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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Sulphonium, diphenyl[4-(phenylthio)phenyl]-, (OC-6-11)-hexafluoroantimonate(1$^-$) (Substance B in Cyracure UVI-6974)

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Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

ASSESSMENT REPORT/FULL PUBLIC REPORT

Sulphonium, diphenyl[4-(phenylthio)phenyl]-, (OC-6-11)-hexafluoroantimonate(1$^-$)
(Substance B in Cyracure UVI-6974)

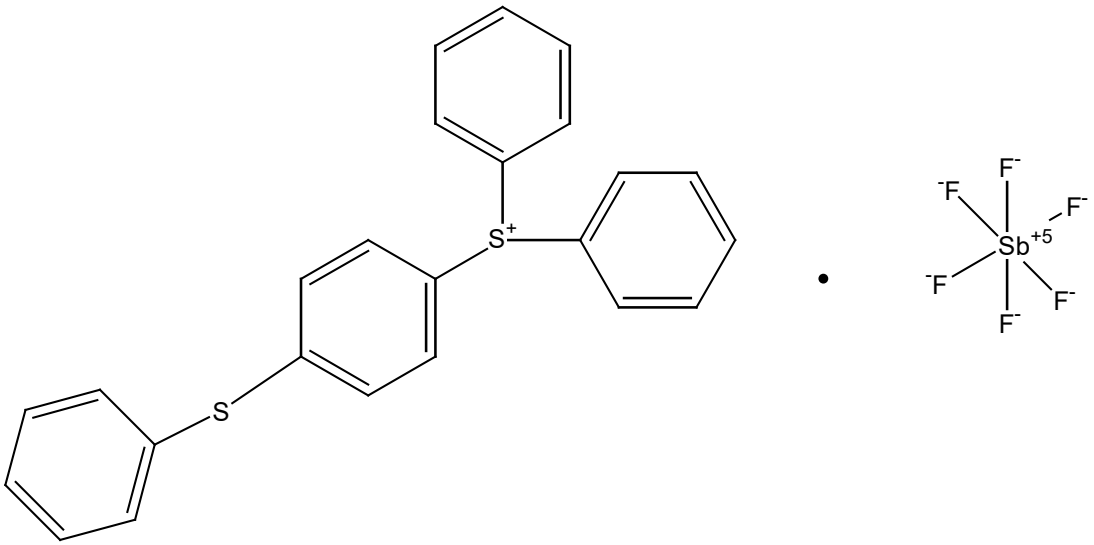
1. APPLICANT

Union Carbide Chemicals (Aust) Pty Ltd of 1002 High Street Armadale Victoria 3143 has submitted a limited notification statement in support of their application for an assessment certificate for Substance B in Cyracure UVI-6974.

The notifier did not make any claim for exempt information.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	Sulphonium, diphenyl[4-(phenylthio)phenyl]-, (OC-6-1l)-hexafluoroantimonate(1$^-$)
Chemical Abstracts Service (CAS) Registry No.:	71449-78-0
Other Names:	Substance B
	Antimonate(1$^-$), hexafluoro-, (OC-6-11)-, diphenyl[4-(phenylthio)phenyl]sulphonium
	Antimonate(1$^-$), hexafluoro-, diphenyl[4-(phenylthio)phenyl]sulphonium
	Sulphonium, diphenyl[4-(phenylthio)phenyll-, hexafluoroantimonate(1$^-$)
	(4-Thiophenoxyphenyl)diphenylsulphonium hexafluoroantimonate
	(*p*-Thiophenoxyphenyl)diphenylsulphonium hexafluoroantimonate
	4-(Phenylthio)phenyldiphenylsulphonium hexafluoroantimonate
	Diphenyl(4-phenylthiophenyl)sulphonium hexafluoroantimonate
	Diphenyl(p-thiophenoxyphenyl)sulphonium hexafluoroantimonate
	Diphenyl[p-(phenylthio)phenyllsulphonium

