File No. SN/13

October 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of KUDE-5

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Component of KUDE-5

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Epson Australia Pty Ltd (ABN 91 002 625 783)
70 Gibbes Street
CHATSWOOD NSW 2067

Toxikos Pty Ltd
293 Waverly Road
MALVERN EAST VIC 3145

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act), as LTD/1062, with the Summary Report of the assessment published in the *Chemical Gazette* of 2nd September 2003.

In June 2004, the Director of NICNAS was informed of changes to the import volume. Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Component of KUDE-5.

In accordance with Section 65 of the IC(NA) Act, a notice requiring the secondary notification of Component of KUDE-5 was published in the *Chemical Gazette.* The notice of 6 July 2004 stipulated the following data were required to undertake further assessment of Component of KUDE-5:

Part B Identity, Properties and Uses

5. Import volume.
9. Physical and chemical data
   (e) Hydrolysis as a function of pH
   (g) Adsorption/Desorption
   (h) Dissociation constant

Part C Toxicity

Repeated dose toxicity
Genetic toxicity
- chromosome damage

Ecotoxicity
- fish, acute toxicity
- alga, growth inhibition test
- inhibition of microbial respiration

Biodegradation
- bioaccumulation

This report, SN/13, represents the revised assessment for Component of KUDE-5. New information submitted by the applicants and considered in this secondary notification assessment are located in this report at Sections:

4.	Import volume
6.	Hydrolysis as a function of pH
6.	Adsorption/Desorption
6.	Dissociation constant
7.6	Repeated dose toxicity
7.8	Chromosome damage
8.2.1	Fish, acute toxicity
8.2.3	Alga, growth inhibition test
8.2.4	Inhibition of microbial respiration
8.1.2	Biodegradation - bioaccumulation

This information completes the notification requirements for the standard category.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

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

- Chemical Identity
- Purity
- Spectral Data
- Bibliographical references which reveal the product code name and manufacturer

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
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
KUDE-5 (contains the notified chemical at less than 10%)

MOLECULAR WEIGHT
> 1000

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD IR, NMR, UV-Vis & MS

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

Chemical Name	Water.		
CAS No.	7732-18-5	*Weight %*	< 20

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is a black dye used in ink-jet reprographic processes. It will be imported primarily from USA and Japan in sealed ink-jet cartridges for use in office printers. The notified chemical is present in the product Ink Cartridge PJ BK 661 at a concentration of up to 5% (typically 3.5%). Ink cartridges range in size up to 55 mL and will be distributed nationwide.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

USE
The notified chemical is a dye component of ink-jet printer cartridges used to print black in general office printing.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not known.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will not be manufactured in Australia but imported from overseas, most likely Japan. The ink-jet cartridges will be distributed and used in offices throughout Australia.

TRANSPORTATION AND PACKAGING
The notified chemical is imported as a component in a liquid ink preparation contained within a closed cartridge.

5.2. Operation description

The notified chemical is imported from overseas as a component of printer ink. The printer ink is contained in a sealed cartridge which itself is packaged in cardboard.

The cartridges will be transported and stored prior to national distribution where they will be used in office or home printing equipment. The cartridges will be installed/replaced either by office workers, service technicians or consumers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importation	10	4 hr	40 days/yr
Storage & Transport	100	6 hr	240 days/yr
Office worker / service technician / consumer	10000	<0.1	20

Exposure Details
Exposure to the notified chemical during the importation transport and storage of the printer cartridges is not expected except in the unlikely event of an accident where the sealed cartridge and its packaging may be breached.

Office workers and service technicians may be exposed to the notified chemical when changing printer cartridges with service technicians also potentially exposed during printer maintenance.

Users of the printers may be exposed to the notified chemical during handling of printed paper, however, in however in this state the notified chemical is bound to the paper matrix and not expected to be readily bioavailable.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer is not manufactured or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE
Release of the ink containing the notified chemical to the environment is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the ink will be contained and presumably disposed of to landfill.

