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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Quinone Methide in IRGASTAB® UV 22

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Identity and % Weight of Hazardous Impurities
Identity and % Weight of Non-Hazardous Impurities
Weight of Additives/Adjuvants
Import Volume
Identity of Customers and Sites where product will be used
Methods of Detection and Determination

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA
Canada
China
Europe
Korea
Japan (notified, not yet listed)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
CXA 6007
TKA 45000
Prostab 6007
Quinone derivative
Quinone methide

MARKETING NAME(S)
IRGASTAB® UV 22

SPECTRAL DATA

METHOD	Nuclear Magnetic Resonance, Infrared and Mass Spectroscopy
Remarks	Reference spectra were provided.
TEST FACILITY	Ciba Specialty Chemicals (1998a, b, c)

METHODS OF DETECTION AND DETERMINATION

METHOD	Various methods of chemical analysis for estimation of impurities.
Remarks	Reports provided.
TEST FACILITY	Ciba Additives (1998)

3. COMPOSITION

DEGREE OF PURITY
60 - 90 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Three hazardous impurities are present at levels below the concentration cutoffs that would render the notified chemical hazardous.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None.

ADDITIVES/ADJUVANTS
None in the notified chemical.

IRGASTAB® UV 22 contains the following acrylic monomer:

Chemical Name	Glycerol, propoxylated, esters with acrylic acid		
CAS No.	52408-84-1	*Weight %*	75 - 90 %

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported by sea as a 10 – 25% component of IRGASTAB® UV 22.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 1	< 1	< 1	< 1

USE
Stabiliser for inhibiting early polymerisation in UV curable inks and overprint varnishes and, therefore, helping to preserve shelf-life stability. The notified chemical is designed as a higher performance less hazardous alternative to existing substances.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Specialty Chemicals Pty Ltd
235 Settlement Road
Thomastown Victoria 3074

TRANSPORTATION AND PACKAGING
IRGASTAB® UV 22, a solution containing 10 - 25% notified chemical, is not manufactured in Australia but will be imported from Europe by sea in 25 kg robust UN approved (3H2) plastic jerricans with removable heads. The product is transported from the dockside to the Ciba Specialty Chemicals warehouse in Thomastown, where it is stored until required for dispatch to customers. The finished ink/varnish products will be packaged in 1 kg, 4 kg and 20 kg sealed cartons. The ink/varnish products will be distributed to numerous (up to 200) printing and coating premises around Australia.

The imported product is stored within the warehouse on sturdy racking until required for dispatch to customer sites. The product is not classified as a dangerous good for transport, so there are no special storage or transport requirements.

5.2. Operation description

IRGASTAB® UV 22 containing the notified chemical will be unloaded using a forklift from the shipping container at the Ciba Specialty Chemicals warehouse and stored in sturdy racks until required for dispatch to up to 6 customers based in Victoria and New South Wales. No repacking of the product is expected to take place.

For reformulation IRGASTAB® UV 22 will be added manually to a mixing vessel (typical size is 1000 litres) together with other substances (acrylate esters, acrylic monomers, photoinitiators and pigments) at a level of 0.2 to 1.5% by weight of the final formulation. The vessel contents will be thoroughly mixed for one hour before being drummed off into either 1 kg, 4 kg or 20 kg plastic pails. The final ink formulation containing up to 0.4% notified chemical will be sold to up to 200 end users for use in printing product labels (e.g. wine bottle labels, food pack labels) or non-flexible food packaging (e.g. fibreboard packaging).

The typical end user will be a printer or a coater, with applications varying from printing on non-flexible packaging to paper or label stock, e.g. flexographic or lithographic printing or roller coating.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport drivers	Up to 5	-	-
Warehouse operators	4 - 5	20 mins per unloading and loading	20 – 40 days per year
Blender operators	10 – 15	15 mins per manual pouring; 1 hour mixing time	50 – 100 days per year
Quality control staff	5 – 15	6 – 8 hours per day	50 – 100 days per year
Printer operators	200 – 400	8 hours per day	240 days per year

Exposure Details

Transport and storage

Waterfront, transport and warehouse workers are not expected to be exposed to the notified chemical except in the case of an accident involving spillage of the IRGASTAB® UV 22 containing the notified chemical. Spills are cleaned up by absorbing with liquid binding material (e.g. sand, diatomite, silica gel, acid binders, universal binders or sawdust) and recovered into containers for disposal in accordance with local government regulations.

