because of their rapidly deteriorating condition. Principal findings at 300 mg/kg/day included a reduction in bodyweight gain and food consumption, pathological changes to the GIT, liver, spleen, mesenteric lymph nodes, thymus, prostate and seminal vesicles and changes in clinical pathology. Evidence of recovery was evident during the recovery period for animals receiving 300 mg/kg/day, although some changes noted in the GIT and liver were still apparent at the end of the recovery period. Similar findings to those seen at 300 mg/kg/day were observed at 150 mg/kg/day during the 4-week treatment period, however, the degree and incidence was lower. At the lowest dose, 15 mg/kg/day, the only finding was vacuolated macrophages in the ileum. This finding was observed at all doses and was considered by the study authors to demonstrate uptake of the test material. In the absence of any signs of systemic toxicity at this dose, the NOAEL was determined to be 15 mg/kg/day.

The notified polymer was not considered mutagenic in a bacterial mutation assay or clastogenic in human lymphocytes *in vitro*.

Under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) Cyasorb UV-3529 is classified as a hazardous substance on the basis of its acute toxicity (LD_{50} >500 mg/kg) and systemic toxicity following repeated oral administration. The acute inhalation 4-hour LC_{50} for an

analogue chemical was 2.79 mg/L (females), and considered to be a representative value for the notified polymer.

The relevant risk phrases for Cyasorb UV-3529 are R20/22 - Harmful By Inhalation and if Swallowed and R22/48 – Harmful: Danger of Serious Damage to Health by Prolonged Exposure if Swallowed.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notified polymer has a NAMW greater than 1 000 g/mol and toxicological information is not required by the Act. However, the notifier has supplied the ecotoxicity studies, which are tabulated below. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

Test	*Species*	*Results*
Acute Toxicity (static) (OECD TG 203)	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC_{50} > 1.5 mg/L
Acute Toxicity Immobilisation Test (Static Test) (OECD TG 202)	Water Flea (*Daphnia magna*)	48 h EC_{50} = 0.64 mg/L
Growth Inhibition (Static Test) (OECD TG 201)	Green Algae (*Selenastrum capricornutum*	72 h EC_{50} > 0.15 mg/L
Activated Sludge Respiration Inhibition (OECD TG 209)	Aerobic Waste-water Bacteria	3 h EC_{50} > 100 mg/L

LC_{50} – median lethal concentration EC_{50} – median effective concentration

The test solutions for fish, aquatic invertebrates and algae were prepared by dispersing an excess of the test substance in the test medium, at an initial loading rate of 100 mg/L. The dispersion was stirred for approximately 12 hours then filtered to remove undissolved test substance. Test concentrations were verified by chemical analysis.

Fish (Kelly, 1998a)

A preliminary range finding test was conducted with test concentrations between 0.2 and 2.0 mg/L. The limit test concentration of 1.5 mg/L was selected based on these results. There were no mortalities or treatment-related signs of toxicity after exposure of the fish to 1.5 mg/L of Cyasorb UV-3529 Light Stabiliser for 96 hours. Hence, the 96 h LC_{50} for Cyasorb UV-3529 Light Stabiliser with rainbow trout was assessed to be greater than 1.5 mg/L. There was

some variation in the concentration of the product at 0 and 72 hours; however this was not considered to be biologically significant.

The notifier also provided ecotoxicological information for the non-methylated analogue of the notified polymer, Cyasorb UV-3346. Under static conditions, the 96 h LC_{50} was 2.25 mg/L in bluegill sunfish (*Lepomis macrochirus*). This is classified as harmful to the environment. Based on this result, Cyasorb UV-3529 would be considered to be moderately toxic to fish.

Aquatic Invertebrates (Kelly, 1998b)

In the 48 hour acute immobilisation study, *Daphnia magna* were exposed to nominal concentrations of Cyasorb UV-3529 Light Stabiliser from 0.5% to 100% saturated solution, with corresponding mean concentrations up to 2.0 mg/L. At least 5% mortality was observed in all of the test and control groups after 48 hours. A level of 10% is not considered to be biologically important. The No Observed Effect Concentration (NOEC) was reported to be < 0.01 mg/L and the 48 h EC_{50} was 0.64 mg/L. Hence, Cyasorb UV-3529 is classified as highly toxic to *Daphnia magna.*

Algae (Kelly, 1998c)

Six replicate algal cultures were exposed to a saturated solution of Cyasorb UV-3529 Light Stabiliser (average concentration 0.15 mg/L) under static conditions for 72 hours. No abnormalities were observed in any of the cultures after the test period. Hence, the 72 h EC_{50} is greater than 0.15 mg/L.