Most of the notified chemical will be bound to printed paper which will be either buried in landfill, with a fraction incinerated or incorporated within the paper recycling process. Recycling of treated paper could result in release of a proportion of the notified chemical to the sewer and potentially the aquatic compartment in effluent as a result of the paper de-inking process. Where paper recycling does not occur, the notified chemical will be mostly disposed of to landfill. Residues in emptied cartridges (~ 2% of notified chemical) will be either recycled or disposed of to landfill.

5.5. Disposal
After use, the majority of the notified polymer will either be disposed of to landfill or incinerated. Small amount may also be released to sewer as a result of paper recycling processes.

5.6. Public exposure
Members of the public may be exposed to the notified chemical through handling of the printed paper. Assuming 1000g of ink produces 3 000 000 A4 pages of text, each page contains 0.3 mg of dye. However, once printed onto paper the notified chemical is bound and unavailable for release.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Black powder.

Melting Point/Freezing Point > 300ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY Toxikos (2002a).

Boiling Point Decomposes without boiling.

METHOD EC Directive 92/69/EEC A.2 using Differential Scanning Calorimetry
TEST FACILITY Toxikos (2002b).

Density 1717 kg/m^3 at 20ºC
TEST FACILITY Toxikos (2002b).

Vapour Pressure << 10^{-3} Pa at 25ºC

METHOD Theoretical Assessment.
Remarks No experimental measurement attempted, due to high boiling point.

Water Solubility 400 - 440 g/L at 25°C

Remarks The water solubility of the test substance was determined by the shake flask method described in EC Directive 92/69/EEC A.6. The notified polymer is a mixed lithium/sodium salt of a sulphonic/carboxylic acid and, as such, is expected to have a high water solubility.
TEST FACILITY Toxikos (2002b).

Surface Tension 72.2 mN/m at 25°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 1.091 g/L. The notified chemical is not surface active at the concentration tested.
TEST FACILITY Toxikos (2002a).

Hydrolysis as a Function of pH

Remarks The notifier indicates that at pH 9, >10% hydrolysis was observed, and at pH 4 and 7, <10% hydrolysis was observed. Test Report not provided, but the notified polymer does not contain any groups expected to hydrolysis in the environmental pH range of 4-9.

Partition Coefficient (n-octanol/water) log P_{ow} at 20°C = < -2.5

Remarks The partition coefficient of the test substance was determined by the HPLC method described in EC Directive 92/69/EEC A.8 Partition Coefficient. The notified polymer's high water solubility is indicative of partitioning into the aqueous phase.
TEST FACILITY Toxikos (2002b).

Adsorption/Desorption – screening test
pH 2 log K_{oc} = >5.0 at 21°C
pH 10 log K_{oc} = <1.5 at 21°C

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using HPLC.
Remarks HPLC Method. K_{oc} of the notified chemical was determined by comparing its retention time against a calibration curve constructed from the retention times of nine reference chemicals (20 mg/L) of known adsorption coefficient (range 1.25-5.63). Sodium nitrate was used to determine the column dead time. All solutions were adjusted to pH 2 or 10. The test described was validated for the quantitative estimation of log Koc in the range of 1.5-5.0 but both results were outside this range. The very strong adsorption at pH 2 is surprising since the notified chemical possesses a number of very acidic groups that are expected to be fully dissociated at this pH, as they would be at pH 10, where weak adsorption is indicated. The latter might be expected throughout the environmental pH range of pH 4-9.
TEST FACILITY Toxikos (2002c).

Dissociation Constant
pKa1 = 10.9 at 22°C
pKa2 = 9.6 at 22°C

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Spectrophotometric determination using a dilute aqueous mixed buffer solution of the test substance. The pH of the test solution was initially raised (10M KOH) and then lowered (10M HCl), and UV/Vis spectrum was obtained at each pH value. The ionic strength of the solution was constant. pKa was determined as the point where absorbance remains constant at change in pH. It is not clear which functionalities in the notified chemical the above involves. The notified chemical

contains fully ionised sulfonate groups, which are expected to remain so in the environmental pH range (4-9) due to their strong acidity.

