File No: STD/1008

5 June 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Orange Textile Dye

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Orange Textile Dye

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toxikos Pty Ltd (ABN 30 095 051 791) 293 Waverly Rd MALVERN EAST VIC 3145.

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 name, other name, CAS No., molecular and structural formulae, molecular weight, purity, impurities, spectral data and import volume.

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
UK, Japan and USA.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Orange Textile Dye.

SPECTRAL DATA Infrared (IR), nuclear magnetic resonance (NMR), ultraviolet/visible (UV/Vis) and mass spectra were provided.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV/Vis spectroscopy
Remarks	The characteristic colour absorbance maximum is used for detection and determination.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/NON-HAZARDOUS

The notified chemical contains < 10% impurities related to itself.

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

Chemical Name	Water		
CAS No.	7732-18-5	*Weight %*	10 - 30

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
As a component of a textile ink in plastic inkjet cartridges.

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 used in preparations in inkjet reprographic processes for printing on textiles.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Unknown.

TRANSPORTATION AND PACKAGING
The ink is contained in sealed ink jet cartridges of up to 2 L capacity and are typically transported in cardboard cartons on pallets which are plastic wrapped.

5.2. Operation Description

Wide format inkjet printing machines are digital graphics printing systems. The image design is created on a computer and the printing is initiated from the computer. The printer has a similar design to paper inkjet printers except they are wider and consume larger (up to 2 litres) single colour cartridges. The printing process is automated. The method of application is the same as for paper inject printing applying approximately 15 mL of ink per square metre of cloth. The dyestuff is fixed by steaming followed by removal of the unreacted hydrolysed compound by washing and is then dried on a continuous automated printing line. The ink jet cartridge is inserted into the fabric printing machine in much the same way as in an office ink jet printer after a plastic sealing tape has been removed from the print head.

5.3. Occupational exposure

Transport and storage workers (10 workers, 4 hours/day, 40 days/year)

Textile workers (up to 5 per customer, up to 8 hours/day, 230 days/year) and printer service technicians may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, and during repair, maintenance and cleaning of the printing machine. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

After application to the textile the dye is fixed by steaming, the hydrolysed dyestuff is removed by washing and the fabric dried on a continuous automated printing line.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

5.4. Release

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

RELEASE OF CHEMICAL FROM USE
The notified substance is a reactive type dye that forms covalent bonds when applied to cellulose. Application to cellulosic textiles will be in an industrial/commercial facility in an automated line where the colourant will be fixed by chemical means to the substrate. Fixation rates of greater than 85% are typically achieved for reactive dyes (European Commission, 1996 – part 4, chapter 7). Dye (the notified chemical) released to wastewater through the washing process will largely be in the hydrolysed form. Cartridge residues are expected to be minimal. The amount of colour applied to fabric will vary depending on the type of cloth, machine speed, depth of shade, etc. but the process is geared towards fine quality subtle print designs which will not cover a large proportion of the cloth as in traditional prints. As the technique is developed printing of cloth 1 metre wide could be carried out using a number of different colours with options up to 10-12 colours.

Articles printed with the notified substance and worn by consumers will at some time be washed. The bleed resistance of the notified chemical compared with other dye types is excellent having a grey scale score of 4-5. This is equivalent to a loss on washing of less than 0.01%.

Virtually all of the notified substance will eventually be released to the environment. Over 85% will be bound to printed materials that are disposed of to landfill or incinerated or released in effluent de-inking processes. The remainder will either be released to sewer or discarded in landfill. Empty cartridges will be disposed of to landfill.

Less than 0.01% of the dye is likely to be released to sewer due to washing during the manufacture of articles. The equates to a release of less than 1 kg per annum.

If a worst case fixation rate is assumed (70% fixation) then 30% of the import volume, or a maximum of 3000 kg will be released to sewer as the hydrolysed form of the notified chemical.

5.5. Disposal

The majority of the notified polymer will either be disposed of to landfill or incinerated. Small amounts may also be released to sewer as a result of washing textiles during production. Insignificant releases to sewer are expected during the washing of clothing to which the dye containing the notified chemical has been applied.

