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February 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CYASORB UV-3853 Light Stabiliser

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

CYASORB UV-3853 Light Stabiliser

1. APPLICANT

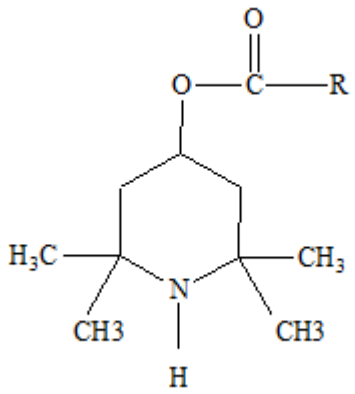
Cytec Australia Holdings Pty Ltd of Suite 1, 7-11 Railway Street, Baulkham Hills, NSW 2153 (ABN 45 081 148 629) has submitted a standard notification statement in support of their application for an assessment certificate for CYASORB UV-3853 Light Stabiliser.

The notifier has not requested any information relating to the notified chemical to be exempt from publication in the Full Public Report and Summary Report.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	Fatty acids, C_{12-21} and C_{18}-unsaturated, 2,2,6,6-tetramethyl-4-piperidinyl esters
Chemical Abstracts Service (CAS) Registry No.:	167078-06-0
Marketing Name:	CYASORB UV-3853 Light Stabilizer
Other Name:	Dastib 845 (100% notified chemical)
Molecular Formula:	The notified chemical is a UVCB substance and cannot be described by single molecular formula.

Structural Formula:



Esters		% Wt. of Notified Chemical
Stearic:	R = — $(CH_2)_{16}$—CH_3	≈ 40 - 65
Palmitic:	R = — $(CH_2)_{14}$—CH_3	≈ 31 - 49
Heptadecanoic:	R = — $(CH_2)_{15}$—CH_3	≈ 0.3 – 4.8
Myristic:	R = — $(CH_2)_{12}$—CH_3	≈ 0.1 – 3.0
Oleic:	R = — $(CH_2)_7$ —CH == $CH(CH_2)_7CH_3$	≈ 0.2 – 4.0
Others:	R = C_{11} — C_{20}	≈ 0.2 – 6.2

Molecular Weight: 294-516 (estimate based on the representative structural formula)

Method of Detection and Determination: Infra-red (IR) spectroscopy

Spectral Data: Major IR peaks were observed at 2957, 2925, 2854, 1735, 1464, 1377, 1365, 1240 and 1170 cm^{-1}.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Light yellow, waxy solid with no characteristic odour.

Melting Point: 28-32°C

Boiling Point: 400°C

Density: 0.39 g/cm^3 at 25°C (50% notified chemical, 50% polyethylene)

Vapour Pressure: $(5.1 \pm 0.5) \times 10^{-5}$ kPa at 25°C

Water Solubility: Immiscible with water at > 0.5mg/L. See comments below.

Partition Co-efficient (n-octanol/water): Log P_{ow} estimated to be 8.92 (see comments below)

Hydrolysis as a Function of pH: The chemical was found to degrade rapidly in water at ambient temperature and a wide range of pH. (See comments below).

Adsorption/Desorption: Not determined due to low water solubility. The chemical is expected to adsorb strongly to organic matter in soil.

Dissociation Constant: Not determined due to low water solubility. (See comments below).

Particle Size:	Not applicable for waxy solid.
Flash Point:	154°C
Flammability Limits:	Combustible.
Autoignition Temperature:	Not determined.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable under normal conditions of use.

3.1 Comments on Physico-Chemical Properties

Prior to determining vapour pressure at 25°C using the Static Technique, the testing laboratory investigated the melting phenomena of the notified chemical and determined that the phase transition already starts at 12°C and is completed by 32°C (de Vries, 1993).

The water solubility of CYASORB UV-3853 was unable to be determined, however the chemical was found to be immiscible with water at concentrations greater than 0.5 mg/L (Schuler, undated). An accurate finding for water solubility using extraction methods was not possible because recovery rates varied significantly and were substantially below 100%. However, it is noted that when the chemical was introduced from surface coated sand into water, no dissolved chemical was detected. Consequently, the chemical could be considered to be of low water solubility under ambient conditions.

Since incomplete recovery and possible degradation was indicated in the water solubility studies, the hydrolytic stability of the notified chemical was investigated (Schuler, undated). The chemical was found to degrade rapidly in water at ambient temperature and a wide range of pH levels. Degradation was fastest in an acid environment. In a neutral environment at ambient temperature, the half-life was estimated to be 2 to 3 days even in the presence of only 20% water. While degradation products were not investigated, the chemical would be expected to hydrolyse at the fatty acid ester linkage. The testing laboratory predicts that studying the rate of hydrolysis in greater detail would involve substantial experimental difficulties due to the low solute concentrations required when following OECD Guideline 111.

The partition coefficient of the notified chemical could not be determined analytically due to its low solubility in water. In addition, an accurate partition coefficient is not possible because the chemical is a mixture and breaks down in water creating further substances. A coarse estimation according to the model of Leo and Hansch of log P_{ow} for the notified chemical was provided. The calculation was based on a structure consisting of the piperidine ring with the ester of myristic acid as a functional group. Esters of larger carboxylic acids will show higher values for log P_{ow} and a strong preference for the organic phase. However, this approach of calculating should be viewed with caution as estimates of log $P_{ow} > 6$ are likely to be oversestimates of the measured log P_{ow}, perhaps by one or more log units (Lyman, 1996).