Printing ink formulation

During printing ink/ varnish formulation there is possible dermal and ocular exposure of workers (blender operators) to drips, spills and splashes of IRGASTAB® UV 22 or formulated ink products containing < 0.4% of the notified chemical. Such exposure could occur during charging of the mixing tank, taking QC testing samples and when plant and equipment is cleaned or maintained. Engineering

controls such as enclosed mixing tanks are expected to be in place to minimise dermal/ocular exposure. Personal protective equipment (PPE) such as coveralls, eye protection and impervious gloves is expected to be worn by workers during this process.

During filling of pails, possible dermal/ocular exposure to ink products containing < 0.3% of the notified chemical may result from drips and spills when connecting filling lines, or during equipment malfunction. Workers will wear coveralls, eye protection and gloves to minimise exposure.

Maintenance workers and laboratory staff may also encounter dermal/ocular exposure during equipment maintenance and testing processes. To minimise exposure, coveralls or laboratory coats, eye protection and gloves are worn.

Inhalation exposure during formulation or filling of ink is unlikely as aerosols are not expected to be formed and exhaust ventilation systems are in place to control exposure to other components of the inks.

Ink/ varnish application
Dermal, ocular and inhalation exposure may occur during ink/varnish product application with the highest exposure during cleaning and maintenance of printers. The inking units are enclosed and the printing inks are distributed around the printing press through pump lines. Printing workers will wear coveralls, gloves and eye protection during printing and cleaning operations. The ink is either pumped or poured or scooped with a knife into the duct of the printing press. Residual ink is either poured or scooped out of the ink duct and stored in the original container for next time. The waste solvent from cleaning of presses is usually distilled by a waste recycler to purify and return. Waste rags and waste inks are usually disposed of through chemical waste removal specialists.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release of the notified chemical is expected during shipping and transport. During formulation of ink preparations, < 15 kg per annum of notified chemical waste will be generated, mainly from washing of mixing vessels and pump lines. Less than 10 kg per annum of the notified chemical will remain as residues in empty import containers. It is expected the imported jerricans containing residual product will be used to collect liquid waste and unused ink, which are collected by a licensed hazardous waste contractor. The liquid contents will be disposed of as described above and the jerricans with any residual solid will be disposed of to a licensed secure waste landfill site.

RELEASE OF CHEMICAL FROM USE
Release from the use of printing ink is estimated at < 50 kg per annum notified chemical.

Printers are cleaned periodically with a blend of ethanol, isopropanol and ethyl acetate solvent and waste from this process will be collected for solvent reclamation. The resulting solid will be disposed of to landfill. It is expected that formulation equipment will be cleaned in a similar manner with the resulting wastes disposed of as described above.

5.5. Disposal

The majority of the notified chemical will be applied to various paper and fibreboard substances which, at the end of their useful life, will be disposed of to landfill.

The wastes derived from the cleaning of formulation equipment, printing equipment and imported empty containers will be disposed of to landfill. Due to the low water solubility, the notified chemical will associate with the soil matrix and degrade slowly through abiotic and biotic processes.

5.6. Public exposure

The public is unlikely to be exposed to the notified chemical during transport, storage, printing ink manufacture and printing ink application, except in the event of an accidental spill.

The printing inks/ varnishes containing < 0.4% of the notified chemical are used for food and general packaging; however, the packaging is not in direct contact with food. The public may make dermal contact with the printed packaging material; however, the printing ink, once cured, is firmly attached

to the surface of the substrate and is not available for exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Granular, orange solid

Melting Point/Freezing Point 54 - 72°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998d)

Boiling Point 358°C at 101.3 kPa (estimated).

Remarks Estimated based on the vapour pressure curve but the notified chemical was observed to thermally degrade above 300°C.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998f)

Density 1050 ± 1 kg/m^3 at 25°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured by gas comparison pycnometer.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998e)

Vapour Pressure 7 x 10^{-6} kPa at 20°C

METHOD ASTM Standard Test Method E1782-96, which is similar to EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Method using differential scanning calorimeter with a pressure DSC cell. Estimated from boiling point data at reduced pressures.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998f)

Water Solubility < 50 ppb at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Saturated aqueous solutions were prepared with the test substance and held at 30°C for 1, 2 and 3 days. The mixtures were equilibrated at 20°C for 1 day and the concentration of the test substance in the water determined by HPLC.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998g)

Surface Tension Not determined.

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Since the water solubility of the notified substance is < 1 mg/L, the surface tension test was not performed.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998k)

Hydrolysis as a Function of pH Not determined.

METHOD OECD TG 111 Hydrolysis as a Function of pH.
Remarks In consequence of the very low water solubility (< 5 ppb) and the fact that an analytical method could not be developed to meet this low detection limit, the hydrolysis test could not be performed.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998h)

Partition Coefficient (n-octanol/water) log Pow at 20°C = > 6

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks An estimation of log Pow for TKA 45000 was determined by computer program CLOPGP version 2.1 within CERES version 3.55 to be 6.332. The log Pow was confirmed using HPLC methodology where it eluted beyond the six reference standards.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998i)

Adsorption/Desorption Not determined.

