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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

H-9605

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

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

H-9605

1. APPLICANT AND NOTIFICATION DETAILS

Applicant(s)
Konica Australia Pty Ltd of 22 Giffnock Avenue NORTH RYDE NSW 2113

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, chemical formula, molecular weight, spectral data, purity and impurities, additives/adjuvants and import volumes.

Variation of Data Requirements (Section 24 of the Act)
Variation to the schedule of data requirements is claimed as follows: melting point/boiling point, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, flash point.

Previous Notification in Australia by Applicant(s)
None.

Notification in Other Countries
Japan (2000), US (2000), and EU (2000).

2. IDENTITY OF CHEMICAL

Chemical Name
Ferric ammonium salt of an organic chelate

Other Name(s)
9625-M,
9602-C

Marketing Name(s)
H-9605

3. COMPOSITION

Degree of Purity

- *Non-Confidential*

High.

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years
Cartridges containing the notified chemical will be imported from overaseas.

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

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

Use

Non-Confidential

H-9605 will be used as a component of formulated colour photo-processing cartridge.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

Port of Entry
Sydney

Identity of Manufacturer/Recipients

- *Non-Confidential*

Konica Australia Ltd

Transportation and Packaging
Sealed plastic cartridges wrapped in humidity proof plastic film placed inside 2-ply honeycomb cardboard boxes.

5.2. Operation Description

The notified chemical will not be manufactured in Australia but will be imported in cartridges used in commercial photo processing equipment. The notified chemical will constitute less than 15% of the ready-to-use product which is in tablet form. The notifier indicates that up to 25 photo shops and photographic laboratories will use the notified chemical. Use will be in all-in-one single cartridge based digital photo-processing equipment.

5.3. Release

Release of Chemical from Use
The notified chemical is a bleaching agent used in the processing of photographic films. The notified chemical is applied to the photographic surface and then rinsed off with water prior to further processing. The notified chemical will be disposed of into the photo processing machine's effluent tank. These wastes will be removed and treated according to Photo Uniform Regulations for the Environment (PURE) code of practice prior to release into the sewer. This process involves the removal of silver residues and further dilution of the waste stream prior to disposal into the sewer. Therefore, the entire import volume of the notified substance will be released into the sewer.

Discarded cartridges will either be recycled or disposed of in landfill. As the photo-processing chemicals are in tablet form, negligible release of the notified chemical will occur from this source. Any chemical residues contained in the empty cartridges are expected to remain within these containers, although release from deterioration of the cartridge may occur.

5.4. Disposal

The total import volume of the notified chemical will be treated (see Section 5.3) prior to disposal of into the sewer. Empty cartridges will either be recycled or disposed of in landfill.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPA Yellow solid.

Melting Point >250°C

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting.

Remarks Test samples noticeably darkened above 250°C indicating decomposition.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Density 1 670 kg/m^3 at 23°C

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Solubility of H-9605 in petroleum fraction <0.1%.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Vapour Pressure 5.6x10^{-9} kPa at 25°C.

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks A vapour pressure balance and linear regression analysis was used to calculate vapour pressure at 25°C. The low value determined indicates that the notified chemical is classified as being very slightly volatile.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Water Solubility >1000 g/L

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility was determined by visual inspection of a solution where 1 g of the notified chemical was added to 1 mL of water. The notified chemical is classified as being readily soluble.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Hydrolysis as a Function of pH

Method EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T°C*	*$t_{½}$ <hours or days>*
4	50	> 1 year
7	50	> 1 year
9	50	> 1 year

Remarks A preliminary investigation indicated that there was no significant change (by HPLC) in the concentration of the notified chemical after incubation at pH 4, 7 and 9 at 50°C.
Test Facility Huntingdon Life Sciences Ltd (1998a).

Partition Coefficient (N-OCTANOL/WATER) log Pow at 20°C = <-5

Method Estimated by calculation
Remarks The partition coefficient was estimated for the notified chemical using its individual solubilities in n-octanol and water. The former is < 10 mg/L as 10 mg did not fully dissolve in 1 L of octanol.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Adsorption/Desorption log K_{oc} = <-1.3 (based on partition coefficient)
– screening test log K_{oc} = < 0.34 (based on water solubility)

Method Estimate using Quantitative Structure Activity Relationships (QSAR) using the relationships $\log_{10} K_{oc} = 0.544 \log K_{ow} + 1.377$ (based on partition coefficient) and $\log_{10} K_{oc} = -0.55 \log S + 3.64$ (based on water solubility).
Remarks The low estimated log K_{oc} indicates that the notified chemical is classified as being mobile in soil. However, the substance would be expected to chelate with metal ions and thus be less mobile than predicted from this estimate.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Dissociation Constant pKa = 3.3-4.5 (carboxylic acids)

Remarks No determination of the dissociation constant was conducted for the notified chemical. However, carboxylic acids are known to have dissociation constants in the range 3.3-4.5.