Determination of a soil adsorption coefficient, K_{oc}, was not attempted due to the low water solubility of the notified chemical. Based on its structure, the chemical is expected to adsorb

strongly to organic matter in soil.

Dissociation tests were not conducted due to the low water solubility of the notified chemical. The secondary amine group in the piperidine ring is sterically hindered by the four methyl substituents on the adjacent carbon atoms. Consequently, while aliphatic secondary amine groups typically have pKa values between 9.5 and 10.5, in the present case the amine group lone pair may be significantly shielded by the four bulky methyl groups resulting in a significantly lower value for pKa.

4. PURITY OF THE CHEMICAL

Degree of Purity: ~ 100%

Hazardous Impurities: None known

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

Additives/Adjuvants:

Chemical name:	Polyethylene
CAS No.:	9002-88-4
Weight percentage:	50%

5. USE, VOLUME AND FORMULATION

The notified chemical is a UV stabiliser and will be used as an additive in the production of moulded polypropylene products such as automotive components and outdoor plastic furniture. The notified chemical will be imported in 50% polyethylene granules as the product CYASORB UV-3853S in 20 or 57kg plastic bags packed in fibreboard cartons.

Between 10 and 200 tonnes of the notified chemical will be imported annually for 5 years.

6. OCCUPATIONAL EXPOSURE

Import, Transport and Storage

The notified chemical will be imported as a 50% component of a granular product in 20 or 57 kg plastic bags in fibreboard cartons (particle size approximately 2mm diameter). Following import, the chemical will be transported by road to a storage warehouse and then to two customer sites.

Between 5 and 10 workers will be involved in initial importation of the chemical and the same number again in transportation and warehouse storage of the chemical. Exposure of these workers will only occur following inadvertent puncture of the containers.

Formulation and Article Production

At the customer sites, the notified chemical will be either blended with other additives and extruded directly into end use articles or blended and extruded to produce intermediate masterbatch pellets which will be sold to customers for later extrusion. A total of 20-50 employees will be involved in the blending and extrusion of the intermediate masterbatch and end use articles. In addition, 5-10 technicians will be involved in sampling and laboratory quality analysis.

Extrusion of Intermediate Masterbatch

Employees involved in extrusion processes will manually open the import bags and pour the granular product containing the notified chemical into the hopper of the extruder. Prior to use, laboratory technicians will also manually scoop a required amount of product for quality analysis sampling.

For employees involved in extrusion processing, dermal, ocular and inhalation exposure to the granules and dusts containing the notified chemical may occur. The physical size of the granules and engineering controls such as local exhaust ventilation will limit inhalation exposure at the extruder hopper. Worker exposure at the loading area will be controlled also by personal protective equipment consisting of overalls, head covering, safety glasses and half-face respirator.

For production of intermediate masterbatch granules, the masterbatch will be extruded as strings that will then be transferred automatically to a pelletiser where the strands are chopped into granules and stored in a hopper ready for bagging and storage.

Dermal and ocular exposure of laboratory technicians may also occur. Inhalation exposure of dusts is also possible during sampling from export containers. Exposure will be controlled via personal protective equipment consisting of a laboratory coat, safety glasses and gloves and engineering controls consisting of ventilated workstations in the laboratory.

Once the polymer containing the notified chemical is extruded, the latter is bound within the polymer matrix and unavailable for absorption.

Extrusion of End-use Articles

Extrusion plant operators producing the intermediate masterbatch or end-use articles will pour granules containing the notified chemical manually into the hopper of the extruder. Engineering controls and personal protective equipment to limit exposure will be similar to that used for extrusion of the intermediate masterbatch.

Extruder operating temperatures during extrusion of both intermediate masterbatches and end-use articles will be monitored by the worker. At recommended processing temperatures, the hot extrusion of polymer containing the notified chemical may produce vapours that may also be inhaled. If the polymer resin is overheated, more extensive decomposition and liberation of irritating carbonaceous oxide fumes may occur. Vapours liberated from hot sections of the extruder will be collected by local exhaust ventilation.

After production of end-use articles, worker exposure to the notified chemical is unlikely as the chemical will be present at low concentration (0.1-0.5%) and bound within a fused polymer matrix.

Maintenance

Although not identified by the notifier, maintenance workers may also be exposed to the notified chemical during routine machinery upkeep and repair. Dermal exposure is possible during these activities.

7. PUBLIC EXPOSURE

The notified chemical will not be sold to the general public. The public will come into contact with the notified chemical only when it has been incorporated into the polymer matrix of finished articles. Consequently, the potential for public exposure to the notified chemical during all phases of its life cycle is considered to be very low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier estimates that the wastage generated from residual material in plastic import bags (approx. 0.1%, up to 200 kg/yr notified chemical) will be negligible because of the compact, free flowing nature of the granular material.