Microorganisms (Barnes, 1998)

Samples of the activated sludge (1.6 g/L suspended solids) were exposed at nominal concentrations of 1, 10 and 100 mg/L Cyasorb UV-3529 Light Stabiliser for 3 hours. No significant inhibition in respiration rate of the sludge was recorded. Therefore, under the conditions used for the test, Cyasorb UV-3529 Light Stabiliser was found to have no inhibitory effect on the respiration rate of activated sewage sludge microorganisms and the EC_{50} was > 100 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is expected that all of the new polymer will be disposed of to landfill eventually. Any spillage during the preparation of the masterbatch or extrusion of the final products can be collected and disposed of to landfill. In the event of accidental spillage of the chemical on land, it is expected to become immobilised in the soil layer, which could be collected and disposed of to landfill. After end-use in agricultural products, it is expected that the products containing the notified polymer will also be disposed of to landfill, although plastic recycling

is an option.

Solid waste consigned to landfill would be expected to be retained at the landfill sites and not be mobile. Movement of the chemical by leaching from landfill sites is not expected because of the low water solubility and high binding affinity to soil. Under these conditions it would be slowly degraded to gases such as carbon dioxide, nitrogen oxide and nitrogen through abiotic and bacteriological processes.

Any chemical spilt into waterways is not expected to disperse but would settle out onto sediments. The reported log P_{ow} of 4.5 indicates significant affinity for the organic component of soils and sediments.

The polymer contains a very high percentage of amine reactive functional groups that are classified as high environmental concern due to their potential toxicity to aquatic organisms (Boethling and Nabholtz, 1997). Ecotoxicological studies showed that the maximum water solubility of the notified polymer is below the effect concentration toxic to fish, algae and wastewater treatment microorganisms, while the notified polymer is classified as highly toxic to aquatic invertebrates. However, the limited release of the polymer to the environment coupled with the low solubility of the polymer suggests that the environmental exposure to aquatic organisms is at levels unlikely to cause any significant effect.

Based on the above discussion, the environmental exposure and the overall environmental hazard of the notified polymer are expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer exhibited low acute oral and dermal toxicity in rats with an LD_{50} > 500 mg/kg and LD_{50} > 2 000 mg/kg, respectively. The inhalation toxicity data were provided from an analogue chemical with a similar chemical structure to that of the notified polymer and are accepted as representative of the notified polymer. The LC_{50} for male and female rats were 2.91 and 2.79 mg/L, respectively. Cyasorb UV-3529 was non-irritating to rabbit skin, non-sensitising to guinea pig skin, but slightly irritating to rabbit eye.

Oral administration of the notified polymer for 28 consecutive days to rats was associated with severe signs of systemic toxicity at 300 mg/kg/day. This group was terminated on day 20 because of their rapidly deteriorating condition. Evidence of recovery was evident during the recovery period for animals receiving 300 mg/kg/day, although some changes noted in the GIT and liver were still apparent at the end of the recovery period. In the absence of any signs of systemic toxicity at 15 mg/kg/day, the NOAEL was determined to be 15 mg/kg/day.

The notified polymer was not considered mutagenic in a bacterial mutation assay or clastogenic in human lymphocytes *in vitro*.

The notified polymer is classified as a hazardous substance in accordance to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) on the basis of its acute toxicity (LD_{50} >500 mg/kg) and systemic toxicity following repeated oral administration. The acute inhalation 4-hour LC_{50} for an analogue chemical was 2.79 mg/L (females), and considered to be a representative value for the notified polymer. The relevant risk phrases for Cyasorb UV-3529 are R20/22 - Harmful By Inhalation and if Swallowed and R22/48 – Harmful: Danger of Serious Damage to Health by Prolonged Exposure if Swallowed.

Under normal working conditions, waterside, warehouse and transport workers are unlikely to be exposed to the notified polymer, as they will be handling sealed packages of products containing the notified polymer. Therefore, occupational risks for these workers are considered to be low.

During reformulation, workers involved in scooping, weighing and manual adding of the pastilles containing the notified polymer and the other raw materials needed to form the compounded plastic pellets, masterbatch pellets, have the highest chance of dermal, inhalation and eye exposure to the notified polymer. Workers involved in other processes, such as extrusion, quality control testing and bagging of plastic pellets, may experience dermal and eye exposure to the notified polymer to a lesser extent, since after compounding, the notified polymer is present at lower concentrations, between 10 to 20% and it is encapsulated in the masterbatch pellets. The solid pastille form of the imported product and the plastic pellet form of the masterbatch pellets are described as anti-dusting forms. They will minimise worker exposure to dusts when handling the products and formulations containing the notified polymer. The notifier states that workers involved in the production of the masterbatch pellets will wear dust masks, gloves and overalls to minimise potential dermal and inhalation exposure to the notified polymer. Workers involved in weighing will also wear safety glasses in addition to the above protective equipment, to prevent eye contact. Dust extraction is employed at the weighing area to minimise inhalation exposure to the notified polymer. The extruder loading area is also fitted with local exhaust ventilation. The laboratory technician will wear protective clothing such as laboratory coat, safety glasses and gloves when carrying quality control tests.