Remarks This study could not be conducted due to the poor solubility in water of the notified substance.

Dissociation Constant Not determined.

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks In consequence of the very low water solubility (< 5 ppb) and the fact that an analytical method could not be developed to meet this low quantification limit, the dissociation test could not be performed. There are no dissociable groups in the notified chemical.
TEST FACILITY Ciba Specialty Chemicals Corporation (1998j)

Particle Size Not relevant for imported form.

Flash Point The notified chemical is a solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (solids).
Remarks The notified did not ignite during the test and is not considered highly flammable.
TEST FACILITY Springborn Laboratories, Inc. (1998a)

Autoignition Temperature No self-ignition.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The notified substance did not self-ignite during this study and does not have an auto-flammability point below the melting point.
TEST FACILITY Springborn Laboratories, Inc. (1998b)

Explosive Properties Explosive with shock.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Based on the results, it was concluded the notified substance does not have explosive properties with respect to friction or flame. Sensitivity with respect to shock was observed for one of the test samples.
TEST FACILITY Springborn Laboratories, Inc. (1998c)

Oxidising Properties Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidising Properties (Solids).
Remarks The notified substance was considered to be a non-oxidising substance because there were no signs of vigorous oxidation reaction.
TEST FACILITY Springborn Laboratories, Inc. (1998d)

Reactivity

Remarks The notified chemical is considered to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50 > 5000 mg/kg bw
Rat, acute dermal	low toxicity, LD50 > 2000 mg/kg bw
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - maximisation test	evidence of sensitisation
Rat, oral gavage repeat dose toxicity – 28 days.	NOAEL = 300 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	genotoxic
Genotoxicity – in vivo mouse bone marrow micronucleus assay	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).

Species/Strain — Rat/Wistar albino
Vehicle — Corn oil
Remarks – Method — No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M	5000	1
I	5 F	5000	0
II	5 M	2000	1
II	5 F	2000	0

LD50 — > 5000 mg/kg bw

Signs of Toxicity — One male rat from the high dose group (5000 mg/kg) died on day 3 and one from the 2000 mg/kg dose group died on day 2. For both the dead and surviving animals physical effects including diarrhoea, soiling of the anogenital area, lethargy, brown staining of the nose and mouth and wetness of the anogenital area were noted. Dead and surviving animals in the high dose group also exhibited piloerection and localised alopecia. Body weight changes were normal in 7/9 surviving animals in the 5000 mg/kg group and 8/9 in 2000 mg/kg group.

Effects in Organs — The animal in the high dose group that died showed abnormalities of the thymus, lungs, kidneys, spleen and gastrointestinal tract. No necropsy could be performed on the animal from the 2000 mg/kg dose group that died because the body had been cannibalised. All other animals were clear of any macroscopic findings of abnormality at necropsy.

Remarks – Results — The LD_{50} is greater than 5000 mg/kg.

CONCLUSION — The notified chemical is of low toxicity via the oral route.

TEST FACILITY — MB Research Laboratories, Inc. (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain — Rabbit/New Zealand White

Vehicle	None
Type of dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M	2000	0
II	5 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Dermal reactions were absent to well defined on day 1, absent to slight on day 2, absent to well defined on day 3, absent to moderate on days 4 and 5, and absent to well defined on day 7. By days 10 and 14, dermal reactions were absent to slight.
Signs of Toxicity - Systemic	There were no abnormal systemic signs noted during the observation period. Body weight changes were normal in 8/10 animals. One male and one female lost weight at some time during the observation period.
Effects in Organs	Necropsy results were normal in 7/10 animals. Kidney abnormalities were noted in two males and treated skin abnormalities in one female.
Remarks – Results	The LD_{50} is greater than 2000 mg/kg of body weight.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY MB Research Laboratories, Inc. (1998b)

7.3. Acute toxicity – inhalation

Not performed.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	0.9% sodium chloride solution
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.11	1	3 days	0
Oedema	0.11	1	3 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks – Results	Erythema and oedema, absent at 30 to 60 minutes after patch removal, were absent to very slight at 24 and 48 hours and cleared by 72 hours. There were no abnormal systemic signs noted during the observation period. Body weight changes were normal.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY MB Research Laboratories, Inc. (1998c)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	72 h
Remarks – Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.72	2	7 days	0
Conjunctiva: chemosis	0.17	2	2 days	0
Conjunctiva: discharge	0.33	2	2 days	0
Corneal opacity	0.06	2	2 days	0
Iridial inflammation	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks – Results Corneal opacity, noted in 1/6 eyes, cleared by 48 hours. Iritis, noted in 2/6 eyes, cleared by 24 hours. Conjunctival irritation, noted in 6/6 eyes, cleared by day 7. There were no abnormal systemic observations.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY MB Research Laboratories, Inc. (1998d)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – Maximisation test