Spillage of the notified chemical during transport, storage and processing is expected to be minimal and largely due to accidents. Release to the aquatic environment from spills during processing is expected to be negligible, as the material would be collected by sweeping and disposed of to land-fill or used again in production. In addition, stormwater drains in production areas would be fitted with filter baskets to collect spilled material.

Production waste is claimed by the notifier to be up to 3% (equivalent to up to 6 tonnes/yr notified chemical) and would encompass waste from production start-up and shut-down, accidental spills, cleaning of equipment, reject products and off-cuts. The majority of this wastage would be in the stabilised polymer form containing up to 0.5% notified chemical. Waste material containing the notified chemical would be collected by licensed waste disposal contractors and disposed of to land-fill.

The majority of the notified chemical will share the fate of the plastic articles into which it is incorporated. At the end of the product's useful lifetime it is expected that disposal will be to either landfill or by incineration.

8.2 Fate

Spillage of raw product containing the notified chemical during transport, storage and processing is expected to be minimal and largely due to accidents. Granules are easily collected and release to the aquatic compartment is unlikely. However, if released to water, the granules containing the notified chemical would be expected to float and as the notified chemical is minimally soluble in water, release to the aquatic compartment would be negligible. After incorporation into final products, the chemical will be bound in an inert, thermoplastic matrix and release to the aquatic environment is not expected.

Residual waste from import bags, consisting of granules containing 50% notified chemical

(approx. 200 kg/year notified chemical), will be disposed of to landfill. The low water solubility of the chemical would indicate that it is unlikely to leach from landfill. It is unlikely that the notified chemical would be released to the environment from final products disposed of to land-fill as the chemical, once bound within the polymer matrix, is not expected to be mobile. Whilst the notifier accepts that the notified chemical may leach from polyethylene granules, data provided from the notifier shows that migration of CYASORB UV-3853 to the surface of the products is not expected for polypropylene end products containing up to 0.45% notified chemical.

Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon and nitrogen.

The biodegradability of the notified chemical was investigated in a Ready Biodegradability; CO_2 Evolution Test (OECD TG 301B, Mead, 1996), using bacteria activated sludge from a domestic waste-water treatment plant. The standard material, sodium benzoate, attained 79% degradation after 14 days, thereby confirming the validity of the test. CYASORB UV-3853 attained 43% biodegradation after 28 days and as such, did not pass the test for ready biodegradability, ie. $\geq$ 60% biodegradation within 28 days.

A study of the potential for CYASORB UV-3853 to bioaccumulate was not conducted. Although the estimated log P_{ow} for the chemical indicates the potential for bioaccumulation, release of the chemical into the environment is expected to be minimal. As an additive to plastic products, the substance will be encapsulated within the polymer matrix and it is expected that either leaching or extraction from the polymer would be low. Therefore, under normal use and handling of the notified substance there should not be a significant release into the environment.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CYASORB®UV-3853 Light Stabilizer

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} >15,000 mg/kg	Rosival and Szokolayová (1985b)
acute oral toxicity	mouse	LD_{50} >10,000 mg/kg	Rosival and Szokolayová (1985b)
acute dermal toxicity	rat	LD_{50} >5,000 mg/kg	Rosival and Szokolayová (1985a)
inhalation toxicity	rat	LC_{50} > 5 mg/m^3	Mejstřik, Šlesinger, Pačobský and Držková (1990)
skin irritation	rat	non-irritating	Rosival and

			Szokolayová (1985c)
skin irritation	rabbit	irritating	Kaufmann (1993a)
eye irritation	rabbit	severely irritating	Kaufmann (1993b)
skin sensitisation	guinea pig	sensitising	Barlogová and Babinská (1990)

9.1.1 Oral Toxicity (Rosival and Szokolayová, 1985b)

Species/strain:	Rats, Wistar; Mice, C57B1/10 and Strain A
Number/sex of animals:	Rat: 5 males per dose; Mouse: 5 males and 5 females per dose
Observation period:	14 days
Method of administration:	Gavage
Test method:	OECD TG 401
Mortality:	None
Clinical observations:	Rats gained weight during the study. No other clinical observations were recorded.
Morphological findings:	No histological changes were observed.
LD_{50}:	> 15,000 mg/kg (rats); >10,000 mg/kg (mice)
Comment:	A poorly reported study with incomplete and contradictory data concerning the number of animals.
Result:	The notified chemical was of very low acute oral toxicity in rats and mice.

9.1.2 Dermal Toxicity (Rosival and Szokolayová, 1985a)

Species/strain:	Rats, Wistar
Number/sex of animals:	5 males and 5 females
Observation period:	14 days
Method of administration:	A single dose of notified chemical in olive oil was applied to clipped unabraded skin for 24 hours.
Test method:	OECD TG 402 (limit test)
Mortality:	None

Clinical observations:	Rats gained weight during the study. No other clinical observations were recorded.
Morphological findings:	No histological changes were observed.
LD_{50}:	> 5000mg/kg
Comment:	The date of conduct of this study is unknown.
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity (Mejstřik, Šlesinger, Pačobský and Držková, 1990)

Species/strain:	Rats, Wistar
Number/sex of animals:	5 males and 5 females control group; 5 males and 5 females treatment group
Observation period:	14 days
Method of administration:	7 hour exposure, whole body
Test method:	OECD TG 403
Mortality:	None
Clinical observations:	All animals were normal in appearance and behaviour and gained weight during the study.
Morphological findings:	In all animals, organs and cavities were of normal appearance.
Comment:	Decreased somatomotor activity was observed in both control and treatment groups. This was attributed to increased temperature within the exposure chamber.
LC_{50}:	> 5 mg/m^3
Result:	The notified chemical was of low acute inhalation toxicity in rats.