5.6. Public exposure

Except in the unlikely event of a transport accident, the public should only be exposed to the notified chemical in the final ink as it is dried on textiles. At this stage the notified chemical should not be bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa	Orange powder.
MELTING POINT/FREEZING POINT	> 330°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY Confidential.

BOILING POINT

Remarks Test not performed given the result of the melting point determination.

DENSITY 1680 kg/m^3 at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY Confidential.

VAPOUR PRESSURE << 10^{-6} kPa at 25ºC.

METHOD The vapour pressure was estimated via a comparison between the notified chemical and compounds that contain similar functional groups. By analogy, the notified chemical is expected to exhibit a vapour pressure much less than 1×10^{-3} Pa. The low value is consistent with its structure.

TEST FACILITY Confidential.

WATER SOLUBILITY > 400 g/L

METHOD The water solubility of the test substance was determined by the shake flask method described in EC Directive 92/69/EEC A.6.

Remarks Consideration of the structure suggests the notified polymer is expected will have a high water solubility.

TEST FACILITY Confidential.

HYDROLYSIS AS A FUNCTION OF PH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH. Solutions of the test substance were prepared in buffer at the appropriate pH and stored in a oven at 50ºC. The concentration of the main component was monitored by HPLC over several days.

PH	*T (°C)*	*% Hydrolysis*
4	50	10.4
7	50	<10
9	50	<10

Remarks The notified chemical contains a linkage that is capable of hydrolysis under extreme conditions. As the test above suggests significant hydrolysis in the environmental pH range of 4-9 is unlikely to occur.

TEST FACILITY Confidential.

PARTITION COEFFICIENT (n-octanol/water) -3.21 at 25ºC

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

Remarks Solutions of the test substance were prepared in octanol saturated water with the concentration of the notified chemical in each layer determined spectrophotometrically by comparison with calibration graphs. The result obtained is indicative of the notified chemical partitioning to the aqueous phase.

TEST FACILITY Confidential.

ADSORPTION/DESORPTION Not determined

Remarks The notifier indicates that no adsorption/desorption tests were conducted for this notification. Although the notified chemical is relatively water soluble, as a consequence of its anionic nature, it is expected to associate with the soil matrix and sediments and as such will be immobile in soil.

DISSOCIATION CONSTANT Not determined

Remarks No dissociation constant tests were conducted for the notified chemical. The notified chemical contains a fully ionised group which is expected to remain so in the environmental pH range (4-9) due to its strong acidity.

PARTICLE SIZE Not applicable.

FLASH POINT Not determined.

FLAMMABILITY LIMITS	Not highly flammable. Does not evolve gas in contact with water. Does not spontaneously ignite at ambient temperature.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids), A 12 and A 13.
TEST FACILITY Confidential.

AUTOIGNITION TEMPERATURE	357°C

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

EXPLOSIVE PROPERTIES	Not explosive.

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

REACTIVITY	Stable at 54 °C for 14 days.

METHOD Not stated.
TEST FACILITY Confidential.

SURFACE TENSION	67.7 mN/m at 23°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: Approximately 1 and 10 g/L.
TEST FACILITY Confidential.

OXIDISING PROPERTIES	Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Confidential.

7. TOXICOLOGICAL INVESTIGATIONS

The name of the notified chemical as given in the toxicological reports has been claimed as confidential as has the name of the test facility. Therefore these information items are not included in the Full Public Report.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
skin sensitisation, neat chemical - mouse local lymph node assay.	evidence of sensitisation
"Golden Yellow" ink - maximisation test	no evidence of sensitisation
Rat, oral (gavage) repeat dose toxicity - 28 days.	NOAEL = 150 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro human lymphocytes chromosomal aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD — Fixed Dose Method (Van de Heuval et al., 1987; British Toxicology Society, 1984)
- Species/Strain: Rat/Wistar
- Vehicle: Deionised water.
- Remarks - Method: None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: None.
- Effects in Organs: None.
- Remarks - Results: None.

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

TEST FACILITY — Confidential.