	hexafluoroantimonate *S,S*-Diphenyl-S-4-thiophenoxyphenylsulphonium hexafluoroantimonate
Marketing Name:	Cyracure UVI-6974 (containing up to 24 % of the notified chemical) Quartz Cationic Lacquer, the Mirage ink to be imported (containing up to 1.2% of the notified chemical)
Molecular Formula:	$C_{24}H_{19}S_2.F_6Sb$
Structural Formula:	
Molecular Weight:	607.3 g/mol
Method of Detection and Determination:	Infra-red, ^{1}H-, ^{13}C-NMR spectroscopy, and HPLC
Spectral Data:	Major IR absorbance peaks were observed at 3000, 1800, 1480, 1400, 1200, 1120, 1060, 680, and 575 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is a major constituent of a UV-curable ink (24 %). The physico-chemical properties discussed below are for the product Cyracure UVI-6974, which contains up to 24 % of the notified chemical in propylene carbonate.

Appearance at 20°C and 101.3 kPa:	Transparent, clear amber liquid with a mild odour.
Boiling Point:	258 °C
Density:	1.4046 g/cm^3 at 22.1 °C

Vapour Pressure:	$9 \pm 2 \times 10^{-3}$ kPa at 25°C (static technique)
Water Solubility:	0.59 g/L at 19.0-19.5 °C (for notified chemical)
Partition Co-efficient (n-octanol/water):	HPLC components of Cyracure UVI-6974 were: log P_{OW} = 2.61, 3.04 and 4.09 .
Hydrolysis as a Function of pH:	Not determined (see comments below)
Adsorption/Desorption:	Not determined (see comments below).
Dissociation Constant:	Not determined (see comments below).
Particle Size:	Not applicable as Cyracure UVI-6974 is a liquid
Flash Point:	90 °C (closed cup method).
Flammability Limits:	Not highly flammable in contact with diatomite.
Autoignition Temperature:	455 °C
Explosive Properties:	Not explosive.
Reactivity/Stability:	Not reactive unless treated with UV light.

Comments on Physico-Chemical Properties

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

Vapour pressure was determined using the static method (OECD No. 104). The vapour pressure cited indicates that the notified chemical is considered to be volatile (Mensink *et al.,* 1995). This volatility is likely to be due to the presence of propylene carbonate.

Water solubility of the notified chemical was determined by the flask method (OECD TG 105).

Hydrolysis was not performed. The notifier has stated that no hydrolysable functionality exists in the notified chemical. The notified chemical is not expected to undergo hydrolysis in the environmental pH range of 4 to 9.

The test substance containing the notified chemical is a mixture of at least 9 components (unidentified). The partition coefficient was therefore determined using HPLC (using a draft method for OECD Guideline No. 117). The pattern of the chromatogram showed three different peaks namely $\log_W P$ = 2.61, 3.04 and 4.09. These values suggest strong partitioning to the oil phase or organic matter.

Adsorption/desorption was not determined but in spite of the moderate water solubility, the log P_{ow} range suggests the notified chemical may slowly leach through the soil profile although electrostatic attraction between the polymer and soil colloidal material may further mitigate mobility. The rate and extent of leaching will depend, in part, on soil texture, organic matter content, clay mineralogy and rainfall.

The dissociation constant was not determined. However, the notified chemical is a salt which is expected to fully dissociate in the aquatic environment.

No detectable amount of the hexafluoroantimonate salts was dissolved in the standard fat and therefore the product was determined to be immiscible with liquefied standard fat.

4. PURITY OF THE CHEMICAL

Degree of Purity: 98 %

Hazardous Impurities: None identified.

Non-hazardous Impurities (> 1% by weight):

Chemical name: Triphenylsulfonium hexafluoroantimonate
CAS No.: 57840-38-7
Weight percentage: < 2 %

Formulated Ingredients Constituents of Cyracure UVI-6974

Chemical name: $C_{24}H_{19}S_2.F_6Sb$ (the notified chemical)
Synonyms: Substance B
CAS No.: 71449-78-0
Weight percentage: Typical 12 %; 2 % > wt > 24 %

Chemical name: $C_{36}H_{28}S_3.2F_6Sb$
Synonyms: Substance A (notified separately in NA /792)
Weight percentage: Typical 38 %; 26% > wt > 48 %
CAS No.: 89452-37-9
Health Effects: Skin sensitiser