9.1.4 Skin Irritation (Rosival and Szokolayová, 1985c)

Species/strain:	Rats, Wistar
Number/sex of animals:	6 males
Observation period:	14 days

Method of administration: A repeated dose of 250mg notified chemical in olive oil was applied daily for 10 days to shaved intact and abraded skin. The application area remained uncovered.

Test method: OECD TG 404

Comment: When assessed at 24, 48, 72 hours and 14 days post commencement of application, no signs of irritation or toxicity were seen in any animal.

Result: Upon repeated dosing, the notified chemical was non-irritating to the skin of rats.

9.1.5 Skin Irritation (Kaufmann, 1993a)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 3 (sex not specified)

Observation period: 11 days

Method of administration: Notified chemical (0.5g) was applied to clipped, intact skin and covered by semi-occlusive dressing for 4 hours.

Test method: OECD TG 404

Draize scores:

	Time after Treatment (days)						
Animal #	***1 hour***	***24 hours***	***48 hours***	***4 days***	***7 days***	***10 days***	***11 days***
Erythema							
1	1[a]	2	2	1	1	1	0
2	0	1	1	1	1	1	0
3	1	1	1	2	2	0	0
Oedema							
1	0	2	2	1	1	0	0
2	0	1	1	1	1	0	0
3	0	1	1	1	1	0	0

[a] see Attachment 1 for Draize scales

Comment: Erythema and oedema were observed in all animals up to 7 days after patch removal.

Result: The notified chemical was slight to moderately irritating to the skin of rabbits.

9.1.6 Eye Irritation (Kaufmann, 1993b)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 1, sex not specified

Observation period: 24 hours

Method of administration: Undiluted test substance (0.1g) instilled into the conjunctival sac of the left eye.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation			
	1 hour		***24 hours***	
Cornea	***o***		***o***	
	0		0	
Iris	1		1	
Conjunctiva	***r***	***c***	***r***	***c***
	2	1	3	4

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: Observed effects were sufficiently serious to terminate the test after 24 hours. The observed findings showed no signs of reversibility during the 24 hour observation period. Observed ocular lesions were considered likely to be indicative of irreversible tissue damage (eye corrosion).

Result: The notified chemical was severely irritating to the eyes of rabbits.

9.1.7 Skin Sensitisation (Barlogová and Babinská, 1990)

Species/strain: Guinea pigs, albino

Number of animals: 72 males – 14 control, 58 treatment

Induction procedure: Five intradermal (ID) injections of 0.1mL of a 20% or 50% solution (w/v) of test substance in alcohol with 0.1mL Freund's complete adjuvant (FCA). One additional group received 0.3 mL neat test substance applied to the shaved, intact skin.

test group: 18 test guinea pigs received ID 20% test substance.
24 test guinea pigs received ID 50% test substance.
16 test guinea pigs received cutaneous neat test substance.

control group: 14 test guinea pigs received FCA alone.

Challenge procedure: On day 14, animals received 0.03mL of a 0.1% solution of test substance in alcohol applied to the shaved, intact skin.

Test method: Similar to OECD TG 406, Magnusson and Kligman test.

Challenge outcome:

Induction Protocol	***Test animals***	
	24 hours*	***48 hours****
Intradermal, 20%	5/18**	6/18
Intradermal, 50%	7/24	8/24
Cutaneous, neat	1/16	1/16

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

Comment: The study was poorly reported and data regarding the treatment of animal groups is not complete. The methodology reported indicates a departure from the usual Magnusson and Kligman protocol.

Result: Based on the positive results observed in animals induced intradermally, the notified chemical was sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Schmidt, 1993)

Species/strain: Rats, Han:Wistar

Number/sex of animals: 4 groups, 5 males and 5 females per group including satellite control and high dose groups.

Method of administration: Gavage

Dose/Study duration: 0, 40, 200, 1000 mg/kg/day for 28 days; additional 14 days for satellite groups.

Test method: OECD TG 407

Clinical observations:
No mortality occurred during the study. A dose-related increase in salivation was observed in mid and high dose groups. All high dose animals showed light-coloured faeces from the second week of treatment onwards until the first week of post-treatment observation. In addition, some high dose animals also showed slightly decreased activity, cutaneous turgor

and slightly to moderately reduced righting reflex. No treatment-related signs could be detected in recovery group animals during the second week post-treatment.

The body weight gain of high dose male animals was significantly decreased throughout the treatment period. However, no significant changes were observed post-treatment. In females, body weight gains did not show any treatment-related differences.

Clinical chemistry/Haematology
No significant, treatment-related differences were found in haematology or clinical chemistry either at the end of treatment or after the post-treatment observation period.