TEST FACILITY Toxikos (2003a).

Flash Point Not determined

Remarks Substance is solid at room temperature

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids

Remarks A 10: The substance did not propagate combustion
A 12: The test substance did not evolve highly flammable gas when in contact with water
A 13: The substance did not spontaneously ignite on contact with air at ambient temperature (18ºC).

TEST FACILITY Toxikos (2002b).

Autoignition Temperature 265 ± 5ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

TEST FACILITY Toxikos (2002b).

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks The notified chemical did not explode when exposed to heat, mechanical shock or friction.

TEST FACILITY Toxikos (2002b).

Stability Testing Stable at 54°C for 2 weeks.

METHOD Substance placed in vial in oven at 54°C for 2 weeks.

Remarks Degradation measured by HPLC.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute oral	low toxicity
Rat, acute dermal	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irreversible colouration
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOEL = 15 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague Dawley CD
Vehicle Distilled Water

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	2000	0
2	3F	2000	0

LD50 >2500 mg/kg bw
Signs of Toxicity No mortality observed over the study period. There were no signs of systemic toxicity.
Effects in Organs Grey coloured kidneys were noted at necropsy in all animals killed at the end of the study.
Remarks - Results Black coloured staining of the urine was observed in all animals during the day of dosing and for up to four days after dosing. Black coloured staining of the fur was noted in three animals during the day of dosing and for up to three days after dosing.

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

TEST FACILITY Safepharm Laboratories Limited (2002a)

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 Rat/Sprague Dawley CD
Vehicle Distilled Water
Type of dressing Semi-occlusive

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M	2000	0
2	5F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation
Signs of Toxicity - Systemic	No abnormalities noted at necropsy
Effects in Organs	None
Remarks - Results	Bodyweight gains were as expected over the study period.

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

TEST FACILITY Safepharm Laboratories Limited (2002b)

7.3. 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	3
Vehicle	Distilled Water (moistened only)
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	

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	0	0	0	-	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	Light purple/grey-coloured staining noted at all treated skin sites throughout the study did not hamper the evaluation of skin reactions. No evidence of skin irritation was noted during the study.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Safepharm Laboratories Limited (2002c)

7.4. 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	3
Observation Period	35

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	0.33†	0.33†	0.33†	1†	35	†
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	††	††	††	††	35	††
Corneal opacity	0†	0†	0†	0†	35	†
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results † In addition to the noted effect staining was observed in all treated eyes until day 14 and persisted until day 35 in two of the three treated eyes.
†† Black staining around the eye was observed.

CONCLUSION The notified chemical causes irreversible colouration of the eyes.

TEST FACILITY Safepharm Laboratories Limited (2002d).

7.5. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation – maximisation test.

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1%
topical: 50%

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal injection 1%
topical application 50%

Signs of Irritation Discrete or patchy erythema was noted at the intradermal induction sites of control group animals. The evaluation of erythema in test animals was prevented by black staining at the intradermal induction sites.

CHALLENGE PHASE

1st challenge topical application: 50% and 25%

2nd challenge topical application: 50% and 25%

Remarks - Method Eight animals were below the minimum weight specified in the Standard Test Method however this was not considered to affect the purpose or integrity of the study.

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	50%	2	0	3(2)	0
	25%	(4)	0	3	0
Control Group	50%	0	0	(3)	0
	25%	(1)	0	(2)	0

Remarks - Results Black staining at the intradermal and topical induction sites prevented the evaluation of erythema in test animals. Discrete or patchy erythema was

noted at the induction sites in both intradermal and topical induction in control animals. Very slight oedema was also noted at the topical induction sites of control group animals.
Black staining of the challenge sites occurred in animals at both the 25% and 50% concentrations of the notified substance. Where this black staining prevented the evaluation of erythema scoring the number of animals is shown in parenthesis. The notified substance induced patchy to moderate erythema in some test animals and very slight oedema in one animal subjected to the 50% rechallenge. Any effect disappeared by the 48-hr observation and therefore the reactions are not attributed to contact sensitisation.

