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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Lexmark Red Dye 93A

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Lexmark Red Dye 93A

1. APPLICANT

Lexmark International Inc of 12A Rodborough Road Frenchs Forest NSW 2086 (ABN 86 050 148 466) has submitted a standard notification statement in support of their application for an assessment certificate for Lexmark Red Dye 93A.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, purity, and details of exact import volume, use and customers have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Lexmark Red Dye 93A

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Dark maroon solid

Melting Point: > 373 ºC

Specific Gravity: 1.74 g/cm^3

Surface Tension: 72.5 mN/m at 20 ºC (for a 1.01 g/L solution)

Vapour Pressure: 2.4 x 10^{-19} kPa at 25ºC (Tremain and Bartlett, 1996)

Water Solubility: 102 g/L at 20ºC

Particle Size: not determined

Partition Co-efficient (n-octanol/water): P_{ow} <1.09 x 10^{-4} ; $\log_{10} P_{ow}$ <-3.96 at 22 ºC

Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 >1 year $T_{1/2}$ at pH 7.0 >1 year $T_{1/2}$ at pH 9.0 >1 year
Adsorption/Desorption:	K_{oc} <58.9; $\log_{10} K_{oc}$ <1.77
Flash Point:	not determined
Autoignition Temperature:	343 °C
Explosive Properties:	non-explosive
Reactivity/Stability:	non-oxidising

Comments on Physico-Chemical Properties

The methods employed to determine the physical chemical properties complied with those specified in the European Commission Directive 92/69/EEC.

The vapour pressure was determined by EC Method 4A using a vapour pressure balance system. Linear regression analysis was used to calculate vapour pressure at 25°C. The low value determined indicates that the chemical in solid form is not volatile.

The Flask method A6 of European Commission Directive 92/69/EEC was used to determine that the notified chemical is highly soluble in water. It is described in the MSDS as miscible.

Hydrolysis as a function of pH was determined following EC Method C7, which indicated that the chemical is stable with respect to hydrolysis in the environmental pH range 4-9.

The octanol-water partition coefficient was determined by the shake-flask method, EC Method A8. The high water solubility is consistent with the low log P_{ow}, indicating a very low affinity for the lipid component of soils and sediments. This is confirmed by the low log K_{oc}, determined using an HPLC screening method.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured, formulated or repackaged in Australia. It will be imported in 50 mL ink cartridge as a component of printing inks containing a maximum of 4% notified chemical. The ink cartridges are sealed in polyester bags and packed in retail boxes, ready for shipping to retail outlets and other customers.

The import volume of the notified chemical is estimated at a maximum of 2500 kg per annum over the next five years.

6. OCCUPATIONAL EXPOSURE

Printing inks containing the notified chemical will be imported in pre-packed cartridges, each containing a maximum of 4% w/w notified chemical. The cartridges are imported either as a traditional foam-filled design which contains the ink, or may contain a bladder which holds the ink.

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

Office workers and printer maintenance workers 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 ink jet printers. Maintenance workers for printers may potentially come in contact with the notified chemical more often than office workers. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Printer maintenance personnel often wear cotton disposable gloves. 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.

Contact with paper printed with printing inks containing the notified chemical is unlikely to result in dermal exposure, as it will be bound in the structure of the paper.

7. PUBLIC EXPOSURE

Exposure of the public as a result of transport and disposal of the ink products containing the notified chemical is assessed as negligible. Ink products containing the notified chemical are fully contained within inkjet cartridges that are sold to the public and are inserted directly into inkjet printers after purchase. Dermal contact with ink deposited onto paper is possible, but public exposure via this route is expected to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Environmental exposure will result from the disposal of printed paper (approximately 95%) and discarded cartridges (approximately 5%) estimated to each contain 2–4 mL, and accidental leakage from the cartridges.

Ink residues contained in the emptied cartridges are expected to remain within the containers, although release could occur from deterioration of the discarded spent cartridge. This could result in widespread release of up to 150 kg per annum of the notified chemical in landfill in the third year of use.

Release of the ink solution to the environment during use is not expected, as the ink cartridge is designed to prevent leakage. However, in the case of leakage, the ink will be wiped up and the absorbent material presumably disposed of in commercial garbage and ultimately to landfill.

8.2 Fate

Some 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 notified substance. Incineration of waste paper will destroy the compound with the generation of water vapours, oxides of carbon, nitrogen and sulfur and sodium containing compounds.

Some of the waste printed 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, therefore at least 30% of the notified chemical in the paper has the potential to end up in landfill and leach.