Pathology:
Macroscopic lesions consisting of white coatings or reddening of the mucous membrane in the stomach and swollen duodenums were found in all high dose animals. One mid dose female additionally showed a swollen duodenum. After the recovery period, neither the duodenum nor the stomach in test animals revealed any macroscopic findings.

No significant differences in absolute or relative organ weights were observed either at the end of treatment or after post-treatment observation.

Histopathology
A dose-related increase in the incidence of mucosal hyperplasia of the duodenum was observed in mid and high dose animals. No similar findings were made in recovery animals after the post-treatment observation period.

Result:
On the basis of lesions of the duodenum observed in mid and high dose animals, no-observed-adverse-effect-level (NOAEL) of 40mg/kg/day was established for the test substance.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Ebringer and Lahitová, 1990a)

Strains:	TA 102, TA100, TA98, TA97
Metabolic activation:	Aroclor 1254-induced rat liver S-9 microsome fraction
Concentration range:	10, 125, 250, 500, 1000 μg/plate
Test method:	OECD TG 471
Comment:	No increase in the number of revertant colonies was observed at any concentration, compared with the negative control. No toxicity was observed.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 *Escherichia Coli* Reverse Mutation Assay and DNA Repair Test (Ebringer and Lahitová, 1990b)

Strains:	WP2, WP2uvrA, WP67, CM611
Metabolic activation:	Aroclor 1254-induced rat liver S-9 microsome fraction
Concentration range:	10, 100, 200, 400, 800 μg/plate
Test method:	OECD TG 472
Comment:	In the E. coli reversion test, no increase in the number of revertant colonies was observed at any concentration, compared with the negative control. In the DNA repair test, no zone of inhibition was observed for the test substance. The positive controls behaved appropriately in both tests.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.3 *Tradescantia* Stamen Hair System (Mičieta, 1990)

Strains:	*Tradescantia* 4430
Concentration range:	0.2% (w/v) test substance in DMSO 0.2% (v/v), Tween 80 (v/v) 0.2% in water.
Test method:	The tester plant species is heterozygous at a flower colour locus. A blue phenotype is a product of a dominant blue allele, and a pink phenotype is controlled by a recessive pink allele unmasked by mutation or deletion of the blue allele. For each treatment, entire inflorescens are immersed in test solution, washed and planted in Hoagland's nutrient solution. For each treatment, 10 flowers/3000 stamen hairs were scored daily between days 4 and 12 after commencement of treatment.
Comment:	The test substance was insoluble in water and of low solubility in organic solvents.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.4 In vivo Cytogenetic Test – *Vicia* Test (Murín, 1990)

Strain:	*Vicia sativa L. cv. Fatima*
Concentration range:	0.2, 0.1 or 0.05% (w/v) test substance in 0.4% (v/v) acetone, Tween 80 (one drop) in water.

Test method:	Seeds were immersed in test substance solutions for 24 hours and then germinated in petri dishes on filter paper wetted by similar solutions. After 72 hours, root tip samples were evaluated for structural and numerical chromosome mutations.
Comment:	The test substance was insoluble in water and of low solubility in organic solvents. No chromosome mutations were observed for any concentration of test substance. The positive and negative controls behaved appropriately.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.3.5 Mammalian Spot Test (Rosival and Szokolayová, 1985d)

Strains:	Mice, C57B1/10 and albino strain A Velaz Šumice
Concentration range:	0, 100, 200 and 400mg/kg body weight
Method of administration:	Gavage, on days 9 –11 of gestation period.
Observation period:	28 days
Test method:	OECD TG 484
Comment:	The test substance induced a dose-related increase in embryotoxicity with 35% mortality at 400mg/kg. In survivors, spot formation was observed in the low and high dose groups, but not the intermediate dose group.
Result:	The notified chemical was embryotoxic and potentially mutagenic under the conditions of the test.

9.3.6 In vivo Mammalian Bone Marrow Cytogenetic Test (Mičieta and Karasová, 1990a)

Species/strain:	Hamsters, Chinese
Number and sex of animals:	5 groups, 5 males and 5 females per group
Doses:	0, 200, 400 and 800 mg/kg body weight
Method of administration:	Gavage
Test method:	OECD TG 475
Comment:	The notified chemical did not induce significant increases in percentages of aberrant cells in the bone marrow of either

male or female animals at any dose level. The positive and negative controls behaved appropriately.

Result: The notified chemical was non clastogenic under the conditions of the test.

9.3.7 Micronucleus Assay in Bone Marrow Cells (Mičieta and Karasová, 1990b)

Species/strain: Hamsters, Chinese

Number and sex of animals: 5 groups, 5 males and 5 females per group

Doses: 0, 200, 400 and 800 mg/kg body weight

Method of administration: Gavage

Test method: OECD TG 474

Comment: No significant increase in the incidence of micronucleated cells was observed at any dose level.

Result: The notified chemical was non clastogenic under the conditions of the test.

9.3.8 Dominant Lethal Test (Rosival and Szokolayová, 1985e)

Species/strain: Rats, Wistar

Number and sex of animals: 20 females, 10 males

Doses: 16.6mg/kg body weight (to males)

Method of administration: Orally by diet

Test method: OECD TG 478

Comment: This is a poorly reported study with no information on control procedures. No mortality in female rats was reported prior to autopsy. Increases in post-implant (0.7%) and total dominant lethality (1.9%) of foetuses were reported compared to controls but these were not deemed statistically significant.