Chemical name: Propylene Carbonate
Weight percentage: (typical 50%); 48 % > wt > 52 %
CAS No.: 108-32-7
Health Effects: Eye irritant (NOHSC, 1999a)

5. USE, VOLUME AND FORMULATION

Use
The notified chemical is a constituent of a photoinitiator, Cyracure UVI-6974 and is present at a maximum concentration of 24 %. Cyracure UVI-6974 is a minor constituent (5%; 1-2 % notified chemical) of an ink (Quartz Cationic Lacquer) manufactured in the UK and to be imported by Union Carbide. The ink is used in formulation as an UV coating, which is applied to a substrate and then cured on a machine to provide an UV-coated article. The other components of the ink are mixed triarylsulfonium hexafluoroantimonate and cycloaliphatic diepoxide (CAS No. 2386-87-0; 50-90 %; Xi; R43). The coatings are used in the labeling and decoration of various containers used in the packaging of beverages, pharmaceuticals and cosmetics. This photoinitiator will be used at the printing site initially. It will not be sold to the public and will only be used for industrial applications. No manufacture or formulation will occur in Australia.

Volume
The annual import volume is 500 kg of the notified chemical for the first five years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The Quartz Cationic Lacquer, containing 1-2% of the notified chemical, will be imported in 20 L metal pails. Transport and storage workers will only be exposed to the notified chemical if the packaging is breached.

End Use
The end-use ink will be delivered directly to the customer's site. No repackaging will be carried out. The typical number and category of workers with a potential to be exposed to the notified chemical is shown in the table below.

Category of Workers	Max. Number Exposed	Type of Exposure	Max. duration of Exposure
Transport and Storage:	10-15	Dermal	Only in event of accident/spill
Manual dispensing of ink; occasional wash-up of rollers and ducts; loading of empty drums into washing machine	7	Dermal / Inhalation	3 hr/day 260 days/yr
Disposal of waste ink; washing machine water	2	Dermal	0.5 hr 26 days/yr

The ink is manually dispensed by the operator directly from the 20 kg container into the ink duct attached to the printing machine. Ink is then transferred by the anilox roll to the printing plate cylinder, which in turn transfers the ink image onto the substrate being printed. The printed substrate subsequently travels a distance of *ca.* 60 cm before being exposed to a

protected UV light, which acts to solidify and cure the ink. The printing and curing process occurs within a closed system.

Dermal exposure to the notified chemical may occur during the manual dispensing of ink. Inhalational exposure to the notified chemical may occur if mists are generated during dispensing. To prevent skin and eye contact, personnel are required to wear Personal Protective Equipment (PPE) in the form of long sleeved overalls, safety glasses and PVC gloves while handling the ink. In instances of high vapour or mist concentrations, self-contained breathing apparatus is used.

Once the printing substrate is coated and cured, the notified chemical will be bound within the printed matrix and not available for exposure.

Washing Operations
The 20 kg ink containers are cleaned by scraping out the remaining ink into the printing equipment. The containers are cleaned in a water-based washing machine and are disposed of in solid waste bins. Occasionally, the anilox rollers and ink ducts are cleaned in the washing machine. Dermal exposure to the notified chemical may occur when handling the waste liquors and personnel wear PPE in the form of long sleeved overalls, safety glasses and PVC gloves to safeguard against possible exposure.

7. PUBLIC EXPOSURE

The notified chemical will be used in a closed industrial process and will not be sold to the public. The public may come into contact with packaging printed using the UV-curable ink. However, once coated and cured, the articles will no longer contain the notified chemical, Public exposure to the notified chemical during transport, printing process and on finished paper goods is considered to be very low.

8. ENVIRONMENTAL EXPOSURE

Release

Release is expected to occur as drum residues, during equipment cleaning, during manual transfer and as a result of disposal of printed articles.

The notifier has indicated that approximately 0.5 % of the notified chemical is expected to remain as residue in import drums. Assuming an annual import volume of 500 kg, up to 2.5 kg of the notified chemical may be released per year as drum residues.

A further 0.15 % of the notified chemical will remain on the rollers and within ducts. This residue will be released during cleaning of the equipment. Assuming an annual import volume of 500 kg, up to 0.75 kg of the notified chemical may be released per year in wash water.