A biodegradation study was conducted using the notified chemical at 92.1 % purity. The test was conducted according to OECD TG 301D – Ready Biodegradability; Closed Bottle Test (Sewell IJ & Mead C, 1995). Activated sludge, obtained from Severn Trent Water Plc sewage treatment plant in Derbyshire, was mixed with the test substance or standard material (sodium benzoate) at final concentrations of 4 mg/L for the test chemical and one drop per L for the activated sludge inoculum. The biodegration of sodium benzoate calculated from BOD values was 88% after 28 days, indicating the test conditions were valid. After 28 days at 20 ± 1°C, the biodegradation of the test substance was determined to be 10%. The test substance was considered not readily biodegradable under the conditions of the Closed Bottle Test.

The substance is not expected to bioaccumulate due to its high water solubility, low log P_{ow} and high molecular weight.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Lexmark Red Dye 93A

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 5000 mg/kg	(Glaza MS, 1993a)
acute dermal toxicity	rat	> 2000 mg/kg	(Allen DJ, 1996)
skin irritation	rabbit	Slight to moderate irritant	(Glaza MS, 1992)
eye irritation	rabbit	Slight irritant	(Glaza MS, 1993c)
skin sensitisation	guinea pig	Non sensitiser	(Glaza MS, 1993b)

9.1.1 Oral Toxicity (Glaza MS, 1993a)

Species/strain:	Rats/Crl:CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single oral dose of 5000 mg/kg (0.5 g/mL in distilled water) was given by gavage
Test method:	OECD TG 401 (limit test)
Mortality:	None
Clinical observations:	Red-stained urine, soft stool and haircoat
Morphological findings:	All animals had diffusely red tail and/or hair coat around the perianal region. Microscopic investigation was not conducted in the study.
Comment:	All animals appeared normal by day 14
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Allen DJ, 1996)

Species/strain:	Rats/Sprague-Dawley

Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single dermal dose of 2000 mg/kg (moistened with distilled water) was applied under a semi-occlusive dressing for 24 hours
Test method:	OECD TG 402 (limit test)
Mortality:	None
Clinical observations:	None
Morphological findings:	No treatment related changes were observed at necropsy. Microscopic investigation was not conducted in the study.
Comment:	Purple coloured staining of the treatment site was noted in all animals which prevented accurate evaluation of erythema during the study.
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

No report on inhalation toxicity was provided.

9.1.4 Skin Irritation (Glaza MS, 1992)

Species/strain:	Rabbits/New Zealand White
Number/sex of animals:	3/sex
Observation period:	7 days
Method of administration:	A single dermal dose of 0.5 g notified chemical (moistened with 0.9% saline) was applied under a semi-occlusive dressing for 4 hours
Test method:	OECD TG 404

Draize scores:

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	2[a,b,c]	2[b,c]	1[c]	1[c]	1[c]	1[c]
2	2[b,c]	2[b,c]	1[c]	1[c]	1[c]	1[c]
3	2[b,c]	2[b,c]	1[c]	1[c]	1[c]	1[c]
4	1	1	0	1	1	0
7	0[d]	0[d]	0	0	0	0
Oedema						
1	0	1	1	0	0	1
2	1	1	1	1	0	1
3	1	1	0	0	0	0
4	1	0	0	0	0	0
7	0	0	0	0	0	0

[a] see Attachment 1 for Draize scales
[b] Blanching
[c] Difficult to score due to test material staining
[d] Desquamation

Comment: The mean value of the scores for erythema or oedema was less than 2. Scoring for erythema was hindered by staining from the test substance.

Blanching and desquamation of the test sites were also observed.

Result: the notified chemical was slightly to moderately irritating to the skin of rabbits

9.1.5 Eye Irritation (Glaza MS, 1993c)

Species/strain: Rabbits/New Zealand White

Number/sex of animals: 3/sex

Observation period: 7 days

Method of administration: A single dose (0.07 g finely ground, equivalent to 0.1 mL notified chemical) was placed into the everted lower lid of the right eye of each animal. The eyes remained unwashed. The untreated eye served as a control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	0*[1]	0	0*	0	0*	0	0	0	0	0
2	0*	0	0*	0	0*	0	0	0	0	0
3	0*	0	0*	0	0*	0	0	0	0	0
4	0*	0	0*	0	0	0	0	0	0	0
5	0*	0	0	0	0	0	0	0	0	0
6	0*	0	0*	0	0*	0	0	0	0	0
Iris	All animals scored zero									

Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
2	2	1	0	1	0	0	1	0	0	0	0	0	0	0	0
3	1	1	0	1	1	0	1	1	0	1	0	0	0	0	0
4	1	0	0	1	0	0	1	0	0	1	0	0	0	0	0
5	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0
6	1	1	0	1	1	0	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
* no apparent opacity; cornea stained light-red to dark purple which resolved by day 4
o = opacity a = area r = redness c = chemosis d = discharge

Comment: No staining was evident in all animals when fluorescein dye was applied to the eyes at 24 and 72 hours, and day 7.