7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

METHOD — Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.
- Species/Strain: Rat/Wistar
- Vehicle: Deionised water.
- Type of dressing: Occlusive.
- Remarks - Method: None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0/10

- LD50: > 2000 mg/kg bw

Signs of Toxicity - Local	Slight irritation was commonly observed.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	None.

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

TEST FACILITY Confidential.

7.3. Acute toxicity - inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Deionised water.
Observation Period	3 days.
Type of Dressing	Occlusive.
Remarks - Method	None.

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	1	30 – 60 min	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 Slight erythema and oedema was observed in one animal 30 – 60 minutes after decontamination.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Confidential.

7.5. Irritation - eye

TEST SUBSTANCE Notified chemical.

METHOD	Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White.
Number of Animals	3
Observation Period	4 days.
Remarks - Method	None.

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	1	0.67	1	3 days	0
Conjunctiva: chemosis	0	0	0	1	< 1 day	0
Conjunctiva: discharge	0	0	0	3	< 1 day	0
Corneal opacity	0	0	0	0		0
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 None.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Confidential.

7.6. Skin sensitisation – Neat chemical, mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical.

METHOD Local lymph node assay (Kimber, Hilton and Weisenberger (1989).
Species/Strain Mouse/CBA/Ca
Number of Animals Test Group: 4 Control Group: 4
Vehicle Propylene glycol
Remarks - Method None.

RESULTS

Concentration	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0	38	
1%	208	5.47
3%	184	4.84
10%	303	7.97
Positive Control		
0	109	
1%	187	1.72
3%	355	3.26
10%	451	4.14

Remarks - Results

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY Confidential.

Skin sensitisation – "Golden Yellow" ink, maximisation test

TEST SUBSTANCE "Golden Yellow" ink, 10% 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/
Number of Animals Test: 9 Control: 5
Vehicle Distilled water.

MAIN STUDY

INDUCTION PHASE	Induction Concentration: intradermal injection, 25% v/v topical application, undiluted
Signs of Irritation	Not stated.
CHALLENGE PHASE	
1st challenge	topical application: 75% v/v topical application: undiluted
2nd challenge	topical application:
Remarks - Method	None.

RESULTS

Remarks - 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	75%	0/9	0/9		
	undiluted	0/9	1/9		
Control Group	75%	0/5	0/5		
	undiluted	0/5	0/5		

CONCLUSION	There was no evidence of skin sensitisation to an ink containing 10% notified chemical under the conditions of the test.
TEST FACILITY	Safepharm (2001).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Alpk:APfSD
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	Distilled water.
Remarks - Method	None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	"	15	"
III (mid dose)	"	150	"
IV (high dose)	"	1000	"
V (control recovery)	"	0	"
VI (high dose recovery)	"	1000	"

Clinical Observations

None.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis, Effects in Organs

Haematology: The platelet count for high dose females was slightly increased at 28 days and in the recovery group and was slightly decreased in low dose males. Prothrombin time was slightly decreased in mid dose males and female high dose recovery animals.

Clinical Chemistry: Gamma-glutamyl transferase was significantly elevated in high dose animals at week 7 but levels in high dose recovery animals were normal.

Total protein levels were slightly elevated in high dose animals but albumin levels were normal suggesting the increase was in globulins. High dose recovery females also exhibited elevated total protein with a slight increase in albumin levels. Slightly elevated total protein was also observed in mid dose males.

Triglyceride levels were lower in male high dose recovery animals.

Cholesterol was slightly elevated in mid dose males and slightly decreased in recovery high dose males.

Urea levels were slightly increased in high dose males but slightly decreased in high dose females (and also low dose females).

Total bilirubin levels were elevated in low, mid and high dose males but not in recovery animals.

Glucose levels were slightly reduced in high dose males.

Akaline phosphatase levels were slightly decreased in high dose recovery females and slightly increased in mid dose males.

Alanine and aspartate transaminase activities were slightly elevated in low and mid dose males and alanine transaminase was slightly reduced in high dose recovery males.