The notifier has not indicated the potential for release during manual decanting of the notified chemical from import drums to the application equipment. However, it is expected this release to be no greater than 3 % per annum. Assuming an annual import volume of 500 kg, this represents a release volume of up to 15 kg per year.

There was no indication by the notifier regarding the nature (*e.g.* plastic, glass, bottles, paper/plastic labels) or fate of the printed articles. Accordingly, it is assumed that all printed articles will be discarded and not recycled. It is estimated that up to 96 % of the notified chemical (in a cured state) may ultimately be released in this way.

Fate

Import drums will be washed prior to their disposal to landfill. The notifier has indicated that all wash waters (from equipment and drum cleaning, and spills) will be collected in a 200 L drum and disposed of to a licensed waste contractor. The notified chemical will be mixed with other waste which is physically separated by precipitation, centrifugation and flocculation processes. Solids are encapsulated in cement and disposed of to landfill. Remaining liquids are then treated via a two-stage aerobic activated sludge process. Solids are dried and encapsulated in cement. The supernatant is then discharged to the sewer (North Head sewage works). A predicted environmental concentration (PEC) has been calculated (0.013 μg/L). The adsorption/desorption potential of the notified chemical was not determined. However, as noted previously, in spite of the moderate water solubility, the log P_{ow} range suggests the notified chemical may be expected to slowly leach through the soil profile although electrostatic attraction between the chemical and soil colloidal material may further mitigate mobility.

The notified chemical was not examined for biodegradation potential. However, given its lack of functionality, it is not expected to be readily biodegradable.

The bioaccumulation potential of the notified chemical was not investigated. However, the high molecular weight (607.3g/mol) and limited release of the notified chemical indicate to the aquatic compartment that significant bioaccumulation is not expected.

The nature of printed articles (containing the notified chemical) is unknown and it is therefore difficult to predict their fate. It is assumed that the majority of the notified chemical will be ultimately discarded to landfill. The notified chemical contained within the cured ink matrix would be expected to slowly degrade via biotic and abiotic processes.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

No toxicological data were provided for the notified chemical. However, several studies were provided for Cyracure UVI-6974, which contains up to 24 % of the notified chemical. The other components of Cyracure UVI-6974 are (i) mixed triarylsulfonium hexafluoroantimonate salts (<2 %; Xi; R43; R50-53) and (ii) propylene carbonate (~50 %).

Summary of the Acute Toxicity of Cyracure UVI-6974

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Reijnders, 1988a)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Reijnders, 1988b)
skin irritation	rabbit	Skin irritant	(Daamen, 1988a)

eye irritation	rabbit	Non-irritant (possible eye irritation potential for hexafluoroantimonate salts when not in 50:50 solution with propylene carbonate)	(Daamen, 1988b)
skin sensitisation	guinea pig	skin sensitiser	(Daamen, 1988c)

9.1.1 Oral Toxicity (Reijnders, 1988a)

Species/strain:	Wistar rats
Number/sex of animals:	5 / sex
Observation period:	14 day
Method of administration:	Gavage, dose level 5000 mg/kg bw; test substance administered as supplied
Test method:	OECD TG 401, limit test
Mortality:	None.
Clinical observations:	No signs of toxicity were observed during the observation period. All animals showed normal body weight gain.
Morphological findings:	No abnormalities were found as a result of treatment.
LD_{50}:	LD_{50} > 5000 mg/kg
Result:	The test substance was of very low acute oral toxicity in rats under the test conditions.

9.1.2 Dermal Toxicity (Reijnders, 1988b)

Species/strain:	Wistar rats
Number/sex of animals:	5 / sex
Observation period:	14 days
Method of administration:	Single dermal dose; dose level 2 000 mg/kg bw; semi-occlusive patch, 24 h exposure; test substance administered as supplied
Test method:	OECD TG 402
Mortality:	None.

Clinical observations: No signs of toxicity or skin irritation were observed during the observation period. All animals showed normal body weight gain.

Morphological findings: No treatment-related changes were observed.

LD_{50}: LD_{50} > 2000 mg/kg for both males and females

Result: the test substance was of low dermal toxicity in rats at 2000 mg/kg.