Particle Size

Method Sieve analysis and image analysis.

Range (μm)	*Mass (%)*
>125	55.8
60-105	5.9
30-60	27.9
10.4-30.9	10.1
0.5-10.4	0.3

Remarks 0.3% (w/w) is smaller than 10 μm.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Flash Point Not determined.

Remarks The notified chemical is solid substance with a low vapour pressure.

Flammability limits The test substance is not highly flammable.

Method EC Directive 92/69/EEC A.10, A.12 and A.13.
Remarks H-9605 did not ignite, but an area of incandescence was observed after application of the test flame for approximately 30 seconds. The area of incandescence spread over a 50 mm length of the pile during the 40 minutes test period.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Autoignition Temperature 235°C

Method 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The temperature of the oven was raised at a rate of 0.5°C per minute.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Explosive Properties Not explosive.

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks In 3 of the 6 tests, an orange spark was observed but there was no evidence of explosion.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Reactivity Non-oxidising.

Method EC Directive 92/69/EEC A.17Oxidizing Properties (Solids).
Remarks The test mixture sustained a weak flame only very briefly (no longer than 20 seconds). An area of incandescence was also noted with spread throughout the test mixture over a period of approximately 10 minutes.

Decomposition products arising from pyrolysis include oxides of carbon, oxides of nitrogen and ammonia.
Test Facility Huntingdon Life Sciences Ltd (1997a).

Surface Tension 72.5 mN/m

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension was measured by the ring method using a surface tension balance. The

result obtained indicates that the notified chemical is not surface active.

Test Facility Huntingdon Life Sciences Ltd (1997a).

7. TOXICOLOGICAL INVESTIGATIONS

7.1. Acute toxicity – oral

Test Substance H-9605

Method EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain Rat/CD Sprague-Dawley
Vehicle 1% aqueous methylcellulose
Remarks - Method GLP & QA.

Results

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2 000	0/10

LD50 >2 000 mg/kg bw
Signs of Toxicity Piloerection, hunched posture and faecal disturbances (soft to liquid and dark brown faeces).
Effects in Organs None.
Remarks - Results LD50>2 000 mg/kg.

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

Test Facility Huntingdon Life Sciences Ltd (1997b).

7.2. Acute toxicity - dermal

Test Substance H-9605

Method EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/CD Sprague-Dawley
Vehicle 1% aqueous methylcellulose
Type of dressing Semi-occlusive.
Remarks - Method GLP & QA.

Results

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2 000	0/10

LD50 >2 000 mg/kg bw
Signs of Toxicity - Local Grade 1 or 2 erythema with or without Grade 1 oedema was seen in 3 animals, with desquamation additionally noted in 3 rats.
Signs of Toxicity - Systemic None.
Effects in Organs None.
Remarks - Results LD50>2 000 mg/kg

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

Test Facility Huntingdon Life Sciences Ltd (1997c).

7.3. Acute toxicity - inhalation

No inhalation study was provided for assessment.

7.4. Irritation – skin

Test Substance H-9605

Method EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle Water.
Observation Period 4 days
Type of Dressing Semi-occlusive.
Remarks - Method GLP & QA.

Results

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	0	0	1	24 hours	0
Oedema	0	0	0	-	-	0

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

Remarks - Results Transient very slight erythema was noted in 1 animal 24 hours after treatment, and recovered at 72 hours.

Conclusion The notified chemical is non-irritating to skin.

Test Facility Huntingdon Life Sciences Ltd (1997d).

7.5. Irritation - eye

Test Substance H-9605

Method EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method GLP & QA.

Results

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.66	0.66	0.33	1	48 hours	0
Conjunctiva: chemosis	0.33	0	0	1	24 hours	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	-	-	0
Iridial inflammation	0	0	0	-	-	0

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

Remarks - Results Conjunctival discharge was not reported.

Transient hyperaemia of blood vessels with slight swelling was seen in all animals, and recovered before 72 hours.