Urinalysis: Slightly reduced protein levels were observed in mid and high dose males and slightly increased urinary pH was observed in high dose males.

Effects in Organs: Slightly elevated absolute adrenal and testis weights were noted for high dose males and relative liver weights were slightly elevated for high dose recovery males but slightly reduced for the females.

Some macroscopic findings in single individuals at the high dose were observed but these were isolated instances.

Microscopic effects were observed in the kidneys of high dose animals. Accumulation of the pigmented test substance was observed in the cortical tubular epithelium. Minimal or slight cortical tubular vacuolation was observed in 3/5 high dose males and minimal vacuolation in one recovery male, demonstrating reversibility of the effect.

Remarks – Results

Haematology changes were minor and sex-limited and therefore not considered toxicologically significant.

Changes in plasma total protein and γ-glutamyl transferase indicate a mild hepatic effect in high dose animals but were not correlated with a change in liver weights or histopathology.

Changes in triglyceride and cholesterol levels were not uniform and were considered to be treatment related.

Changes in plasma urea levels were not consistent in males and females at the high dose and were, therefore, not considered to be compound related.

Elevation of bilirubin in all male dose groups was within the reference range and were not considered to be compound related.

Effects on glucose, alkaline phosphatase, alanine and aspartate transaminase levels were sporadic and unlikely to be compound related.

Changes in urinalysis parameters were within the reference range or otherwise not considered to be compound related.

Changes in the adrenal, testis and liver weights were not correlated with any microscopic effects and were considered minor.

CONCLUSION
The No Observed (Adverse) Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on a mild renal response of pigmentation of the cortical tubular epithelium in high dose males and females and of cortical tubular vacuolation in high dose males.

TEST FACILITY Confidential.

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 *uvrA* (pKM101), WP2 (pKM101).
Metabolic Activation System	Phenobarbital/β-naphthaflavone-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 200 - 5800 µg/plate. b) Without metabolic activation: 200 - 5800 µg/plate.
Vehicle	Deionised water.
Remarks - Method	None.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	not reported	5800	not reported	negative
Test 2	not reported	5800	not reported	negative
Absent				
Test 1	not reported	5000	not reported	negative
Test 2	not reported	5000	not reported	negative

Remarks - Results

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

TEST FACILITY Confidential.

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line Human lymphocytes.
Metabolic Activation System Rat liver auxiliary metabolic activation system (S9-mix).
Vehicle Supplemented RPMI-1640 culture medium.
Remarks - Method

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hours)*[a]	*Harvest Time (hours)*
Present			
Donor 1	0, 500, 2500, 5000	68	68
Donor 2, Test 1	0, 500, 2500, 5000	68	68
Donor 2, Test 2	5000	92	92
Absent			
Donor 1	0, 100, 1000, 2000	68	68
Donor 2, Test 1	0, 100, 1000, 2000	68	68
Donor 2, Test 2	2000	92	92

[a] this is the assumed exposure period; it is unclear from the method description whether the test substance was present during the 2-hour treatment with colcemid prior to harvest.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity[b] *in PreliminaryTest*	*Cytotoxicity*[b] *in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Donor 1, 68 hours		5000		negative
Donor 2, 68 hours		No dose response		negative
Donor 2, 92 hours		5000		negative
Absent				
Donor 1, 68 hours		2000	2500	negative
Donor 2, 68 hours		1000		negative
Donor 2, 92 hours		2000		negative

[b] measured as reduction in mitotic index

Remarks - Results

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

TEST FACILITY Confidential.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
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 biochemical oxygen demand after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 20ºC for 28 days. Sodium acetate was used as the standard material.