CONCLUSION The notified chemical is non- sensitising to guinea pigs under the conditions of the test.

TEST FACILITY Safepharm Laboratories Limited (2002e)

7.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Japanese Ministry of Health and Welfare Guidelines (1986) for a 28-day repeat dose oral toxicity study.
US EPA Health Effects Test Guidelines, OPPTS 870.350 Repeated Dose 28-Day Toxicity Study in Rodents, July 2000.

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: 2 weeks.
Vehicle	Distilled water.
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	"	15	0
III (mid dose)	"	150	0
IV (high dose)	"	500	0
V (control recovery)	"	0	0
VI (high dose recovery)	"	500	0

Clinical Observations
Increased salivation in high dose animals and to a lesser extent in mid dose animals. Dark faeces. There were no effects on behaviour, bodyweight, food consumption, functional performance or sensory reactivity. An increase in water consumption was observed in high dose animals and less so in mid dose animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry: Males exhibited reduced sodium in all dose groups accompanied by reduced chloride in the mid and high dose groups. This was not observed in high dose recovery animals.

Haematology: No significant changes.

Urinalysis: High dose females exhibited increased urine volume of reduced specific gravity as did mid dose males. This was not observed in high dose recovery animals.

Effects in Organs
Organ weights: High dose females exhibited elevated absolute and relative adrenal weights.

Macroscopic effects: Blue stained kidneys were observed in mid and high dose animals and in high dose recovery animals.

Microscopic effects: In the kidneys, hypertrophy of the epithelial lining of collecting ducts, and occasionally distal tubules was observed in high dose animals and 2 mid dose males. There was evidence of regression in recovery high dose animals at the end of the recovery period.

Effects of the stomach in high dose animals included agglomeration of gastric secretion, hypertrophy/hyperplasia of mucus secreting cells, basophilia/atrophy of the superficial gastric mucosa and acanthosis/hyperkeratosis of the limiting ridge. There was evidence of appreciable regression in recovery high dose animals at the end of the recovery period.

Remarks – Results
Excessive salivation was judged to be due to the unpalatable or locally irritant nature of the test substance which also coloured the faeces. The unpalatable or locally irritant nature of the test substance may have caused the animals of the mid and high dose groups to drink and therefore urinate excessively. However, diuresis may also have been associated with kidney changes which may have been linked to reduced plasma chloride in mid and high dose males and reduced sodium in all treated male groups. The kidney effects were judged to be adaptive responses to a xenobiotic and the stomach effects were likely to reflect local irritation.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on the stomach and kidney effects seen at the higher doses.

TEST FACILITY Safepharm Laboratories Limited (2003a).

7.7. Genotoxicity - bacteria

TEST SUBSTANCE Dye in Epson Inkjet Cartridge

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA
Metabolic Activation System	Liver Microsomal Preparation (S9-mix) rat.
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate. b) Without metabolic activation: 0-5000 µg/plate.
Vehicle	Distilled Water
Remarks - Method	

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None	1500	None	None
Test 2	N/A	5000	None	None
Present				
Test 1	None	5000	None	None
Test 2	N/A	5000	None	None

Remarks - Results No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose level either with or

without metabolic activation. Results of positive controls confirmed the activity of the S9-mix and the sensitivity of the bacterial strains.

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

TEST FACILITY Safepharm Laboratories Limited (2002f)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Japanese New Chemical Substance Law (METI).