9.1.3 Skin Irritation (Daamen, 1988a)

Species/strain: rabbit / New Zealand White

Number/sex of animals: 3 female

Observation period: 7 days

Method of administration: Semi-occlusive dressing to flank skin, single dose, 500 µL for 4 hours

Test method: OECD TG 404

Draize scores

Time after treatment (days)	***Animal #***		
	1	***2***	***3***
Erythema			
1 day	1[a]	1	1
2 days	1	1	1
3 days	0	1	0
7 days	0	0	0

[a] see Attachment 1 for Draize scales

Comment: Slight erythema was observed in all three animals; on the edges of the treated skin in animal one, and on 80 % of the treated skin for animals two and three. The erythema was resolved in two animals by day 3, and in the third between days 3 and 7. The calculated Primary Irritation Index was 0.7. No Oedema was observed in any of the animals.

Result: the notified chemical was slightly irritating to the skin of rabbits

9.1.4 Eye Irritation (Daamen, 1988b)

Species/strain: rabbit / New Zealand White

Number/sex of animals: 3 female

Observation period: 14 days

Method of administration: 100 µL test substance instilled into conjunctival sac of left eye of each animal.

Test method: EEC method B.5, as described in *Methods for Determination of Toxicity: "Acute Toxicity – eye irritation", Annex of EEC Directive 84/449/EEC (1984).*

Draize scores:

	Time after instillation														
Animal	***1 day***			***2 days***			***3 days***			***7 days***			***14 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	0			0			0			0			0		
2	0			0			0			0			0		
3	0			0			0			0			0		
Iris															
1	0			0			0			0			0		
2	0			0			0			0			0		
3	0			0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	1	3	1	1	1	1	0	0	1	0	0	0	0	0
2	2	1	1	2	1	1	1	0	0	1	0	0	0	0	0
3	2	1	1	1	1	1	1	0	0	1	0	0	0	0	0

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

Comment: Adverse effects were observed on the conjunctivae only. Approximately 1 hour after exposure, all three animals showed slight conjunctival redness and two animals slight chemosis. The slight conjunctival redness noted increased to diffuse in all three animals. Between days 7 and 14, the redness resolved in all three animals. Slight chemosis was observed in the third animal by day 1. The chemosis resolved in all three animals by day 3.

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

9.1.5 Skin Sensitisation (Daamen, 1988c)

Species/strain: Guinea pig/ Dunkin-Hartley White

Number of animals: 30 female (20 test, 10 control)

Test method: OECD TG 406, Magnusson & Kligman Maximisation Test

Induction procedure: Intradermal injections of test substance (5 % w/w) in propylene glycol, followed by epicutaneous application of the test substance (50 % in propylene glycol).

test group:

day 0

A: 100 µL test substance in propylene glycol (5 % w/w)
B: Three pairs of injections, consisting of 100 µL Freunds Complete Adjuvant (FCA) with emulsified with 100 µL distilled water
C: 100 µL test substance (10 % w/w in propylene glycol), emulsified with 100 µL distilled water

day 7

Animals were exposed topically to *ca.* 500 µL (50 % in propylene glycol). The area was secured by dressings (2 days) and then scored.

control group:

day 0

A: 100 µL vehicle alone (propylene glycol)
B: 100 µL FCA with 100 µL distilled water
C: 100 µL FCA, emulsified with 100 µL propylene glycol.

day 7

The skin of the shoulder was re-shaved and propylene glycol (500 µL) was applied topically. The area was secured by dressings for 2 days.

Challenge procedure: Three test concentrations of 10, 25 and 50 % w/w were used.

day 21

The test substance (50 µL in propylene glycol) was applied to each animal at four different concentrations (0, 10, 25 and 50 %). The bandages were kept in place for 24 hours, then removed and the area scored.

Challenge Outcome (total animal values given):

	Test animals		***Control animals***	
Challenge concentration	***24 hour****	***48 hour****	***24 hour****	***48 hour****
10 %	4/20 **	9/20**	0/10	0/10
25 %	6/20	11/20	0/10	0/10

50 %	9/20	11/20[#]	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response (≥grade 2)
\# many sites showed scaliness and on one occasion, brownish discolouration was observed

Comment: After challenge, twelve animals showed a positive response (grade 2 or more) in reaction to the 50 % concentration, eleven animals showed a positive response in reaction to the 25 %, and nine animals to the 10 % concentration. Three control animals showed red spots in reaction to one or two of the concentrations tested.