All treated eyes returned to normal by day 7

Result: the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Glaza MS, 1993b)

Species/strain: Guinea pigs/Crl: (HA)BR

Number of animals: Control group: 10
Test group: 20

Induction procedure:

test group: day 1	Intradermal Induction: Three pairs of intradermal injections (0.1mL) across the shoulder region of the animals: - Freund's complete adjuvant (FCA) 1:1 in sterile water - 5% w/v notified chemical in sterile water - 5% w/v notified chemical in a 1:1 mixture of FCA and sterile water
day 7	Local Irritation: Animals pre-treated with 10% w/w sodium lauryl sulphate in petrolatum at the induction site
day 8	Topical Induction: A 48-hour occluded application of 25% w/w notified chemical in petrolatum to the test area.
control group: day	Treated similarly to the test animals using sterile water in intradermal injections and petrolatum in the topical application instead of the notified chemical.

Challenge procedure:

day 22	Test and Control animals: Occluded applications of a patch of 25% w/w notified chemical in petrolatum on the right flank and petrolatum on the left flank of each animal for 24 hours.

Test method: OECD TG 406, Magnusson and Kligman maximisation test

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
25%	**0/20	0/20	0/10	0/10
Petrolatum (control)	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Comment: None of the animals exhibited a dermal reaction in the study.

Result: the notified chemical was not sensitising to the skin of guinea pigs

9.2 28 Day Repeated Dose Oral Toxicity (Coles LJ et al., 1996)

Species/strain:	Rats/Sprague-Dawley
Number/sex of animals:	5/sex/group
Method of administration:	Oral (gavage)
Dose/Study duration:	Control: 0 mg/kg Low dose: 15 mg/kg Mid dose: 150 mg/kg High dose: 1000 mg/kg (vehicle: distilled water)
Test method:	OECD TG 407

Clinical observations:
There were no deaths during the study.

Transient increased salivation immediately after dosing from day 14 was noted in high dose group and one male from the same group had noisy respiration on day 17. However, these observations are common to oral administration of an unpalatable or locally irritant test material.

Red staining of the fur was observed at the high dose group and all treatment groups showed crimson-coloured urine and/or dark faeces from day 4. These observations were due to the oral administration of a coloured test material and not indicative of systemic toxicity.

High dose males had slight reduction in body weight gain during the first week of treatment and slight reduction in dietary intake throughout the study compared with controls. No adverse effect on body weight development and dietary intake or food efficiency were seen in high dose females.

Clinical chemistry/Haematology
Slight reductions in haemoglobin concentration and haematocrit were noted in high dose males.

Reduced aspartate aminotransferase (AST) and alanine aminotransferase (ALT) concentrations were seen in high and low dose males. A non-dose related increase in plasma alkaline phosphatase and an increase in plasma chloride were seen in high and mid dose females. The plasma chloride values were within the expected normal range.

The increase in alkaline phosphatase was not dose related and as such the effects was not considered toxicologically significant.

Pathology:
Statistically significant reduction in absolute brain weight was seen in high dose males but no corresponding effect was noted for the respective relative weights.

Dark patches or multiple dark foci on the lungs and enlarged testis found at terminal kill were consistent with spontaneous effects in rats.

No treatment related macroscopic abnormalities were detected.

Comment:
The statistically significant reduction in haemoglobin and haematocrit was due to one animal with unusually low values, and in the absence of any other changes associated with the haematological parameters, these findings were considered not of toxicological importance.

Result:
The no observed adverse effect level (NOAEL) is considered to be 1000 mg/kg/day, the highest dose tested, based on no significant adverse health effects at this dose.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Thompson PW, 1995)

Strains:	*Salmonella typhimurium*: TA1535, TA1537, TA1538, TA98 and TA100
Metabolic activation:	Liver S9 fraction from rats pretreated with Aroclor 1254
Concentration range:	0, 8, 40, 200, 1000, 5000 μg/plate of test substance in distilled water Each concentration was tested in triplicate, with or without metabolic activation S9, in two independent experiments. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 471
Comment:	No toxicity was observed in any of the tested strains of *Salmonella*. There were no significant increases in the numbers of revertant colonies in the presence or absence of metabolic activation at any test concentration. Concurrent positive controls induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	the notified chemical was non mutagenic under the conditions of the test

9.3.2 *Escherichia coli* Reverse Mutation Assay (Thompson PW, 1997)