Cell Type/Cell Line	Human lymphocytes.
Metabolic Activation System	Phenobarbitone/β-naphthoflavone induced rat liver S9 fraction.
Vehicle	Minimal Essential Medium.
Remarks - Method	None.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 625, 1250*, 1875, 2500*, 3750, 5000*	6 hours	24 hours
Test 2	0*, 78.13, 156.25, 312.5, 625*, 937.5*, 1250*	24 hours	24 hours
Present			
Test 1	0*, 625, 1250*, 1875, 2500*, 3750, 5000*	6 hours	24 hours
Test 2	0*, 625, 1250*, 1875, 2500*, 3750, 5000*	6 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results No increases in the frequency of cells with chromosomal aberrations were observed at any dose either in the presence or absence of metabolic activation.

Approximately 50% growth inhibition was observed at 1250 μg/mL (6 hours exposure, 24 hours harvest with or without metabolic activation). No precipitation was observed at any dose level. Positive controls demonstrated the sensitivity of the assay system and negative controls were within acceptable limits.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY Safepharm Laboratories Limited (2003b).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry
Inoculum	Activated sewage sludge.
Exposure Period	28 days.
Remarks - Method	The biodegradation of the notified chemical was determined by the measurement of oxygen uptake after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 22°C for 28 days. Sodium acetate was used as the standard material.

RESULTS

Test substance		*Sodium Acetate*	
Day	*% degradation*	*Day*	*% degradation*
15	< 7	15	65
28	< 7	28	65

Remarks - Results	The results indicated that < 7% of the notified chemical had degraded, while 65% of the standard degraded in 28 days. Chromatographic analysis of the test substance solutions showed 100% of the nominal concentration.
CONCLUSION	The results indicate that the notified chemical is not ready biodegradable.
TEST FACILITY	Toxikos (2002d).

8.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305C Bioconcentration: Flow-through Fish Test.
Species	Carp (*Cyprinus carpio*), 10.5 g, 7.4 cm length, Fat content 5.8%.
Exposure Period	Exposure: 4 weeks Depuration: 0 days
Auxiliary Solvent	None
Concentration Range	
Nominal	0.54 and 4.7 mg/L
Actual	0.47-0.60 and 4.6-4.7
Analytical Monitoring	HPLC of test solutions (days 0, 1, 5, 7, 10, 11, 15, 20, 24 and 28) and whole fish (days 0, 5, 10, 15, 20, 28).
Remarks - Method	Test aquaria (120 L) received a flow of >580 mL/min of test solution. Stock solutions (0.84 mg/l and 8.4 mg/L) were prepared by dissolving test substance directly in deionised water (hardness ~50 mg/L), which was discharged into test solution at a rate of 0.40 mL/min. Fish were fed during the test. Water temperature: 25±1°C, dissolved oxygen: 6.4-8.4 mg/L, pH 7.2-7.8. 54 fish/aquaria.

RESULTS

	Bioconcentration Factor (BCF)	
Test solution (mg/L)	Level 1	Level 2
0.54	<2.6	
4.7		<0.30

Remarks - Results	HPLC analysis of stored test substance indicated that it was stable during the period of the test.
CONCLUSION	BCF (whole fish) values of <0.30 and <2.6 resulted after 28 days exposure to 0.4 and 4.7 mg/L, respectively. The test substance has a low potential to bioconcentrate in fish.
TEST FACILITY	Toxikos (2003b).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Carp (*Cyprinus carpio*), 0.91 g, 3.3 cm length.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	~45 mg/L (as $CaCO_3$)
Analytical Monitoring	HPLC analysis of test solutions at 0 and 96 h.
Remarks – Method	Dilution water consisted of dechlorinated (carbon-filtered) tap water. Test aquaria (15 L glass) contained 10 fish each and were maintained at 22±1°C, DO >8.5 mg/L and pH 7.7-7.9. LC50 values were calculated using the moving average angle method of Stephan (1977).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual***		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	<LOQ*	10	0	0	0	0	0
120	100	10	0	0	0	0	0
240	200	10	0	0	0	0	0
480	420	10	0	0	0	0	20
960	820	10	0	0	0	80	100
1920	1700	10	0	20	100	100	100

* LOQ = 0.32 mg/L. ** Time weighted arithmetic mean (0 & 96 h) adjusted for 83.4% w/w purity.