Species/Strain	Guinea pig/Hartley-derived albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: None: oedema and blanching noted at lowest dose (0.1%) topical: 100% (ill-defined erythema)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
induction phase	Induction concentration: intradermal injection, 3% (w/w) topical application, 100%
Signs of Irritation	Not noted.
CHALLENGE PHASE	
1st challenge	topical application: 100%
2nd challenge	topical application: not done
Remarks – Method	No significant protocol deviations

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	16	16		

Control Group	100%	0	0

Remarks – Results	16/20 animals exhibited some degree of sensitisation at 24 and 48 hours. No toxic symptoms were observed in the test or control groups. No deaths occurred and all animals gained weight. One animal was observed to have red extremities which was possibly an indication of whole body sensitisation.
CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Springborn Laboratories, Inc. (1998e)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10 F, 10 M	0	0
II (low dose)	5 F, 5 M	10	0
III (mid dose)	5 F, 5 M	30	0
IV (high dose)	5 F, 5 M	100	0
V (very high dose)	10 F, 10 M	300	3

Mortality and Time to Death

One female and one male given 300 mg/kg/day died on days 6 and 29, respectively, with no clinical observations noted for either animal. Another male, given 300 mg/kg/day was noted as pale on day 29 and was found dead on day 30. These deaths were not related to test substance administration, as microscopic examination of the tissues indicated that death was due to gavage-related trauma as a result of the difficulty in dosing.

Clinical Observations

One very high dose male, noted to have audible respiration on days, 29, 36 and 43, survived to scheduled sacrifice. Very high dose animals were observed to struggle against dosing at the beginning of week 2, with resultant backwash out of the mouth noted. Additional care and handling reduced the struggling and the backwash.

There were no other remarkable clinical observations noted for animals in the control or test groups throughout the course of the study.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology: The mean values for prothrombin time and activated partial tissue thromboplastin time were higher in high dose males and very high dose animals, significantly for the very high dose males, at day 30; the increases were of low magnitude for the females. The values remained slightly higher in very high dose animals relative to control values at day 44, significantly for the males. The mechanism of the increases is not apparent from the data examined (clinical observations, body weights, body weight changes, food

consumption, necropsy findings, organ weights and remaining clinical laboratory data), but the increases are attributed to treatment.

The platelet counts were > 10^6/µg/L in each very high dose animal, with a significantly increased mean noted for the female platelet count at day 30. The mechanism behind this increase is not apparent from the data examined, but it is suspected to be an effect of the administration of the test substance; the values at day 44 were comparable to those of the control animals.

The mean alanine aminotransferase values were slightly higher in the very high dose animals at day 30, significantly for the females. Although of low magnitude, these increases may be related to treatment and, for the females, were accompanied by higher liver weights at terminal sacrifice.

Effects in Organs
Mean liver weights at terminal sacrifice were slightly elevated in the females that received 100 (liver-to-body weight percentage only) and 300 mg/kg/day with increases in the incidence and severity of periportal vacuolation in the livers of the 30, 100, and 300 mg/kg/day females. After the recovery period, the incidence of periportal vacuolation in the 300 mg/kg/day rats was not remarkably different from that of the control group.

Remarks – Results
There were no adverse effects noted in males given 300 mg/kg/day or less. In females given 30, 100 and 300 mg/kg/day, there was an increase in the incidence and severity of periportal hepatocellular vacuolation and increased liver weights in females given 100 and 300 mg/kg/day; based upon the histopathology, the No Observed Effect Level (NOEL) is 10 mg/kg bw/day. Slight increases in alanine aminotransferase were noted in the 300 mg/kg/day animals. After the 14-day recovery period, these differences were not noted between the controls and the rats that received 300 mg/kg/day and therefore, based upon the lack of effects after a recovery period, the No Observed Adverse Effect Level (NOAEL) for the notified chemical in both males and females is 300 mg/kg bw/day.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 300 mg/kg bw/day in this study, based on the lack of severe effects (particularly in the liver) at this dose.