Conclusion The notified chemical is slightly irritating to the eye.

Test Facility Huntingdon Life Sciences Ltd (1997e).

7.6. Skin sensitisation

Test Substance H-9605

Method EC Directive 96/54/EC B.6 Skin Sensitization - Magnusson & Kligman method.

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: <0.25%
topical: 1%

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

induction phase Induction Concentration:
intradermal injection 0.25%
topical application 1%

Signs of Irritation After intradermal injections, slight irritation was seen in test animals and the controls.
After topical induction, slight erythema was seen in test animals and the controls.

CHALLENGE PHASE

1st challenge topical application: 1%
topical application: 0.5%

Remarks - Method GLP & QA.

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	1%	0	0		
	0.5%	0	0		
Control Group		1	0		
		0	0		

Remarks - Results Positive control group was not included in the study, however, historic data of positive controls were presented in the report.

Conclusion There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

Test Facility Huntingdon Life Sciences Ltd (1997f).

7.7. Repeat dose toxicity

Test Substance H-9605

Method EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain

Route of Administration Oral – gavage.

Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: none.
Vehicle	
Remarks - Method	GLP & QA.

Results

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	5/sex	0	0
Low-dose	5/sex	15	0
Mid-dose	5/sex	150	0
High-dose	5/sex	1 000	0

Mortality and Time to Death
No mortality occurred during the study.

Clinical Observations
Dark faeces were observed in mid-dose group animals from day 15, and in high-dose group animals from 8.

Bodyweight gains, food intakes and food conversion efficiencies of high-dose animals were lower than that of the controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematological examinations revealed increases in packed cell volumes, haemoglobin concentrations and erythrocyte counts in males of the high-dose group, and increased erythrocyte counts in high-dose females.

On day 27, clinical chemical examination showed that animals in the high-dose group had lower alkaline phosphatase levels and albumin concentrations. In addition, the high-dose females had lower urea and phosphorus concentrations. Treatment-related changes at mid dose were confined to slightly low alkaline phosphatase levels in both males and females, and low phosphorus concentrations in females.

Effects in Organs
High-dose females had increases in liver and kidney weights when compared to the controls. One high-dose female had dark contents of ileum, caecum and colon.

Remarks – Results
Vacuolation of Sertoli cells of the testes was seen in 3 mid-dose males and in all high-dose males. Two high-dose males also showed germ cell depletion.

Conclusion
The No Observed Adverse Effect Level (NOAEL) in this study was established as 150 mg/kg bw/day for females based on the changes in bodyweight gains, clinical chemistry, and organ weights, and 15 mg/kg/ bw/day for males based on the testicular toxicity.

Test Facility Huntingdon Life Sciences Ltd (1997g).

7.8. Genotoxicity - bacteria

Test Substance	9625-M
Method	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	Rat S9 mix
Concentration Range in Main Test	a) With metabolic activation: 0-5 000 µg/plate. b) Without metabolic activation: 0-5 000 µg/plate.

Vehicle	Water
Remarks - Method	QA.

Results

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1				No
Test 2				No
Test 3				No
Absent				
Test 1				No
Test 2				No
Test 3				No

Remarks - Results	No data of preliminary test were reported. No data of cytotoxicity and precipitation were reported.
Conclusion	The notified chemical was not mutagenic to bacteria under the conditions of the test.
Test Facility	Konica Corporation (1997a).

7.9. Genotoxicity – in vitro

Test Substance	9602-C
Method	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese hamster fibroblasts (CHL)
Metabolic Activation System	Rat S9-mix
Vehicle	Saline.
Remarks - Method	QA

Metabolic Activation	*Test Substance Concentration (mg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	0.021, 0.043, 0.085, 0.17	6 h	18 h
Test 2	0.021, 0.043, 0.085, 0.17	6 h	18 h
Absent			
Test 1	0.375, 0.75, 1.5, 3.0	18 h	18 h
Test 2	0.375, 0.75, 1.5, 3.0	18 h	18 h

Results

Metabolic Activation	*Test Substance Concentration (mg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		-	No	Yes
Test 2		-	No	Yes
Absent				
Test 1		3	No	Yes
Test 2		3	No	Yes

Remarks - Results	In the preliminary study, the LC50 for cell inhibition in the absence and presence of S9-mix were 3 mg/mL and 0.17 mg/mL, respectively.