Strains:	Escherichia coli: WP2*uvr*A
Metabolic activation:	Liver S9 fraction from rats pretreated with Aroclor 1254
Concentration range:	0, 8, 40, 200, 1000, 5000 μg/plate of test substance in distilled water (Experiment 1) 0, 312.5, 625, 1250, 2500, 5000 μg/plate of test substance in distilled water (Experiment 2) Each concentration was tested in triplicate, with or without metabolic activation. Appropriate strain specific positive control reference substances were used.
Test method:	OECD TG 472
Comment:	No toxicity was observed at any test concentration. Precipitation and intense colouration were observed at and above 1000 μg/plate and 1250 μg/plate, respectively, but did not interfere with the scoring of revertant colonies. There were no significant increases in the numbers of revertant colonies in the presence or absence of metabolic activation at any test concentration. Concurrent positive controls induced marked increases in the frequency of revertant colonies.
Result:	the notified chemical was non mutagenic under the conditions of the test

9.3.3 Chromosomal Aberration Assay in Human Lymphocytes *In Vitro* (Dunward R, 1996)

Cells:	Human lymphocytes
Metabolic activation system:	Liver S9 fraction from rats pretreated with Aroclor 1254
Dosing schedule:	Each concentration was tested in duplicate, with or without metabolic activation (S9), in two independent experiments.

Metabolic Activation	*Experiment Number*	*Test concentration (μg/mL)*	*Controls*
-S9	I	treatment time = 4 hours (20 hours harvest) 0, 39, 78.1, 156.25*, 312.5*, 625*, 1250, 2500 and 5000 μg/mL	Positive: EMS Negative: vehicle
	II	treatment time = 4 hours (20 hours harvest) 0, 156.25, 312.5, 468.75*, 625*, 937.5*, 1250 μg/mL treatment time = 4 hours (44 hours harvest) 0, 156.25, 312.5, 625* μg/mL	
+S9	I	treatment time = 4 hours (20 hours harvest) 0, 156.25, 312.5, 625, 1250*, 2500*, 5000* μg/mL	Positive: CP Negative: vehicle
	II	treatment time = 4 hours (20 hours harvest) 0, 625, 1250*, 2500*, 5000* μg/mL treatment time = 4 hours (44 hours harvest) 0, 1250, 2500, 5000* μg/mL	

EMS - ethyl methanesulphonate CP - cyclophosphamide
* - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment:

Experiments 1 and 2 (+S9)
There was no evidence of toxicity and metaphase cells were present up to 5000 μg/mL (maximum dose tested). No statistically significant increase in the frequency of aberrant cells was observed.

Experiment 1 (-S9)
Dose-related toxicity was induced with the test material in the absence of S9. Dose levels at and above 1250 μg/mL showed excessive toxicity, therefore, the dose levels selected for metaphase analysis were 156.25, 312.5 and 625 μg/mL.

A small but statistically significant increase in the frequency of chromosome aberration (without gaps) was observed at 625 μg/mL. According to the test report, the response was outside but close to the historical range.

Experiment 2 (-S9)
The level of toxicity with the test material is similar to Experiment 1. The test material induced dose related toxicity.

At the 20 hour harvest point, small but statistically significant increases in the frequency of cells with aberrations were observed at two dose levels (468.75 and 937.5 μg/mL). However, the response was only significant when gaps were included, did not show dose-response relationship and was not present at the 44 hour harvest. Therefore, the increases observed were not considered to be of toxicological significance.

Conclusion:
The increase in cells with aberrations seen in Experiment 1 did not show dose-response relationship, was close to historical control data and was not reproducible. Similarly, the increase in cells with aberrations seen in Experiment 2 was only significant when gaps were included and did not show dose-response relationship. Overall, the increases observed were not considered to be of toxicological significance.

Positive controls used in the test caused marked increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.

The test material did not induce significant increases in the numbers of polyploid cells in both experiments at any dose level, in the presence or absence of S9.

Result: the notified chemical was non clastogenic under the conditions of the test

9.3.4 Micronucleus Assay in the Bone Marrow Cells of the Mouse

No report of *in vivo* micronucleus assay was provided.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral (LD_{50} >5000 mg/kg) and low acute dermal toxicity (LD_{50} >2000 mg/kg) in rats. No report on inhalation toxicity was provided.

It was a slight eye irritant and slight to moderate skin irritant to rabbits. Evidence of skin sensitisation potential was not observed in guinea pigs in an adjuvant study.