TEST FACILITY Covance Laboratories Inc (1998a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2 *uvr*A
Metabolic Activation System	Rat livers (S9 fraction)
Concentration Range in Main Test	a) With metabolic activation: 10 – 5000 µg/plate. b) Without metabolic activation: 10 – 5000 µg/plate.
Vehicle	DMSO
Remarks – Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	> 5000	> 5000	1000	-
Test 2				
Absent				

Test 1	> 5000	> 5000	1000	-
Test 2				

Remarks – Results: The notified chemical did not cause a positive increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254™ induced rat liver (S9) microsomal fraction. The positive controls demonstrated the sensitivity of the test and the negative controls were within historical limits.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Covance Laboratories Inc (1998b)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical.

METHOD: EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test

Species/Strain	Chinese hamster ovary cells (CHO)
Cell Type/Cell Line	WBL
Metabolic Activation System	S9 mix
Vehicle	DMSO
Remarks – Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (h)*	*Harvest Time (h)*
Present			
Test 1	1.18, 1.68, 2.40*, 3.43*, 4.90*, 7.00*, 10.0	3	20
Test 2	1.50, 2.00*, 2.75*, 3.50*, 5.00*, 7.50	3	20
Absent			
Test 1	0.405, 0.578, 0.826*, 1.18*, 1.68*, 2.40*, 3.43	3	20
Test 2	0.350, 0.500*, 0.750*, 1.00*, 1.50*	17.8	17.8

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	> 1.0	> 0.75		+
Test 2				+
Absent				
Test 1	> 3.43	> 0.405	> 72.1	+
Test 2				-

Remarks – Results: The notified substance was considered positive for inducing chromosomal aberrations in CHO cells with and without metabolic activation. The positive controls confirmed the sensitivity of the test and the negative controls were within historical limits.

CONCLUSION: The notified chemical was clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY: Covance Laboratories Inc (1998c)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test. EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Crl:CD-1® (ICR) BR mouse bone marrow
Route of Administration	Intraperitoneal
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
I	6 M	225	24
II	6 M	450	24
III	6 M	900	24
IV	6 M	500	48
V	6 M	750	48

CP=cyclophosphamide. M=mitomycin C.

RESULTS

Doses Producing Toxicity	900 mg/kg The notified chemical induced signs of clinical toxicity in the treated animals. There was a statistically significant decrease in the PCE:NCE ratio at 225 and 450 mg/kg at the 24-hour harvest time, demonstrating that the test substance was cytotoxic to the bone marrow.
Genotoxic Effects	The notified chemical did not induce a statistically significant increase in the frequency of micronucleated PCEs.
Remarks – Results	The notified chemical is considered negative in the mouse bone marrow micronucleus assay under the conditions of this assay. The positive control demonstrated the sensitivity of the test and the negative controls were within historical limits.

CONCLUSION	The notified chemical was not clastogenic in this in vivo mouse bone marrow micronucleus assay under the conditions of the test.
TEST FACILITY	Covance Laboratories Inc (1998d)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	TKA 45000
METHOD	TKA45000: Ready Bio-degradability: CO_2 Evolution Test (Modified Sturm Test). Based on OECD TG 301 B, Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test).
Inoculum	Loxahatchee Environmental Control District Sewage Treatment Plant (Jupiter, Florida, USA)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Untreated $Ba(OH)_2$ in the CO_2 washing bottle was titrated with HCl to the phenolphthalein end point.
Remarks - Method	A stock solution of the test substance was not prepared due to the low solubility of the test substance in water. The test substance was applied directly to the test container, and a uniform suspension obtained following ultrasonic dispersion. The carbon content was analysed using an elemental analyser. The test substance contained the equivalent carbon concentration of 84.2%. Test bottles were prepared with a concentration of 20 mg carbon/L, as was the aniline standard. The concentration of inoculum in the test solution was ~1% (v/v). Aeration was maintained for the duration of the test, and evolved CO_2 trapped in a series of gas washing bottles containing $Ba(OH)_2$. No significant deviations from OECD TG 301 B were documented.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (Average)*	*Day*	*% Degradation (Average)*
1	0.2	3	0.8
3	0.5	5	10.1
5	1.1	7	27.1
7	1.9	7	44.5
10	2.6	10	56.5
13	3.3	13	62.8
21	5.3	21	71.1
28	7.3	28	75.6

Remarks - Results	The notified chemical is not biodegradable when exposed to a 1% inoculum concentration of micro-organisms maintained in an aerobic, aqueous mineralised environment (< 10% cumulative CO_2 biodegradation rate within a 28-day test period). The half-life of TKA 45000 was calculated to be 267 days.
CONCLUSION	The notified chemical cannot be classed as readily biodegradable.
TEST FACILITY	Toxikon Corporation (1998a)