LC50	470 mg/L at 96 hours.
NOEC	200 mg/L at 96 hours.
Remarks – Results	Reported as part of the bioaccumulation study (refer Section 8.2.1). Due to the intensity of colour of the test solutions, observations of sublethal effects were unable to be made. Stability testing indicated <1% loss of the notified chemical from the test solutions during the tests.
CONCLUSION	The test material is practically non-toxic to fish (LC50 >100 mg/L).
TEST FACILITY	Toxikos (2002e).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	Cladoceran (*Daphnia magna*)
Exposure Period	48 hours
Auxiliary Solvent	None
Analytical Monitoring	Spectrophotometric

RESULTS

Concentration mg/L *Nominal*	*Number of D. magna*	*Number Immobilised* *24 h*	*48 h*
0	20	*	0
120	20	*	0

* 24 h observations not possible due to opaque dark blue/black test solution colouration.

LC50	> 120 mg/L at 48 hours
NOEC (or LOEC)	> 120 mg/L at 48 hours
Remarks - Results	The immobilisation tests with *Daphnia* were conducted using 5 daphnids per flask with observations performed at 48 hours. Observation at 24 h were not possible due to the test solutions exhibiting opaque dark blue/black colouration The tests were conducted using a nominal test substance concentration of 144 mg/L (corrected to 120 mg/L for moisture content). After 48 h, no immobilised daphnids were observed in any of the test vessels. The 48-hour EC50 for the notified chemical to *Daphnia magna* is greater than 120 mg/L based on concentrations corrected for moisture content.

CONCLUSION The test material is practically non-toxic to daphnids (LC50 >100 mg/L).

TEST FACILITY Toxikos (2002f).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green algae (*Scenedesmus subspicatus*; freshwater unicellular).
Exposure Period	72 hours (shaken)
Concentration Range	
Nominal	1.0, 2.3, 5.0, 11, 25, 55 and 120 mg/L equivalent to 0.83, 1.9, 4.2, 9.2, 21, 46 and 100 mg/L (corrected for moisture content).
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	Spectrophotometric analysis of test solutions at 0 and 72 h.
Remarks - Method	Stock solution (120 mg/L) was prepared by addition of test substance (0.24 g) in 2 L sterile culture medium. Test chambers (250-400 mL bottles containing 100 mL of test solution) were incubated at 24±2°C. Light intensity in exposed solutions: 3490 lux. The stock solution was observed to be a blue/black opaque solution. Initial and final pH: 7.4-7.7 and 7.4-7.7 (no change). Cells density was determined by electronic particle counting (Coulter Counter). Inoculum (0.735 mL) was added to each test chamber to give a nominal cell density of ~10^4 cells/mL. Cells were counted at 24, 48 and 72 h.

RESULTS

Biomass				*Growth*			
EbC50 *mg/L at 72 h*		*NOEC* *mg/L*		*ErC50* *mg/L 0-72 h*		*NOEC* *mg/L*	
Exposed	Shaded	Exposed	Shaded	Exposed	Shaded	Exposed	Shaded
0.283	0.801	<0.83	<0.83	2.97	2.86	<0.83	<0.83

Remarks - Results The mean measured concentrations of the test substance were 98-113% of nominal. Consequently, the toxicity values are based on nominal

concentrations, corrected for moisture content. No definitive conclusion regarding toxicity to algae can be made as inhibition curves were essentially the same for exposed and shaded solutions, indicating a physical (light reduction) effect was operating.

CONCLUSION The results satisfy the EU exemption clause in Annex VI (Dir. 93/21/EEC) and should not be used for classification of the hazard of the chemical.

TEST FACILITY Toxikos (2002g).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum: Mixed biological population from a secondary treated (activated) sludge, Buckland STP, Devon, UK, receiving mainly domestic sewage (pH 6.6; Total filterable solids 5132 mg/L).