	The two main experiments showed dose-related increases in the frequency of cells with aberrations both with and without metabolic activation.
Conclusion	The notified chemical was clastogenic to CHL treated in vitro under the conditions of the test.
Test Facility	Konica Corporation (1997b).

7.10. Genotoxicity – in vivo

Test Substance	H-9605
Method	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/CD-1
Route of Administration	Oral – gavage
Vehicle	Water
Remarks - Method	GLP & QA.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Vehicle	10/sex	0	24 (5/sex) 48 (5/sex)
Low-dose	5/sex	500	24
Mid-dose	5/sex	1 000	24
High-dose	10/sex	2 000	24 (5/sex) 48 (5/sex)
Positive control	5/sex	12 (Mitomycin C)	24

Results

Doses Producing Toxicity	Loose black faeces was evident in all animals treated with the notified chemical.
Genotoxic Effects	Low and high-dose mice killed after 24 hours had higher frequencies of micronucleated immature erythrocytes than the controls. However, all the values were within the historical control range of the laboratory. The proportions of immature erythrocytes for all groups treated with H-9605 were similar to the vehicle control group values at each sacrifice time.
Remarks - Results	One high-dose male died 21 hours after treatment due to an unknown reason.
Conclusion	The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test.
Test Facility	Huntingdon Life Sciences Ltd (1998b).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

No test was submitted by the notifier except a test for inherent biodegradability has been provided.

Inherent biodegradability

Test Substance	The notified chemical
Method	OECD TG 302 B Inherent Biodegradability (modified Zahn-Wellens/EMPA test)
Inoculum	Activated sewage sludge
Exposure Period	28 days
Remarks - Method	The biodegradation of the notified chemical was determined by the measurement of dissolved organic carbon produced after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 24ºC for 28 days. Diethylene glycol was used as the standard material. The results indicated that 50% of the chemical had degraded, while 99% of the standard degraded in 28 days. The results indicate that the notified chemical is not ultimately biodegradable but given its high level of degradation it may be considered to be inherently biodegradable. The notifier further indicates that the notified chemical did not exhibit any sign of inhibition towards the aquatic micro-organisms, as the rate of oxygen depletion was the same as the controls when synthetic sewerage was added at the test's end (days 33-34).
Conclusion	The notified chemical can be considered to be inherently biodegradable.
Test Facility	Huntingdon Life Sciences Ltd (1997h).

8.2. Environmental Effects

8.2.1. Acute toxicity to fish

Test Substance	The notified chemical
Method	OECD TG 203 Fish, Acute Toxicity Test
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	none
Water Hardness	131-171 mg $CaCO_3$/L
Remarks – Method	The tests on fish were performed using a semi-static methodology in which test preparations were renewed daily to ensure that concentrations of test material were maintained near nominal and to prevent the accumulation of nitrogenous wastes. Observations were performed at 3, 6, 24, 48, 72 and 96 hours. The test was performed using ten specimen fish per loading rate at a temperature of 13 ºC. The tests were conducted using a test substance made up at nominal concentration of 100 mg/L. Analysis after 96 h showed a measured concentration 98.2 mg/L. The results of the definitive study showed that no mortalities or sublethal effects were observed in the test. The 96-hour LC_{50} for the notified chemical to *Oncorhynchus mykiss* is > 100 mg/L.
CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to fish.
TEST FACILITY	Huntingdon Life Sciences Ltd (1997i)

8.2.2. Acute toxicity to aquatic invertebrates

Test Substance	The notified chemical
Method	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	none
Analytical Method	AAS

Results

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	ND	20	0	0
10	8.8	20	0	0
22	18	20	0	0
46	37	20	0	0
100	85	20	3	9
220	210	20	15	19
460	440	20	20	20
1000	930	20	20	20

LC50	120 mg/L at 24 hours 88 mg/L at 48 hours (CI = 73-110 mg/L)
NOEC (or LOEC)	37 mg/L at 48 hours
Remarks - Results	The immobilisation tests with *Daphnia* were performed in duplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. The tests were conducted using a measured test substance concentrations of 8.8, 18, 37, 85, 210, 440 and 930 mg/L. After 48 h, no immobilised daphnids were observed in the test vessels with less than 37 mg/L, while 45, 95, 100 and 100% mortality was observed at test concentrations of 85, 210, 440 and 930 mg/L, respectively. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is 88 mg/L based on measured concentrations as determined by probit analysis.
Conclusion	The ecotoxicity data indicates the notified chemical is slightly toxic to daphnia.
Test Facility	Huntingdon Life Sciences Ltd (1997j).