Result: The notified chemical appears non mutagenic under the conditions of this test.

9.3.9 Teratogenicity (Rosival and Szokolayová, 1985f)

Species/strain: Mice, ICR strain

Number and sex of animals:	4 groups, 20 females per group
Doses:	0, 100, 200, 300 (or 400) mg/kg/day, days 6-15 of pregnancy.
Method of administration:	Gavage
Test method:	OECD TG 414
Comment:	This is a poorly reported study with contradictory information on doses. Additive and dislocated ossification nuclei and sternebrae dislocations were reported in both test and control groups. Differences were not deemed statistically significant. No statistically significant differences in numbers of nidations and live foetuses compared to controls were reported at any dose.
Result:	The notified chemical was neither teratogenic nor embryotoxic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical showed very low acute oral toxicity and low acute dermal and inhalation toxicity.

In a rat repeated dose skin irritation study, no signs of irritation or toxicity were seen in any animal at any timepoint. However, in a skin irritation study in the rabbit, significant and persistent erythema and oedema were observed in some animals indicating that the notified chemical is irritating to the skin. However, the magnitude of irritation was insufficient for hazardous classification. In contrast, an eye irritation study with the notified chemical in a single test animal revealed rapid irreversible tissue damage.

In a skin sensitisation study in guinea-pigs, the notified chemical induced positive allergic responses (mild, scattered erythema) at 24 and 48 hours in approximately one third of the test animals.

No mortality was observed in a repeat dose oral study in rats. Some high dose animals showed slightly decreased activity, cutaneous turgor and slightly to moderately reduced righting reflex. In addition, body weight gain was significantly reduced in males in this group. However, no treatment-related signs could be detected in recovery group animals during the second week post-treatment. Based on the incidence of mucosal hyperplasia of the duodenum, a NOAEL of 40 mg/kg/day was established for the notified chemical.

Two *in vitro* reverse mutation genotoxicity assays revealed the notified chemical to be non mutagenic. An *in vivo* dominant lethal test showed differences in resorptions and numbers of live foetuses but the differences were not statistically significant. Thus, mutagenicity could not be completely excluded. An *in vivo* mutagenicity test using *Tradescantia* plants also showed the notified chemical to be non mutagenic. An *in vivo* mammalian bone marrow cytogenetic test and micronucleus assay failed to show clastogenic effects. An *in vivo* cytogenetic test using seedlings was also negative. In a mammalian spot test, the notified

chemical was foetotoxic in a dose-dependent fashion and spot formation was observed in low and high, but not intermediate dose groups.

A study of teratogenic effects revealed the chemical to be neither teratogenic nor embryotoxic. Despite the predominance of negative results in genotoxicity tests, indications of embryotoxic and foetotoxic effects in the dominant lethal test and spot test of the notified chemical suggest that in vivo mutagenic and teratogenic properties cannot be excluded completely. The results are insufficient to warrant hazard classification for these toxicological endpoints.

On the basis of toxicity testing, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the notified chemical should be classified Irritant (Xi) with the risk phrases R36 - Irritating to Eyes and R43 - May Cause Sensitisation by Skin Contact.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. The notifier has supplied the following ecotoxicity studies.

Test	***Species***	***Results (Nominal) mg/L***	***References***
Acute Toxicity (Semi-Static Test) (OECD TG 203)	Rainbow Trout *(Oncorhynchus mykiss)*	96 h LC50 > 0.8 NOEC > 0.8	Wetton and Bartlett (1996)
Acute Toxicity - Immobilisation (StaticTest) (OECD TG 202 & EEC Directive 92/69)	Water Flea (*Daphnia magna*)	48 h EC_{50} = 0.1 NOEC = 0.02	Thun (1993)
Growth Inhibition - (Static Test) (OECD TG 201)	Green Algae (*Selenastrum capricornutum*)	EC_{50} < 0.013 NOEC < 0.013	Kroon (2000)
Growth Inhibition - (Static Test) (OECD TG 201	Green Algae (*Selenastrum capricornutum*)	E_rC_{50} > 0.495 E_bC_{50} > 0.495 NOEC ≥ 0.495	Mayer and Oldersma (2000)

* NOEC - no observable effect concentration

Fish (Oncorhynchus mykiss)

Twenty fish (in two groups of ten) were exposed to a single nominal concentration of 0.8 mg/L of CYASORB UV-3853 in duplicate. During preliminary solubility investigations, precipitation of the test material was observed at 1.0 mg/L. The test concentration of 0.8 mg/L was the highest attainable test concentration that could be prepared given the low solubility of the test material and having due regard to the amount of auxiliary solvent

permitted in the study under OECD Guidelines. Tetrahydrofuran (at 100 µL/L) was selected as an auxiliary solvent, as it was found to give the best testable dispersion of the test material in water. The experimental design is said to conform to a "Limit test", to confirm that at the highest attainable test concentration of 0.8 mg/L, no mortalities or sub-lethal effects were observed. A semi-static test regime was employed involving a daily renewal of the test preparations. No mortalities or other significant adverse effects were observed at 0.8 mg/L. An estimate of the LC_{50} values was given by inspection of the mortality data.