Result: A sensitisation rate of 60 % was obtained, indicating that the notified chemical was moderately sensitising to the skin of guinea pigs

9.2 28-Day Repeated Dose Oral Toxicity (Reijnders, 1989)

Species/strain: rat / Charles River Sprague-Dawley

Number/sex of animals: 5 / sex/ dose

Method of administration: Oral (gavage)

Dose/Study duration: 0, 300, 600 or 1000 mg/kg/day for 28-days

Test method: OECD TG 407

Mortality: There were no deaths during the study.

Clinical observations: No definitive signs of ill-health associated with treatment were noted during the course of the study, with the exception of hair loss in 3 males receiving 600 and 4 at 1000 mg/kg/day. No hair loss was observed for females.

On days 21 and 27, body weights of males receiving 600 or 1000 mg/kg/day were statistically significant lower than controls and persisted over the study period. The body weight gain was statistically significantly reduced in these males. The body weights of all other groups were similar to control groups. There was no observable difference in food intake between the groups.

Haematology: Statistically significant increase in white blood cell counts in comparison with controls were noted in females receiving 600 mg/kg/day, however this was considered the result of abnormally low control value and not of biological

significance. Small but statistically significant neutrophil counts were observed for females receiving 1000 mg/kg/day *cf.* to controls.

Blood Chemistry:

Statistically significant increases in serum alkaline phosphatase levels (ALP) were noted for males receiving 600 or 1000 mg/kg/day. ALP increases were also noted in these dose groups for females. Slight increases in serum Ca^{2+} and PO_4^{3-} concentrations were noted

Blood serum lactate dehydrogenase and creatine kinase activities were significantly lower for males receiving 600 and 1000 mg/kg/day. These levels were also lower for females at receiving 1000 mg/kg/day.

Small but statistically significant decrease in glucose levels, were noted in females receiving 1000 mg/kg/day.

Pathology:

Macroscopic observation at the termination of the study showed a swollen intestine in 3 males receiving 1000 mg/kg/day (one also showing a swollen stomach with hairy content).

A statistically significant decrease in lung weights was observed in the males receiving 600 and 1000 mg/kg/day *cf.* the controls. After adjusting for body weight changes, there were no other statistically significant differences in organ weights.

Microscopic observation of male rats receiving 1000 mg/kg/day showed congestion of swollen intestine in one rat and dilation of the lumen in another.

Comment:

A primary effect of the notified chemical found was the decrease of body weight in males. The increase in alkaline phosphatase levels may be related to swollen intestine or stomach, as the study author reported that damage of the gastrointestinal epithelium is known to be a possible source of enhanced levels.

Result:

The NOAEL was 300 mg/kg/day, based on decreases in body weight gain and significant increases in ALP of blood serum. The ALP increases may be indicative of intestinal effects observed in male rats at 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Enninga 1988a)

Strains:	*S. typhimurium* strains: TA 98, TA 100, TA 1535, TA 1537
Concentration range:	0, 1, 3, 10, 33, 100 μg/plate
Metabolic activation:	With and without rat liver S9 from animals pretreated with Aroclor 1254
Test method:	OECD TG 471
Comment:	In the preliminary toxicity test, the test substance was cytotoxic at and above 333 μg/plate, with and without S9. The notified chemical was tested with and without metabolic activation over a low dose range (to 100 μL/plate). Positive dose-related, 2.6-31-fold increases in the number of revertant (His^+) colonies were found in the strains TA 98, TA 100 and TA 1535. Both negative and positive controls scored within expected ranges.
Result:	The test substance was mutagenic at low doses (3-100 μL/plate) both in frameshift and base-pair detecting strains.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Enninga, 1988b)