8.1.2. Bioaccumulation

Remarks	No bioaccumulation data were provided, rather the notifier provided the following argument "The test substance is not readily biodegradable (<10%), has a partition coefficient of log P_{ow} > 6 and has low solubility in water (< 0.00005 mg/L at 20°C). Based on these data, the new substance is classified as causing long-term adverse effects in the aquatic environment (R53), and indicates the notified substance has the potential to bio-accumulate". It is also noted that the release to the aquatic compartment will be very low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	TKA 45000
METHOD	TKA 45000: Acute Toxicity To Rainbow Trout, *Oncorhynchus mykiss,* Under Static-Renewal Test Conditions. Based on OECD TG 203 Fish, Acute Toxicity Test – Static Renewal Test Conditions.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	52 mg $CaCO_3$/L
Analytical Monitoring	GC/FID
Remarks – Method	The measured concentrations of TKA 45000 were not determined in this study, due to the low solubility of the notified chemical. The chemical concentration was expressed as the water available fraction (WAF). The WAF was analysed according to OECD manual "Guidance Documentation on Aquatic Toxicity Testing for Difficult Substances". To prepare the test solution, TKA45000 was added directly to each test chamber at a concentration of 100 mg/L. The solution was stirred for 24 h and filtered through a 0.2 µm filter. TKA45000 was extracted from samples of the test solution using methylene chloride, and the extract analysed by GC with FID. The method only allowed comparison of initial and final WAF. Due to a reduction in the concentration of the WAF by 61.9% in the first test (possibly due to volatility), a second test was conducted as a static-renewal test with no aeration. The deviation was in accordance with OECD TG 203. Survival of the rainbow trout was monitored daily and dead fish removed. Treatments and controls were renewed at 48 h. Dissolved O_2 fell below 60% saturation toward the end of the 48 h period, but was not added as per the amended protocol. Fish were not fed during the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Cumulative Mortality (Percent Mortality)*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	27	-	0	2 (7)	2 (7)	2 (7)
100 mg/L	WAF 74.1% @ 48 h WAF 64.1% @ 96 h	30	-	3 (10)	5 (17)	5 (17)	5 (17)

LC50 > 100 mg WAF/L at 96 hours.

NOEC (or LOEC)	> 100 mg WAF/L at 96 hours.
Remarks – Results	The WAF concentration was 74.1% of the initial at the end of the first 48 h, and 64.1% at the end of the second 48 h. The control only included 27 fish following the 'escape' of three fish during water renewal. The study author noted that the reduced level of dissolved oxygen in the chambers may have contributed to fish mortality.
CONCLUSION	The notified chemical shows some acute toxicity to *Oncorhynchus mykiss* at the limit of its water solubility. This may have been caused by low oxygen levels.
TEST FACILITY	Toxikon Corporation (1999a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	TKA 45000
METHOD	TKA 450000: Acute Toxicity To Daphnia sp, *Daphnia magna,* Under Static-Renewal Test Conditions. Based on OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static Conditions (Part I)
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	66 mg $CaCO_3$/L
Analytical Monitoring	GC/FID
Remarks - Method	The measured concentrations of TKA 45000 were not determined in this study, due to the low solubility of the notified chemical. The chemical concentration was expressed as the water available fraction (WAF), which was prepared and analysed as for fish above. Four replicates of the control and test treatments were established, resulting in 20 fleas per treatment, each replicate contained ~200 mL of dilution water. Test chambers were maintained at 20°C and monitored daily for abnormalities or death. Daphnids were not fed during the test, nor were the test solutions aerated. Two definitive limit tests were conducted. Results from the first test were discarded as the final WAF was higher than the initial WAF. The error was attributed to sampling technique.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
100 mg/L	WAF 93% @ 48 h	20	0	0

LC50	> 100 mg WAF/L at 48 hours
NOEC (or LOEC)	≥ 100 mg WAF/L at 48 hours
Remarks - Results	The 48 h EC50 and NOEC were ≥100 mg WAF/L based on the lack of mortality and sub-lethal effects observed at this, and lower test concentrations. The 48-hour EC50 was incalculable because of the absence of mortality during the 48-hour test.
CONCLUSION	The notified chemical was not acutely toxic to *Daphnia magna* at the limit of its water solubility.
TEST FACILITY	Toxikon Corporation (1999b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	TKA 45000
METHOD	TKA 450000: Toxicity To Freshwater Green Alga, *Selenastrum capricornutum* Under Static-Renewal Test Conditions. Based on OECD TG 201 Alga, Growth Inhibition Test.
Species	Freshwater Green Alga (*Selenastrum capricornutum*)
Exposure Period	72 h
Concentration Range	Nominal: 100 mg WAF/L Actual: WAF 35.3% of the initial @ 72 h
Auxiliary Solvent	-
Water Hardness	Not stated
Analytical Monitoring	GC/FID
Remarks - Method	The measured concentrations of TKA 45000 were not determined in this study, due to the low solubility of the notified chemical. The chemical concentration was expressed as the water available fraction (WAF), which was prepared and analysed as for fish above. A limit test was established with three replicates for the test substance and six replicates for the control. All flasks were covered with gas exchange caps. Tests were initiated with the inoculation of ~10,000 cells/mL. The test was conducted under static conditions under fluorescent light and the temperature maintained at 23°C. Alga growth was measured by direct cell count under a compound microscope on a daily basis. Morphological observations were also conducted to detect abnormal morphology or colouration compared to the control.