Aquatic Invertebrates

Daphnia magna were exposed for 48 hours to 8 concentration levels of CYASORB UV-3853, with 4 replicates of 5 animals in each level. The testing facility was unable to develop a reliable analytical technique for determining the solubility of the test material in water, and after investigation estimated the limit of solubility to be 0.5 mg/L. Serial dilution of a saturated solution, assumed to have a maximum solubility of 0.5 mg/L, allowed preparation of a further 7 concentration levels ranging down to 0.0005 mg/L.

The 48 hour NOEC and EC_{100} values were observed to be 0.02 mg/L and 0.5 mg/L, respectively, and were based on the assumption of a limit of solubility for the test material of 0.5 mg/L. The 48 hour EC_{50} value is in between these two values and the testing facility calculated the EC_{50} to be 0.1 mg/L, based on the geometric mean value of the NOEC and EC_{100}.

In comparison to the control group, no obvious abnormalities were seen at or below a concentration of 0.02 mg/L, which is considered to represent the NOEC of the test substance. At time 48 hours, in all concentrations, singular animals displayed a tendency to stay towards the top of the test medium.

Algae

An algal growth inhibition test was carried out using the species Selenastrum capricornutum. A stock solution prepared from 250 mg CYASORB UV-3853 in 500 mL test medium, was mixed and filtered and used to prepare 3 replicates for each of 5 nominal concentration levels ranging from 0.5 mg/L (assumed limit of solubility) down to 0.013 mg/L. All test levels inhibited growth completely and therefore the EC50 and NOEC values could not be determined. An expert statement (Verhaar, 2000) suggests that a totally inappropriate method was used to determine the amount of test material dissolved in water from a saturated solution of the test material (ie 0.5 mg/L) and that no, or a very insignificant fraction of the nominal amount of test material, was available for uptake by any organisms. It is proposed that this study and the fish and daphnia studies were performed at concentrations that are orders of magnitude higher than the aqueous solubility of the test material. The deduction was made that the effects observed in this study and the daphnia study, are of a physico-chemical nature instead of a 'classic' aquatic toxicological nature.

A further algal toxicity test was submitted using a much more dilute stock solution to prepare test concentrations, as recommended by the German competent authorities. CYASORB UV-3853 (2.5 mg) was weighed into 5 litres of test medium, mixed filtered and used to prepare a test substance loading rate series of 0, 5.5, 18, 56, 178 and 495 µg/L. It is noted that whereas the filtered stock solution prepared in the first study was opaque (turbid), the filtered stock solution in the second study was clear. However, determination of the concentration of the test solutions by chemical analysis was yet again not performed, as a test method for

analysing the substance at the low levels involved was not available. It is expected that concentrations would decline over time due to absorption to the vessels and algae. CYASORB UV-3853 did not inhibit the growth of algae for loading rates up to 495 μg/L, and it was thus observed not to inhibit algal growth near its aqueous solubility limit. The results from the second test support the finding that physical fouling may be a cause for the apparent toxicity to alga in the first test and Daphnia.

Micro-organisms

Assessment of the toxic effect of the notified chemical on sewage sludge micro-organisms using the method described in OECD TG 209 'Activated Sludge Respiration Inhibition Test' could not be performed, due to the insoluble nature of the test material. Therefore, a Toxicity Control (CYASORB UV-3853 plus sodium benzoate, equivalent to 30 mg carbon/L), was included in the Ready Biodegradability Study to assess any toxic effect of the test material on the sewage sludge micro-organisms. The Toxicity Control attained 48% degradation after 14 days, thereby passing the validation criteria of ≥ 25% degradation by day 14, confirming that the test material was not toxic to the sewage treatment organisms used in the study. It is noted that % degradation of the Toxicity Control did not increase after day 14 and remained at 48% by day 28, whereas duplicate Controls containing sodium benzoate alone (equivalent to 10 mg carbon/L), reached an average of 79% degradation by day 14 and 89% degradation by day 28. This suggests that either CYASORB UV-3853 has a significant inhibitory affect on micro-organisms in sewage sludge, or as the testing laboratory suggests, the sewage micro-organisms were unable to degrade both the sodium benzoate and test material simultaneously.

Conclusion

The ecotoxicity data for CYASORB UV-3853 indicate that based on the conditions of the individual tests, the chemical is not toxic to fish up to the apparent limit of its water solubility. Although an initial test for alga indicated that the substance is highly toxic to algae, a subsequent test indicates that the substance is not toxic to algae up to the apparent limit of its water solubility. This supports the findings that the effects observed for daphnia and in initial algae studies may be of a physico-chemical nature and not due to classic aquatic toxicity. CYASORB UV-3853 may be toxic to sewage sludge micro-organisms at a concentration equivalent to 20 mg carbon/L. However, as the actual test concentrations are not accurately known, further tests involving analytical determination of test concentration levels would be required if there was to be increased exposure of CYASORB UV-3853 to the aquatic compartment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as a UV light stabiliser for plastics. Once incorporated into these products, the notified chemical is expected to remain within the product matrix and share the fate of the articles into which it is incorporated. Articles are anticipated to be disposed of either to landfill or by incineration. In landfill, it is expected that the notified chemical will remain immobile within the plastic polymer matrix. Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon and nitrogen.