Species/strain:	Swiss mice
Number and sex of animals:	15 / sex/dose
Doses:	1000 mg/kg
Method of administration:	Single oral (gavage)
Test method:	OECD TG 474
Comment:	In a preliminary dose-finding study, 3 males and 3 females were given a single oral dose of 500, 1000, 1500, 2000 and 5000 mg/kg, resulting in substantial attrition rates 24 hour - post dosing. All mice within the 5000 mg group, 3 males and two females within the 2000 mg group and one male in the 1500 mg/kg died. One male in the 1000 mg group showed pilo-erection. Consequently, 1000 mg/kg dose was used for the main study.
Test Results:	The test substance did not induce any increase in the frequency of micronucleated polychromatic erythrocytes (MN) above the negative control level. Both sexes treated with positive control Cyclophosphamide showed an increase in the incidence of micronuclei in polychromatic erythrocytes.

Result: The test substance was non-mutagenic under the stated conditions at 1000 mg/kg. However it is evident that the notified chemical is severely toxic above this dosage to Swiss mice.

9.4 Overall Assessment of Toxicological Data

Cyracure UVI-6974 was found to have very low acute oral and low dermal toxicity in rats, LD_{50} > 5000 mg/kg and > 2000 mg/kg respectively. It was slightly irritating to the skin and eyes of rabbits. A sensitisation rate of 60 % was obtained in a Maximisation test, indicating that Cyracure UVI-6974 was moderately sensitising to the skin of guinea pigs.

In a 28-day repeated dose oral study in rats, the no observable adverse effect level (NOAEL) was 300 mg/kg/day, based on decreases in body weight gain and significant increases in the ALP in blood serum. The ALP increases may be indicative of intestinal effects observed in male rats at 1000 mg/kg/day.

Cyracure UVI-6974 was mutagenic in the Ames Test in both frameshift and base-pair detecting strains, however was non-mutagenic in a mouse micronucleus assay at 1000 mg/kg.

Based on the toxicological data provided, Cyracure UVI-6974 is a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) and the risk phrase R43 - may cause sensitisation by skin contact is assigned.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

While ecotoxicity data are not required for chemicals imported in quantities of up to 1 tonne, the notifier has provided the following data for the mixture (Cyracure UVI-6974) containing the notified chemical.

Species	Test	Concentrations (mg/L)	Result (mg/L)
Guppy *Poecilia reticulata*	96 h acute	1.8, 3.1, 5.5, 9.9, 13.8, 17.6, 27.5	3.1< LC_{50} < 5.5 NOEC = 1.8
Water Flea (*Daphnia magna*)	48 h acute	0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10.0	EC_{50} = 0.68 NOEC = 0.32

The acute toxicity test for fish was carried out according to OECD TG 203. Results reported are actual and not nominal concentrations. At 96 hours, the highest test concentration resulting in 0 % mortality was 3.1 mg/L. At this concentration, a single fish was observed to be swimming at the bottom of the tank. The lowest test concentration resulting in 100 % mortality was 5.5 mg/L. These values indicate that the slope of the dose response curve is very steep. Probit analysis could not be undertaken on fish toxicity test due to the experimental design. Consequently, the EC_{50} values for this species could only estimated. From the data provided, it is estimated that the EC_{50} lies between 3.1 and 5.5 mg/L.

The acute immobilisation test for daphnia was carried out according to OECD TG 202. Although not stated, it is presumed that the test concentrations were actual and not nominal. EC_{50} values at 24 h and 48 h were calculated from the probits of the percentages of affected Daphnia and the logarithms of the corresponding concentrations using the maximum likelihood estimation method (Finney, 1971). Under the conditions of the study, 10 % immobilisation was not considered to be biologically significant (NOEC). Therefore, 0.32 mg/L was considered to be a close approximation of the highest test concentration resulting in 0 % immobilisation.

The ecotoxicity data indicate that the notified chemical is moderately toxic to fish and highly toxic to Daphnia.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The PEC has been calculated assuming that the notified chemical will be used at a single site, and that all waste from wash waters is released to the sewer system at North Head (390 ML capacity).