RESULTS

Test substance		*Sodium Acetate*	
Day	*% degradation*	*Day*	*% degradation*
28	12	28	-

Remarks - Results	The results indicated that 12% of the notified chemical degraded in 28 days based on biochemical oxygen demand. Chromatographic analysis of the test substance solutions showed between 97 and 107% of the nominal concentration. The test report supplied did not indicate the extent of degradation of the standard so it is difficult to assess the validity of the test. As such this result should be treated with caution.
CONCLUSION	An assessment of the notified chemical's potential to be readily biodegradable cannot be made due to concerns regarding the validity of the test.
TEST FACILITY	Confidential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – 96 h
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Water hardness	29 mg/L $CaCO_3$
Auxiliary Solvent	None
Analytical Monitoring	Spectrophotometric

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*
Nominal	*Actual*		*96h*
0	-	10	0
180	180	10	0

LC50	> 180 mg/L at 96 hours.
Remarks – Results	The results of the definitive study showed that no mortalities were observed in any test substance concentration. The 96-hour EC_{50} for the

notified chemical to *Oncorhynchus mykiss* is greater than 180 mg/L.

CONCLUSION The ecotoxicity data indicates the notified chemical is practically non-toxic to fish.

TEST FACILITY Confidential.

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 159 mg $CaCO_3$/L
Analytical Monitoring Spectrophotometric

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
180	150	20	0	0

LC50 > 150 mg/L at 48 hours
Remarks - Results The immobilisation tests with *Daphnia* were conducted using 5 daphnids per flask with observations performed at 24 and 48 hours. The tests were conducted using a nominal test substance concentrations of 180 mg/L (corrected to 150 mg/L). 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 150 mg/L based on the corrected concentration.

CONCLUSION The ecotoxicity data indicates the notified chemical is practically non-toxic to aquatic invertebrates.

TEST FACILITY Confidential.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species *Selenastrum capricornutum*
Exposure Period 72 hours
Concentration Range Nominal 0, 1.4, 2.8, 5.6, 11.3, 22.5, 45, 90 and 180 mg/L
Concentration Range Actual 0, 0.88, 1.9, 3.7, 8.4, 19, 41, 81 and 180 mg/L
Auxiliary Solvent None
Analytical Monitoring Spectrophotometric

RESULTS

Biomass	*Growth*	*NOEC*	
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*Biomass mg/L at 72 h*	*Growth mg/L at 72 h*
62 (CI = 12->180)	> 180	3.7	8.4

Remarks - Results: Algae were exposed to the test substance at the nominal concentrations of 0, 1.4, 2.8, 5.6, 11.3, 22.5, 45, 90 and 180 mg/L for 72 h at 24˚C under constant illumination and shaking. Analysis of the test substance concentrations after 72 h showed measured concentrations to range from 0.88-180 mg/L. No abnormalities were detected in any of the replicate test samples. The biomass of *Selenastrum capricornutum* was adversely affected by the test substance.

CONCLUSION: The ecotoxicity data indicates the notified chemical is harmful to algae.

TEST FACILITY: Confidential.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: ETAD Method 103
- Inoculum: Activated sludge
- Exposure Period: 3 hours
- Concentration Range Nominal: 1000 mg/L

RESULTS
- EC50: > 1000 mg/L
- Remarks – Results: The organisms in synthetic sewerage sludge were exposed to the test substance at the nominal concentration of 1000 mg/L for 3 h. The test showed no inhibition of respiration and no inhibition of nitrifying ability.

CONCLUSION: The ecotoxicity data indicates the notified chemical does not inhibit respiration of sewerage sludge organisms.

TEST FACILITY: Confidential.

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 to landfill. Environmental exposure will result from the disposal of textiles 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 via landfill or incineration. According to an EC Technical Guidance Document (European Commission, 1996 – Part 4, chapter 7), the fixation rates for reactive dyes of the type of the notified chemical to a variety of substrates range between 70 and 95%.

At the end of their useful lives, textiles are expected to be disposed of directly to landfill with the notified chemical strongly bound to the cellulose fibres. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance through abiotic or slow biotic processes as it is not expected to be readily biodegradable. Any unbound notified chemical disposed to landfill is likely to be immobilised through adsorption onto soil particles and sediments as a consequence of its anionic nature. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, sulphur and nitrogen.

In addition to releases to landfill, some of the notified chemical may be released to sewer as a result of textile washing. Give the high fixation rates it is expected that these releases will be low and widespread.