Waste from residual material in plastic import bags (up to 200 kg/yr notified chemical) will be disposed of to landfill where the notified chemical is expected to be immobile, due to the

low water solubility. Production waste (up to 6 tonnes/yr notified chemical) will be disposed of to landfill where the notified chemical is expected to remain immobile within the plastic polymer matrix. Hence, despite the uncertainty regarding toxicity to daphnia and algae, the overall environmental hazard of the chemical with the usage patterns described by the notifier can be rated as low, given the low environmental exposure.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

Toxicological data have been provided for the notified chemical. The notified chemical was shown to possess very low oral and low dermal and inhalation acute toxicity. A skin irritation test revealed irritant properties although the magnitude of irritation was insufficient for hazardous classification. In contrast, an eye irritation study in a single test animal revealed rapid irreversible tissue damage warranting a hazardous classification (Xi) and the risk phrase R36 – Irritating to eyes according to the NOHSC *Approved Criteria* (NOHSC, 1999).

Positive allergic responses were observed in one third of guinea-pigs in a skin sensitisation study. Thus, the notified chemical is also assigned the risk phrase R43 – May cause sensitisation by skin contact according to the NOHSC *Approved Criteria* (NOHSC, 1999).

Although the majority of mutagenicity assays for the notified chemical were negative, non-statistically significant positive effects were observed in a single *in vivo* dominant lethal test. Thus, mutagenicity could not be completely excluded. A study of teratogenic effects revealed the chemical to be neither teratogenic nor embryotoxic. However, in a similar fashion to mutagenicity, evidence of embryotoxic and foetotoxic effects in a dominant lethal test and spot test show that *in vivo* teratogenic properties cannot be excluded.

A repeat dose oral study in rats revealed mucosal hyperplasia of the duodenum. On this basis, a NOAEL of 40mg/kg/day was established.

Occupational Health and Safety

The notified chemical will not be manufactured in Australia but imported in plastic bags in fibreboard cartons. Occupational exposure to the notified chemical is unlikely during import, transport and storage and would only be envisaged following accidental puncture of the cartons and plastic bags. If exposure does occur, skin irritation and severe eye irritation is possible. Containers remain unopened prior to use so exposure of transport and storage workers to the notified chemical is unlikely. Thus, the health risk for these workers is low.

The notified chemical will be incorporated firstly into an extrusion masterbatch or immediately into moulded articles at two customer sites. Dermal and ocular exposure of process workers to the notified chemical may occur from spillage during initial weighing, blending and manual loading of the extrusion hopper with the imported product granules. Similar exposure to the notified chemical is possible but less likely during packing and later use of masterbatch granules. At this point, the notified chemical will be embedded within a polymer matrix. In addition, inhalation exposure is possible from fugitive dusts generated from loading the hopper and packaging of masterbatch granules or from vapours liberated from the hot extrusion process.

Maintenance workers and laboratory technicians are likely also to experience dermal contact with the notified chemical during routine machinery upkeep and quality analysis testing.

Adverse health effects could occur after exposure to the notified chemical. Ocular exposure is likely to be associated with severe irreversible eye damage. Dermal exposure may induce skin irritation and in the long term, skin sensitisation. The dermal sensitisation potential also suggests the possibility of respiratory sensitisation following repeated inhalation. However, the risk of adverse effects is mitigated by the granular nature of the notified chemical is the imported product.

Notwithstanding the seriousness of dermal and in particular ocular irritation, the unpredictable nature of allergic reactivity and long-term consequences of occupational sensitisation indicate that contact with the notified chemical is to be prevented. For these reasons, it is essential that exposure is controlled through engineering controls such as local exhaust ventilation at loading and packaging points and at hot sections of the extruder and secondarily by the use of personal protective equipment.

Following extrusion, the notified chemical will be immobilised in a polymer matrix. In this form, it is essentially unavailable for absorption and thus the health risk to workers from the notified chemical after extrusion would be negligible.

Public Health

The potential for public exposure to CYASORB UV-3853 Light Stabiliser during all phases of its life cycle is considered to be very low. The notified chemical will not pose a significant risk to public health when used in the proposed manner.

13. RECOMMENDATIONS

It is recommended that the following health hazard classification be referred to the NOHSC Hazardous Substances Sub-committee for consideration: R36 - Irritating to Eyes, R43 - May Cause Sensitisation by Skin Contact and S24 - Avoid Contact with Skin.

To minimise occupational exposure to CYASORB UV-3853 Light Stabiliser, the following guidelines and precautions should be observed:

- Skin contact with the notified chemical should be prevented during occupational use;
- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified chemical. Where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an organic vapour negative pressure respirator should also be used;
- Spillage of the notified chemical should be avoided. Spillages should be swept up and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. In particular, clarification of the algal toxicity would be required if a new use resulted in greater contamination of the aquatic compartment. No other specific conditions are prescribed.

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Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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

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