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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dye in Epson Inkjet Cartridge

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Dye in Epson Inkjet Cartridge

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

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 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. Some data items are not provided however the notifier plans to re-submit the notification in the near future as a secondary notification and will supply all data items at that time.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dye in Epson Inkjet Cartridge

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD IR, NMR, UV-Vis & MS
Remarks

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	< 1	< 1	< 1	< 1	< 1

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
Virtually all of the notified chemical will eventually be released to the environment. Over 99.9% of the notified chemical will be bound to printed paper which will either be buried in landfills, incinerated or released from effluent deinking processes. Recycling of treated paper could result in release of a proportion of the notified chemical to the aquatic compartment. However, the environmental concentration is expected to be negligible. Where recycling does not occur the notified chemical will be disposed of to landfill where it is expected to remain bound to paper.

5.5. Disposal
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.
Remarks

Boiling Point Decomposes without boiling

METHOD EC Directive 92/69/EEC A.2 using Differential Scanning Calorimetry
Remarks

Density 1717 kg/m^3 at 20ºC

METHOD
Remarks
TEST FACILITY Not known

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 25ºC

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.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer does not contain any groups expected to hydrolysis in the environmental pH rang of 4-9.

Partition Coefficient (n-octanol/water) log Pow at 25ºC = < -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.

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. Although, the notified chemical contains a fully ionised sulfonate groups, which is expected to remain so in the environmental pH range (4-9) due to its strong acidity.

Flash Point Not determined

METHOD
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).

Autoignition Temperature 265 ± 5ºC

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

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.

ADDITIONAL TESTS

Surface Tension 72.2 mN/m

METHOD Not known
Remarks Surface tension given on MSDS for notified chemical.

Oxidizing Properties Not oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks

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.
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Dye in Epson Inkjet Cartridge

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: Dye in Epson Inkjet Cartridge

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)

7.4. Irritation – skin

TEST SUBSTANCE Dye in Epson Inkjet Cartridge

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)

7.5. Irritation - eye

TEST SUBSTANCE Dye in Epson Inkjet Cartridge

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)

7.6. Skin sensitisation

TEST SUBSTANCE

Dye in Epson Inkjet Cartridge

METHOD

OECD TG 406 Skin Sensitisation - <insert test type>.
EC Directive 96/54/EC B.6 Skin Sensitization - <insert test type>.

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)

7.8. 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)

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 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	Brixham (2002a)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

REMARKS	While no test report for toxicity to fish was provided, the MSDS included in the submission indicates that the EC50 for the notified chemical to Mirror carp is 470 mg/L.

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
Analytical Monitoring	Spectrophotometric

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal		*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 concentrations 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 ecotoxicity data indicates the notified chemical is practically non-toxic to aquatic organisms.

TEST FACILITY Brixham (2002b)

8.2.3. Algal growth inhibition test

REMARKS While no test report for toxicity to algae was provided, the MSDS included in the submission indicates that the E_bC50 and E_rC50 for the notified chemical to algae are 0.283 and less than 0.83 mg/L, respectively. It should be noted that the toxicity of the notified chemical to algae may be due to its light excluding properties.

ADDITIONAL TESTS

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 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. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill.

Assuming a worst-case situation in which the entire import volume is released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 8.2 kg/day. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 2.1 μg/L.

Amount entering sewer annually	≈1000 kg
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC	≈ 0.7 μg/L (0.7 ppb)

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

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.

9.1.2. Environment – effects assessment

Results provided in the notification dossier are provided above in Section 8.2. While acute toxicity results for fish, *Daphnia* and algae are available, only the report for *Daphnia* has been provided and reviewed. The notifier has stated that the reports for toxicity to fish and algae are available and will be provided in March 2003 as part of a Secondary Notification.

The most sensitive acute toxicity result is for algae and indicates the notified chemical is very toxic to aquatic life with an EC50 of 0.83 mg/L. This result would appear to be algistatic rather than algicidal but, without reviewing the test report, has been adopted in the determination of the PNEC. QSAR modelling indicates the chemical would be significantly less toxic than this to

algae with chronic toxicity predicted to be greater than 10 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 8.3 μg/L.

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.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.25. 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 not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

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 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 however hamper the evaluation of irritational effects. 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.

No genotoxic effects were observed in vitro in a Bacterial Reverse Mutation Test.

Hazard classification for health effects.
On the basis of results of eye irritation studies using the notified chemical, Dye in Epson Inkjet Cartridge is classified as an Irritant (Xi) R41 Risk of serious damage to eyes, in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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.
Therefore, the risk to public health from exposure to the notified chemical is considered low.

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, 1999). The classification and labelling details are:

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

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is 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 for the intended purpose and in the manner described by the notifier.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier was were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 products containing the 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
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 Dye in Epson Inkjet Cartridge are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), 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.

Disposal

- The MSDS for the ink containing the notified polymer recommends that the substance be disposed through a licensed waste contractor in accordance with Local and State regulations.

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(1) of the Act;
  - If the import volume increases above 1000 kg; or

- On completion of the toxicity test reports on fish, Daphnia and algae. In this regard, the notifier has agreed to provide results and test reports on fish, Daphnia and algae when they are finalised as part of a Secondary Notification. These studies are anticipated to be available in March 2003.

or

(2) 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.

13. BIBLIOGRAPHY

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