Exposure Period: 3 hours

Concentration Range Nominal: 1.0, 3.2, 10, 32 and 100 mg/L

Remarks – Method: Test material was aerated for 3 h at 20±2°C in the presence of activated sewage sludge and synthetic sewage. The rate of respiration of activated sludge was determined 3 hours after feeding an excess amount of synthetic sewage and comparison to the respiration rate of activated sludge in the presence of the test material. Final solids concentration in test bottles was ~1600 mg/L. Test bottles were set up at 10 minute intervals and aerated for 3 h. The rate of oxygen uptake was measured using a polarographic oxygen electrode. The EC50 was estimated using a graphical representation of the data.

RESULTS

Concentration (mg/L)	Respiration Rate (mg O_2/L/h)	% Inhibition
Control	43.2	-
1.0	44.6	<10
3.2	44	<10
10	45	<10
32	44	<10
100	43	<10
3,5-DCP		
1.0	40.0	10
3.2	32.7	26
10	15.0	66
32	7.7	83
100	3.0	93

EC50: >100 mg/L at 3 hours

NOEC: 100 mg/L at 3 hours (highest concentration tested).

Remarks – Results: The two control replicates were within 15% of each other (ie. ±1%), and the EC50 of the reference toxicant was within the range of 5-30 mg/L (ie. 10 mg/L), thereby validating the test conditions.

CONCLUSION The test material did not inhibit the respiration by sewage sludge microbes at a concentration up to 100 mg/L after 3 h contact time.

TEST FACILITY Toxikos (2002h).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the ink containing the notified chemical to the environment is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the ink will be contained and presumably disposed of in landfill. Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Ink residues contained in the empty cartridges are expected to be about 2% of the import volume and to remain within these containers, although release could occur from deterioration of the cartridge. The total import volume of the notified chemical will ultimately be disposed of in either landfill or be incinerated or recycled with paper.

Waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the compound. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, sulphur and nitrogen.

In addition to landfill, some (estimated ~50%) of the ink printed on paper will enter the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes are expected to go to trade waste sewers.

Assuming a worst-case situation in which 50% of the entire import volume (10 tpa) is released to sewer and not removed or attenuated during sewage treatment processes (due to its high water solubility), the daily release on a nationwide basis to receiving waters is estimated to be 13.2 kg/day. Assuming a national population of 20.1 million and that each person generates ~200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated to be 3.4 µg/L. Assuming dilution factors for freshwater and marine environments of 1 and 10, respectively, $PEC_{freshwater}$ and PEC_{marine} of 3.4 µg/L and 0.34 µg/L, respectively, may be calculated.

Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. As a consequence of its anionic nature, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments. The substance is not expected to bioaccumulate based on bioaccumulation test results BCF <2.6).

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate that the notified chemical is practically not toxic to aquatic animals (ie. L{E}C50 >100 mg/L, Mensink *et al*., 1995). However, exposure to the notified chemically poses a physical effect on algae growth (ErC50 2.97 mg/L in the exposed population). A predicted no effect concentration ($PNEC_{freshwater}$) of 30 µg/L has been derived by dividing this value for algae by an assessment (uncertainty) factor of 100 to account for intra and inter species sensitivity and potential chronic effects of the notified chemical. In the absence of marine toxicity data, the $PNEC_{freshwater}$ is tentatively extrapolated to the marine environment, an approach is supported by a preliminary review of comparative data by ECETOC (2003). The NOEC for activated sewage sludge microbes is 100 mg/L at 3 hours; however, such concentrations are unlikely in the sewerage system.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the import volume, method of packaging and low concentration in ink, release of the notified chemical to the environment is expected to be low and widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and any of the notified chemical partitioned to the supernatant water will be

released to sewer.