At the customer site, the masterbatch pellets will be re-extruded to form plastic products, such as agricultural greenhouse covers. The notifier did not provide details on the re-extrusion process. However, since the notified polymer is encapsulated within the masterbatch pellets, exposure of workers to the notified polymer during the extrusion process is considered to be low. The use of protective equipment will further control exposure to the notified polymer. Similarly, worker exposure to the plastic products containing the notified polymer is considered to be low since the notified polymer will be present at low concentration (between 0.5 – 1%) and the notified polymer will be bound within the plastic products.

The potential for public exposure to the notified polymer during transport, storage, processing and use is considered to be low. Although the public will make dermal contact with plastic products containing the notified polymer exposure is assessed as negligible because of the low concentration of the notified polymer in the products. In addition, the

notified polymer will be encapsulated within the plastic products from which the notified polymer is not expected to leach, thus the notified polymer is not expected to be dermally absorbed.

13. RECOMMENDATIONS

1. The notified polymer may be recommended to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

2. To minimise occupational exposure to Cyasorb UV-3529 the following guidelines and precautions should be observed:

    - Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

    - Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

    - Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998);

    - All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

    - Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

    - Good personal hygiene should be practised to minimise the potential for ingestion; and

    - A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

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 polymer 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

Akhurst LC (1997) *In Vitro* Mammalian Chromosome Aberration Test in Human Lymphocytes, Project No. CTI 052/974040, Huntingdon Life Sciences Ltd, England.

Barnes SP (1998) Activated Sludge - Respiration Inhibition Test, Project No. CTI 095/982962, Huntingdon Life Sciences Ltd, England.

Biesemeier JA (1982) EPA Acute Inhalation LC50 Toxicity Study, Project No. 910639, Hazleton Raltech. Inc, Wisconsin, USA.

Boethling R S and Nabholtz J V (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD and Sutcliffe R ed. Ecological Assessment of Polymers: Strategies for Product Stewardship and Regulatory Programs. Van Nostrand Reinhold, New York.

Chambers PR (1998) Toxicity Study by Oral Administration to CD Rats for 4 Weeks followed by a 2-Week Recovery Period, Project No. CTI 087/983459, Huntingdon Life Sciences Ltd, England.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, **49**: 2-56.

European Economic Community (1992) Methods for the Determination of Toxicity. In: EEC Directive 92/69, Annex V, Part A, EEC Publication No. L383. EEC.

European Economic Community (1992) Methods for the Determination of Physico-Chemical Properties. In: EEC Directive 92/69, Annex V, Part A, EEC Publication No. L383. EEC.

Kelly C (1998a) Acute Toxicity for Rainbow Trout *(Oncorhynchus mykiss)*, Project No. CTI 091/983787, Huntingdon Life Sciences Ltd, England.

Kelly C (1998b) Acute Toxicity to *Daphnia magna*, Project No. CTI 092/983788, Huntingdon Life Sciences Ltd, England.

Kelly C (1998c) Algal Growth Inhibition, Project No. CTI 093/983789, Huntingdon Life Sciences Ltd, England.

Kitching J (1996) Bacterial Mutation Assay, Project No. CTI 31/960372, Huntingdon Life Sciences Ltd, England.

Liggett MP (1996) Skin Sensitisation in the Guinea-Pig, Project No. CTI 30/960567/SS, Huntingdon Life Sciences Ltd, England.

McRae LA (1996a) Acute Dermal Toxicity to the Rat, Project No. CTI 27/960318/AC, Huntingdon Life Sciences Ltd, England.

McRae LA (1996b) Acute Oral Toxicity to the Rat, Project No. CTI 26/960319/AC, Huntingdon Life Sciences Ltd, England.

Mensinck BJWG et al (1995) Manual for Summarising and Evaluating the Environmental Aspects of Pesticides, Project No. 679101022, National Institute of Public Health and Environmental Protection, The Netherlands.

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

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

Organisation for Economic Co-operation and Development (1992) OECD Guidelines for the Testing of Chemicals. Paris, OECD.

Parcell BI (1996a) Eye Irritation to the Rabbit, Project No. CTI 29/960572/SE, Huntingdon Life Sciences Ltd, England.

Parcell BI (1996b) Skin Irritation to the Rabbit, Project No. CTI 28/960430/SE, Huntingdon Life Sciences Ltd, England.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

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

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Sydney, Standards Association of Australia.

Standards Australia (1998) Australian Standard 2161.2:1998, Occupational Protective Gloves, Part 2: General Requirements. Sydney, Standards Association of Australia.

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

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

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