8.2.3. Algal growth inhibition test

Test Substance	The notified chemical
Method	OECD TG 201 Alga, Growth Inhibition Test
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	10-220 mg/L
Concentration Range Actual	6-200 mg/L

Results

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
9.3	6	60	Not provided

Remarks - Results	Algae were exposed to the test substance at the measured concentrations of 6, 9.8, 27, 73 and 200 mg/L for 72 h at 24˚C under constant illumination and shaking. No abnormalities were detected in any of the replicate test samples. Both biomass or growth rate of *Scenedesmus subspicatus* was adversely affected by the test substance.
Conclusion	The ecotoxicity data indicates the notified chemical is moderately toxic to algae.
Test Facility	Huntingdon Life Sciences Ltd (1997k).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will enter environmental compartments indirectly through the release of treated wastes into the sewer and by direct release from discarded cartridges at landfill sites. Based on the import volume, method of packaging and low concentration of the notified chemical, release of the notified chemical to the environment is expected to be low but widespread.

Although it is not considered to be readily biodegradable, significant biodegradation of the notified chemical did occur over the 28 day test. The low expected octanol-water partition coefficient and high water solubility indicate the notified chemical will be predominantly distributed in the aqueous compartment, where it will become diluted and dispersed. As a consequence of its anionic nature, the notified chemical is expected to chelate with metals on the surface of soil and sediment particles and eventually degrading to water and oxides of carbon and nitrogen through biological processes.

The substance is not expected to bioaccumulate due to its high water solubility (Connell, 1990). Furthermore, release of the notified chemical to the aquatic compartment will be low and dispersed.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified substance is practically non-toxic to moderately toxic to aquatic organisms. The most sensitive species is algae, where the 72 hour E_bC50 is 9.3 mg/L.

A predicted no effects concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, *Daphnia*, algae). The PNEC is calculated by taking the EC50 value of the most sensitive species, and dividing this value by an assessment safety factor of either 100 (OECD) or 1000 (EU). Using a worst case scenario safety factor of 100, the PNEC is 93 µg/L.

Based on annual imports of 600 kg/annum, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 1.64 kg/day. Assuming a national population of 19,000,000 and that each person contributes an average 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.57 µg/L.

Amount entering sewer annually	600 kg
Population of Australia	*19 million*
Amount of water used per person per day	*150 L*
Number of days in a year	*365*
Estimated PEC	*0.57 µg/L (0.57 ppb)*

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 0.057 µg/L.

9.1.3. Environment – risk characterisation

The notified chemical will be used as a bleaching agent used in the processing of photographic films and most will eventually be released into domestic sewage systems as a consequence of product use. The compound is inherently biodegradable (50% over 28 days), and has a low partition coefficient and Log Koc and a high water solubility, all indicating that most of the material would eventually partition to the aqueous compartment. As a consequence of its anionic nature, the notified chemical is expected to eventually associate with the soil matrix and sediments and slowly degrade to water and oxides of carbon and nitrogen through

biological processes.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.0006. This value is significantly less than 1, indicating no immediate concern to the aquatic compartment even if release is more concentrated than assumed.

The above considerations indicate minimal hazard 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

9.2.1.1 OCCUPATIONAL EXPOSURE ASSESSMENT

Up to 25 photo shops and photographic laboratories in Australia have photo-processing equipment using this all-in-one single cartridge. There will be 2-4 photographic laboratory operators per establishment replacing the cartridges once a day or every second day. The cartridge will be handled for less than 1-2 minutes per day. The tablets are coated with another chemical for safety reasons. Therefore, exposure to the notified chemical is expected to be negligible because the design of cartridge and the coating material prevents any direct contact with the notified chemical.

About 5 L waste containing <1.5% notified chemical will be produced per day. A full liquid waste container (effluent tank) is exchanged for an empty one manually once or twice per day for each photo-processing equipment. The duration of potential exposure to the waste liquid is estimated to be a maximum of 40-50 hours per worker per year. The main route of potential occupational exposure to the notified chemical will be via dermal contact. Occasional ocular contamination may occur due to splash. The notifier indicated that photo-processing machines are located in a well-ventilated area and operators will wear impervious PVC, nitrile or rubber gloves, splash goggles or safety spectacles with side shields, and overalls or dust coat. The waste will be collected and treated according to the Photographic Uniform Regulations for the Environment (P.U.R.E.) code of practice.