Import rate	500 kg/annum
Release rate (potential)	18.25 kg/annum
Release rate per day	0.05 kg
Volume of sewerage per day	390 ML
Volume released from sewage plant per day	0.128 µg/L

On release to receiving waters (after treatment at the sewage treatment plant), it is usually assumed that the effluent is diluted by a factor of 10. This gives a final PEC of 0.013 µg/L. Using Daphnia acute toxicity data, there is at least a 10 000 fold safety margin, keeping in mind the presence of the other notified substance in Cyracure. It should be noted that in the absence of adsorption/desorption data, it is assumed that all notified chemical treated by waste contractor and by sewage treatment plant will remain in the water column. In addition, release predictions are based on a maximum import volume of 500 kg per annum.

As a result, it is likely that the actual PEC will be considerably lower than that calculated above. Provided levels of release remain low, the notified chemical is not expected to pose a hazard to the aquatic environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
No toxicological information has been provided for the notified chemical and therefore the substance cannot be assessed against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b). However, several studies were provided for Cyracure UVI-6974, which contains up to 24 % of the notified chemical. Accordingly, Cyracure UVI-6974 has very low acute oral and low dermal toxicity in rats (LD_{50} of >5000 mg/kg and >2000 mg/kg, respectively). It is a slight skin and eye irritant in rabbits and a

moderate skin sensitiser in guinea pigs. In a 28-day repeated dose oral study in rats, the NOAEL was 300 mg/kg/day, based on decreases in body weight gain and significant increases in serum alkaline phosphatase (ALP) at high doses. Cyracure UVI-6974 was mutagenic in the Ames test but was negative in the *in vivo* mouse micronucleus test.

In accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999b), Cyracure UVI-6974 is a hazardous substance and the risk phrase R43 - may cause sensitisation by skin contact is assigned.

Workers who have become sensitised to inks containing the notified chemical, either by inhalation or skin exposure, should not continue to handle them in the workplace.

Occupational Health and Safety
The imported ink containing the notified chemical at 1-2 % is manually dispensed or decanted by the operator directly from a 20 kg container into the ink duct attached to the printing machine. There is a risk of skin sensitisation if skin contact occurs during these operations. There is also some risk of skin and/or eye irritation if dermal or occular exposure occurs during the handling of the ink products. To prevent skin and eye contact, printing operators should wear PPE in the form of long sleeved overalls, safety glasses and PVC gloves while handling the ink containing the notified chemical. Due to the risk of sensitisation and irritation, the generation of aerosol mists should be avoided, however, in instances of high vapour or mist concentrations, self-contained breathing apparatus is to be used. Once the printing substrate is coated and cured, the notified chemical will be bound within the printed matrix and not available for exposure.

Transport and warehouse personnel would only be exposed to the chemical in the event of a drum rupture. Therefore, the risk of skin sensitisation and irritation to these workers is low. Dermal exposure may also occur during the cleaning and maintenance of equipment, hence similar PPE should be worn during these operations to minimise the risk of skin and eye irritation and skin sensitisation.

Public Health
The notified chemical will be used in a closed industrial process and will not be sold to the public. The public may come into contact with packaging printed using the UV-curable ink. Since at this stage, coated and cured articles will no longer contain the notified chemical, public exposure to the notified chemical is considered to be negligible. Based on this information, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

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

- Avoid skin and eye contact with products containing the notified chemical;
- 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 3765.2 (Standards Australia, 1990) impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees;
- Workers who become sensitised to inks containing the notified chemical should not continue to handle them in the workplace; and
- That deficiencies in the MSDS for the ink, Quartz Cationic Lacquer, be rectified as follows:

  - Ingredient composition:
    Include the risk phrase R43 for Cyracure UVI-6974.

  - Add the following to S.3.1.2:
    "Workers who become sensitised should not continue working with this substance".

  - S.8:
    Replace entry for VENTILATION with the following:
    "Use under local exhaust ventilation. If ventilation inadequate, use self-contained breathing apparatus or respirator with organic vapour cartridge".

  - Remove last statement in S.11. This statement does not provide a description of health effects.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical and the product containing the chemical were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC (1994)]. However, deficiencies in the MSDS were noted and amendments recommended.

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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

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Standards Australia/Standards New Zealand (1994) AS 1336-1994, Australian Standard Eye Protection in the Industrial Environment. Standards Australia and Standards New Zealand: Sydney/Wellington.

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

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

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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