The chemical will be used in inks used on textiles with widespread exposure to the aquatic compartment. Assuming a worst-case situation in which 30% of the import volume (up to 3000 kg) is released to sewer (resulting from a worst case fixation rate of 70%) and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 13.04 kg/day, assuming 230 days production per year. According to the Simple Treat Model (European Commission, 1996 – chapter III) 100% of the chemical partitions to the water column and there is no biodegradation or volatilisation, the following PECwater and PECsoil values are obtained:

Concentration in effluent/day		**3.34** µg/L	(Assuming 230 days production)
Concentration in biosolids		0 mg/L	
PECwater (µg/L) with 100% release to:			
		Ocean	River
100% population		0.33	3.34
75% population		0.45	4.46
50% population		0.67	6.69
25% population		1.34	13.37
PECsoil (mg/kg) (assumes no degradation)			
		Recycled water	Application of biosolids
Soil concentration	1 year	0.03	0
	5 years	0.15	0
	10 years	0.30	0

The substance is not expected to bioaccumulate due to its high water solubility (Connell 1990).

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified substance is practically non-toxic to fish and Daphnia and harmful to algae. The most sensitive species are algae, where the 72 hour E_bC50 is 62 mg/L and the NOEC was 3.7 mg/L.

Acute results are available for 3 trophic levels. Applying an assessment factor of 100 to the most sensitive species (algae), the predicted no effect concentration (PNEC) is 620 μg/L.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste textiles (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.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.005. This value is significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that ink fixation rates are expected to be higher thus limiting the exposure of the notified chemical to sewer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to printing inks containing the notified chemical during transport of pre-packed cartridges should not result in exposure except in the event of accidental spillage.

Maximum exposure of workers in printing works is to 10% notified chemical. This exposure can potentially occur briefly when changing cartridges or more rarely if the machine becomes jammed or requires adjustment. Dermal exposure of maintenance workers to the notified chemical is possible during routine maintenance but is expected to be low due to the low concentration of the notified chemical in the ink and the fact that the majority of ink will be deposited on textiles. Removal of unfixed dye by steam treatment should result its exit with the waste stream. Once the ink is dried on the textile it should not be bioavailable.

9.2.2. Public health – exposure assessment

There will be no significant public exposure to the notified chemical given the low concentration in the ink product and the design of the cartridges. Contact with printed textile is unlikely to lead to significant dermal exposure, as the chemical will be bound to the textile.

9.2.3. Human health - effects assessment

Based on the toxicological data provided, the notified chemical would not be acutely toxic via oral or dermal routes. It is a slight skin and eye irritant and a skin sensitiser. An ink such as that likely to be imported was tested and found not to elicit skin sensitisation. The notified chemical is not mutagenic in bacteria or clastogenic in human peripheral lymphocytes. The results of a 28-day repeated dose oral study in rats suggest the notified chemical would not be classified as hazardous on repeated or prolonged exposure according to the Approved Criteria as a NOAEL of 150 mg/kg/day was established.

9.2.4. Human health – risk characterisation

9.2.4.1 OCCUPATIONAL HEALTH AND SAFETY

The critical potential hazard to workers exposed to the notified chemical is skin sensitisation. However, an ink similar in formulation to that to be imported in the ink jet cartridges was shown not to be sensitising to the skin of guinea pigs. With the low and intermittent exposure to process or maintenance workers, the notified chemical is not likely to produce an allergic response. However, given that there is a wide variation in the population in allergen susceptibility, it is recommended that PVC gloves be worn by workers who may come in contact with the notified chemical.

9.2.4.2 PUBLIC HEALTH

The public is only likely to be exposed to the notified chemical when it is dried onto textiles. At this stage, the notified chemical is not bioavailable and presents no significant risk.

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.

10.1. 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 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 provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact

  Consideration should be given to revising the concentration cut-off from 1% to 10% for inks containing the notified chemical on the basis of a skin sensitisation study for a representative ink
  .
- The following safety phrase should be included on the label for the imported ink products:
  - S24: Avoid contact with skin

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the imported ink:

- PVC 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

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

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:

(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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