Less than 10 service engineers will be involved in installation and maintenance of photo-processing machines. Some potential dermal contamination may occur. However, the exposure is considered to be low.

Since the wrapped and sealed cartridges remain in the cardboard boxes, waterside, storage and transport workers are not expected to be exposed to the notified chemical except in the event of accident spills or mishandling.

9.2.2. Public health

The notified chemical is expected to be fully removed from photographs in the washing process following development, and there is unlikely to be any public exposure to the notified chemicals by contact with dry processed photographs.

9.2.3. Human health - effects assessment

9.2.3.1 *Summary of toxicological investigations*

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2 000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2 000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Rat, oral-gavage Repeat Dose Toxicity - 28 Days.	NOAEL = 50 mg/kg/day (male), NOAEL= 150 mg/kg/day (female).
Genotoxicity - bacterial reverse mutation	Non mutagenic

Genotoxicity – in vitro chromosomal aberration	Genotoxic
Genotoxicity – in vivo micronucleus test	Non genotoxic

9.2.3.2 *Discussion*

Irritation and Sensitisation.

In the eye irritation study, conjunctival redness of Draize score 1 was seen in one rabbit up to 24 hours, and in two rabbits up to 48 hours. Conjunctival chemosis was observed in one animal up to 24 hours. The notified chemical is considered to be a slight eye irritant.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).

The 28-day repeat dose study in rats showed that the testis was the major target for the toxicity of the notified chemical. As the primary toxic effect of the notified chemical on testis, histopathological examination found vacuolation of Sertoli cells in 3/5 mid-dose males and 5/5 high-dose males. In addition, there was secondary depletion of the germ cells in 2/5 high-dose males. No treatment related histopathological evidence was found in the low-dose males and the controls. Statistically significant changes in bodyweight gain and some haematological and blood chemistry parameters were observed in high-dose animals. The liver and kidney weights were elevated in high-dose females. Therefore, the NOAEL for males was determined to be 15 mg/kg/day in this study based on the testicular toxicity. The NOAEL for females was 150 mg/kg/day based on general systemic toxicity.

Mutagenicity.

In the in vitro chromosomal aberration study in CHL, dose-related increases in the frequency of the cells with aberrations were observed in the presence and absence of metabolic activation. However, overall, the notified chemical is considered not to be clastogenic as it was found to be non-genotoxic in an in vivo micronucleus test.

9.2.4. Human health – risk characterisation

9.2.4.1 *Occupational Health and Safety*

The health risk for operators of the photo-processing machines replacing the cartridges is expected to be very low due to the low potential for exposure to the notified chemical. However, limited dermal exposure during exchange waste containers may occur and splashing should be avoided. These operators should wear industrial working clothes, gloves and eye protections to minimise the exposure.

The health risk for service engineers involved in installation and maintenance of photo-processing machines is also considered to be low due to the low potential for exposure to the notified chemical.

The adverse health risk for waterside, storage and transport workers handling the cardboard boxed containing wrapped and sealed cartridges is expected to be negligible except in the event of accident spills.

9.2.4.2 *Public Health*

Exposure of the general public as a result of transport and disposal of products containing the notified chemical is assessed as being negligible. Members of the public will not use products containing the notified chemical, as they will only be used in photo-processing machines. Public exposure via contact with processed photographs is expected to be negligible, as the photographs are washed and dried after development, which would be expected to remove the residual notified chemical.

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

10.1. Environment

On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

10.2. Health hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances.

The product containing the notified chemical is classified as hazardous. The MSDS states that the product can cause severe eye irritation, skin irritation, allergic skin reaction, skin sensitisation, and nose and throat mucous membrane irritation. These effects may be contributed by the other ingredients in the product.

10.3. Human health risk

10.3.1. Human health – Occupational health and safety

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

10.3.2. Human health – public

There is No Significant Concern to public health under the use conditions described.

11. RECOMMENDATIONS

Control Measures
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the product:
  - Ventilation at the workplaces

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product:
  - Protective clothing
  - Eye protection
  - Gloves

  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 into the photo processing machine's effluent tank and treated according to Photo Uniform Regulations for the Environment (PURE) code of practice prior to release into the sewer.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (collected and placed into the photo processing machine's effluent tank) and treated according to Photo Uniform Regulations for the Environment (PURE) code of practice

prior to release into the sewer.

11.1. Secondary notification

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

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.

12. MATERIAL SAFETY DATA SHEET

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

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

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