Using a risk quotient (RQ; where RQ = PEC/PNEC ratio) approach for freshwater and marine environments, assuming nationwide use, RQ values are 0.1 (ie. 3.4 ÷ 30) and 0.01 (ie. 0.34 ÷ 30), respectively. These are less than 1 and indicate no immediate concern to the aquatic compartment particularly given the low toxicity of the notified chemical to aquatic animals and the PNEC being based on a physical effect in algae. Environmental risk to the aquatic environment is expected to be much lower than suggested above given the expected attenuation of the notified chemical in on-site industrial wastewater treatment plants and the sewerage system including adsorption to sludge.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

There is low potential for worker exposure to the notified chemical when replacing spent cartridges as the ink formulations are in a liquid form and therefore are unlikely to generate residual dusts. Service technicians may occasionally experience skin contact with the notified chemical during maintenance, however, the notified chemical is at low concentrations (< 5%) in the ink formulations. Exposure to the notified chemical on printed paper is low as the dye is bound to the paper matrix.

9.2.2. Public health – exposure assessment

Public exposure through importation, transportation or storage is assessed as negligible. There is little potential for exposure during cartridge changes. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available. Public exposure is assessed as low.

9.2.3. Human health - effects assessment

The notified chemical has a high molecular weight (> 1000) and a low octanol/water partition coefficient, indicating a low degree of lipophilicity and low potential to cross biological membranes.

The notified chemical was found to be of low acute oral toxicity with LD_{50} for the rat determined to be > 2500 mg/kg by the acute toxic class method. Acute dermal toxicity studies demonstrated that the notified chemical is also of low toxicity with the LD_{50} for the rat estimated to be > 2000 mg/kg using a limit test method.

Dermal irritation studies found the notified chemical to be non-irritating to the skin although some staining of the skin was noted. This staining did not hamper the evaluation of irritation. Eye irritation studies revealed that the notified chemical causes irreversible discolouration of the eyes. The notified chemical is therefore classified as a severe irritant, with the risk phrase R41 assigned.

Skin sensitisation studies on guinea pigs revealed no evidence of reactions indicative of skin sensitisation to the notified chemical.

The NOEL in a 28-day repeated dose oral toxicity study in rats was 15 mg/kg/day but effects at higher doses were adaptive or due to local irritation.

No genotoxic effects were observed in vitro in a bacterial reverse mutation test or in a chromosomal aberration test in human lymphocytes in vitro.

On the basis of results of eye irritation studies the notified chemical is classified as an irritant and assigned the risk phrase R41 Risk of serious eye damage, in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low given that the notified polymer is present in the ink at below 5%, and the ink is contained in enclosed cartridges. Although the notified chemical is classified as hazardous due to the irreversible eye discolouration observed in animal eye irritation studies, the ink containing the notified chemical is not classified as hazardous.

9.2.5. Public health – risk characterisation

Members of the public are not likely to make contact with the notified chemical during cartridge changes unless the cartridge is ruptured or otherwise tampered with. Additionally the notified chemical is present at low concentrations in a formulation which is not classified as hazardous. Ink containing the notified chemical on the printed pages is bound to the paper and is not 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* (NOHSC, 2002). The classification and labelling details are:

- Irritant (Xi)
- R41 Risk of serious damage to eyes

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is as Serious eye damage/eye irritation (category I)-causes serious eye damage.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, 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 Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). They are 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 the notified chemical and products containing the notified chemical provided by the notifier were 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 NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R41 Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 5%-10%: R36 Irritating to eyes
  - ≥10% R41 Risk of serious damage to eyes

- Suppliers should label the notified chemical with the signal word 'Hazardous' and the risk phrases listed above.

CONTROL MEASURES
Occupational Health and Safety

- Eye protection is essential when handling the notified chemical.

- 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* (NOHSC, 2002), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Emergency procedures

- Spills of the ink formulation should be contained and collected by sweeping or wiping and placed into labelled sealable containers for disposal. Generation of dusts should be avoided.

Disposal

- The ink containing the notified polymer should be disposed of by incineration or landfill in accordance with Local and State regulations.

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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