RESULTS

Nominal Concentration mg wm/L	Growth (mean cell number)			% Change (72 h) in relation to the control
	24 h	48 h	72 h	
Control	4.0	33.3	175	-
100	4.3	65.1	163	-7

Remarks - Results	At test termination, the remaining WAF was 35.3% of the initial WAF. Partial loss of the test substance was anticipated due to volatility or partial volatility of the test substance in water. Additional loss of material may have resulted from metabolism or absorption by algae. The E_bC_{50} and E_rC (0 – 72 hours) was >100 mg WAF/L. The 72-hour no-observable-effect concentration (NOEC) was 100 mg WAF/L. Growth curves of both the control and test solution both exhibited a pattern of exponential growth during the 72 h growth period. Observations of cell morphology detected no changes in TKA 450000 exposed cells. There was no significant statistical difference between the algal growth of the control ad test solution
CONCLUSION	The notified chemical was not acutely toxic to *Selenastrum capricornutum* at the limit of its water solubility.
TEST FACILITY	Toxikon Corporation (1999c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	TKA 45000
METHOD	Assessment of the Acute Toxicity of TKA 45000 on Aerobic Waste Water Bacteria. Based on OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Loxahatchee Environmental Control District sewage treatment plant (Jupiter, Florida, USA)
Exposure Period	3 hours
Concentration Range	1.6 – 99.6 mg/L
Remarks – Method	The extent of acute toxicity was determined by comparison of the oxygen consumption of an aerobic activated bacteria fed with a reference compound to that of the same bacteria fed with the test substance. Stock solutions of the reference standard were prepared at concentrations of 5, 16, 50 and 160 mg/L, and the test solution at 0.16, 3.2, 10.8, 32.2 and 99.6 mg/L. Sampling was conducted following 3 h of aeration at the test temperature. Entire samples were sacrificed, with the contents transferred to a BOD bottle for measurement of oxygen consumption. The reduction of oxygen concentration was measured with an oxygen meter.
RESULTS	
IC50	> 100 mg wm/L
NOEC	> 100 mg wm/L
Remarks – Results	The oxygen consumption of activated sludge was inhibited ~84% at the concentration of 100 mg/L. The EC_{50} value of the reference substance was determined to be 15.6-23.4 mg/L. The oxygen consumption of activated sludge was not inhibited at the test concentration range; hence a EC_{50} value could not be determined. It was concluded that the EC_{50} value was >100 mg/L
CONCLUSION	The notified chemical was not acutely toxic to aerobic waste water bacteria.
TEST FACILITY	Toxikon Corporation (1998b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be manufactured overseas and imported into Australia where it will be formulated into an end use product (UV curable ink). The notified chemical will be imported into Australia in 25 kg open headed jerricans and stored in a warehouse prior to dispatch to customers.

Currently the notified chemical will be supplied to 6 customers within Australia who formulate ink products. The inks are typically produced in 1000 L vessels, to which the notified chemical comprises 0.2-1.5% of the final formulation.

The proposed use pattern and waste management practices indicate that wastes from the formulation of inks containing the notified chemical will be <15 kg/annum (~1.5% of the anticipated import volume). The waste will result mainly from washing of the mixing vessel and pump lines. Less than 10 kg (~1% of the anticipated import volume) will be retained as residue in the import containers. The formulated inks will be packaged into 1, 4 or 20 kg containers and distributed to up to 200 end users.

The end product will be used in printers and coaters for the production of product labels (for example food packaging labels) and non-flexible packaging (for example fibre board packaging). It is estimated that the total release of the notified chemical resulting from the use of printing inks will be < 50 kg/annum (~5% of the anticipated import volume).

It is anticipated that printing and formulation equipment will be cleaned using a blend of ethanol, isopropanol and ethyl acetate solvent. The waste from this process will be collected for solvent reclamation. The resulting solid waste, including the notified chemical, will be moved to landfill.

After the useful life of the printed article, the notified chemical will suffer the same fate as the article. It is anticipated that these will be disposed of to landfill or incinerated. If printed articles are recycled, the waste paper will be repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, inc detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

In landfill it is expected that the notified chemical will remain immobile within the soil. Incineration of the notified chemical will result in the formation of water vapour and oxides of carbon and nitrogen.

9.1.2. Environment – effects assessment

Due to the intended end use of the notified chemical and the fate of treated articles, as well as the inherent insolubility of the notified chemical, it is unlikely that a significant amount of the notified chemical will be released into the sewer. Even so, the aquatic toxicity of the notified chemical is classified as non-toxic, at the limit of its water solubility, to fish, aquatic invertebrates and alga, hence in the event of unintentional release to the sewer, the risk to the environment is considered to be low.

9.1.3. Environment – risk characterisation

Very little if any will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC).

The above considerations indicate minimal risk to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The highest likely worker exposure scenario concerns manual transfer of IRGASTAB® UV 22 containing < 25% notified chemical from 25 L jerricans to a large mixer. A maximum of 16 L will be transferred manually from 25 L jerricans per 1000 L batch. Based on the scenario outlined in Marquart et al. (2006) entitled "Loading and filling of large containers (or mixers) with large amounts (many litres) of liquids", typical exposure in a 30 minute period is estimated as 410 mg with a reasonable worst case of 11 500 mg. This translates to 102.5 mg and 2875 mg for the notified chemical itself or 1.46 and 41 mg/kg/day, respectively, for a single worker. At the NOAEL of 300 mg/kg bw/day the margin of exposure is between 7.3 and 205. As there are a minimum of 10 blenders and the above scenario is more suited to large processes (for example, 70 L/min for a continuous loading system), the margins of exposure are expected to be somewhat greater. The estimates of exposure to blenders would be at least 10 fold greater than for QC workers which would in turn be greater than for any of the other workers.

The end users of the formulated ink/varnish are exposed to products containing at most 0.4% notified chemical. It can be assumed that cleaning of the printing machines could result in extensive exposure to solvent containing ink in the absence of PPE but that PPE to control exposure to solvents would be used. Scooping of ink with a knife either into or out of ducts on the printing machine could also potentially result in extensive exposure to the ink in the absence of PPE.

9.2.2. Public health – exposure assessment

The public may make dermal contact with the printed packaging material; however, the printing ink, once cured, is firmly attached to the surface of the substrate and is not available for exposure.

9.2.3. Human health – effects assessment

The notified chemical is likely to be of low acute oral toxicity via the oral and dermal routes, is not likely to be a skin irritant or an eye irritant but is likely to be a skin sensitiser. It was shown to be a clastogen in vitro but was not clastogenic in vivo in the mouse micronucleus test. No adverse effects were noted in a 28-day oral rat repeated dose study at the top dose of 300 mg/kg bw/day and the notified chemical is unlikely to cause severe effects after repeated or prolonged exposure.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) and is assigned the risk phrase R43: May cause sensitisation by skin contact.

9.2.4. Occupational health and safety – risk characterisation

Given the log P_{ow} of the notified chemical of > 6, it is reasonable to assume a dermal absorption of no more than 10%. Thus the risk of severe effects after repeated or prolonged exposure is considered acceptable based on a margin of exposure of at least 70 for ink/varnish blenders.

However, the notified chemical is a skin sensitiser and therefore there is a potential for ink/varnish blenders to contract allergic dermatitis. This is somewhat mitigated by the short time it takes to transfer the notified chemical to the mixer but management of this risk requires the use of adequate dermal protection. The risk of allergic dermatitis in QC samplers is lower given that the final ink/varnish contains the notified chemical at < 0.4% and the ink/varnish would therefore not be classified as a skin sensitiser according to the NOHSC Approved Criteria.

Transport and storage workers should only be exposed to the notified chemical in the event of an accident involving rupture of the containers and disposal of empty jerricans containing residues of the notified chemical in waste solvent will be conducted by licensed hazardous waste contractors.

9.2.5. Public health – risk characterisation

The public may (rarely) come into contact with the notified chemical in the event of a transport accident. Otherwise extensive exposure to packaging printed with ink/varnish containing the

notified chemical will occur. However, as the notified chemical will be enscapsulated in the dried coating it will not be bioavailable.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R43: May cause sensitisation by skin contact

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Chronic ecotoxicity	4	May cause long lasting harmful effects to aquatic life
Skin sensitiser	1	May cause allergic skin reaction

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is High Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of IRGASTAB® UV 22 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for IRGASTAB® UV 22 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified chemical:
  – R43: May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  – > 1%: R43: May cause sensitisation by skin contact

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  – Pumps and lines which limit the release of the imported formulation should be considered for use in transfers to mixers.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  – Impervious gloves, overalls and face shield or chemical safety goggles.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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