In a repeat dose oral toxicity study in rats, a NOAEL was established as >1000 mg/kg/day

based on no adverse effects at the highest dose tested. The notified chemical was not mutagenic in the bacterial stains tested. In an *in vitro* chromosome aberration study using human lymphocytes, a non-dose response slight increase in aberrant cells were observed in the absence of metabolic activation (S9). No report of an *in vivo* micronucleus assay was provided.

Based on the toxicological data provided, the notified chemical, Lexmark Red Dye 93A is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier and are summarised in the following table. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

Test	***Species***	***Results*** (Nominal concentrations)
Acute Toxicity – Semi-Static (OECD TG 203)	Rainbow Trout *Oncorhynchus mykiss*	96 h LC_{50} > 100 mg/L NOEC > 100 mg/L
Acute Toxicity – Immobilisation (OECD TG 204)	Water Flea *Daphnia magna*	48 h EC_{50} > 100 mg/L NOEC > 100 mg/L
Acute Toxicity – Growth Inhibition (OECD TG 201)	Algae *Scenedesmus subspicatus*	72 h EC_{50} > 100 mg/L NOEC > 100 mg/L

- NOEC - no observable effect concentration
- LC_{50} - median lethal concentration
- EC_{50} – median effect concentration

Fish (Sewell IJ et al., 1995a)
Rainbow trout juveniles (mean length 4.7 cm, mean mass 1.83 g) were exposed to 100 mg/L notified chemical for 96 h. Treatments were replicated twice (10 fish each) with a single control of 10 fish. The static test solutions were renewed daily and held at 14˚C and 16 h light. As no mortalities or sublethal effects were observed in any test vessel, the 96 h LC_{50} and NOEC were >100 mg/L indicating that the notified chemical is practically non toxic to trout.

Aquatic Invertebrates (Sewell IJ et al., 1995b)
Neonate *Daphnia magna* (24 h old) were exposed to the test substance at a nominal concentration of 100 mg/L. The four replicate treatments and duplicate controls (containing 10 daphnids each) were held static at 21ºC and 16 h light for 48 h. No immobilisation or adverse effects were observed in any test vessel, giving a 48-h EC_{50} and NOEC of >100 mg/L. Therefore the notified chemical is considered to be practically non toxic to daphnids.

Algal Inhibition Test (Sewell IJ & Mead C, 1995)

Algae were exposed to the test substance at a concentration of 100 mg/L for 72 h at 24±1˚C under constant illumination and shaking. Six replicate test flasks were prepared for the test substance and three controls. No abnormalities were detected in any of the replicate test samples. Neither biomass or growth of *Scenedesmus subspicatus* was adversely affected by the test substance, giving a 72 h EC_{50} and NOEC of > 100 mg/L. Therefore the notified chemical is considered to be practically non toxic to algae.

Conclusion
The notified chemical caused no adverse effects, mortality or growth inhibition on fish, daphnia or algae and would be considered practically non-toxic to these organisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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

Abiotic or slow biotic processes would be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. The low octanol-water partition coefficient and high water solubility indicate the notified chemical will be predominantly distributed in water, where it will become diluted and dispersed.

Any released chemical is not expected to adversely affect aquatic organisms, since it is practically non-toxic to trout, daphnia and algae. In addition, bioaccumulation is not expected because the low log P_{ow}, indicating low lipid solubility, and large molecular weight (>700) will inhibit passage through cell membranes.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
Based on the toxicological data provided, the notified chemical would not be acutely toxic via oral or dermal routes. It is not likely to be a skin sensitiser or genotoxic. However, it is likely to be a slight eye and a slight to moderate skin irritant. Upon repeated exposure, organ or systemic effects are not expected. The notified chemical would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data provided.
Occupational Health and Safety
Exposure to printing inks containing the notified chemical during transport of pre-filled cartridges should not result in exposure except in the event of accidental spillage.

The notified chemical will be in imported inkjet cartridges at a maximum of 4%. Dermal exposure of office workers to the notified chemical will potentially occur when replacing spent cartridges and clearing paper jams from the printer. However, the design of the cartridges is such that exposure to the notified chemical should be negligible.

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. However, due to their frequent exposure to inks and toners, and printer personnel should wear cotton disposable gloves.

It is concluded that the risk of skin and eye irritation in workers involved in transport, storage, use and disposal of the notified chemical in this application is low.

In the event that the notified chemical will be handled as a raw ingredient at high concentrations, workers should be protected from skin contamination because it can cause slight topical effects and has staining properties.

Public Health
Exposure of the public as a result of transport and disposal of products containing the notified chemical is assessed as negligible. Dermal contact with ink deposited onto paper is a possible route of public exposure but given the low concentration of the notified chemical and the low toxicological hazard posed by the notified chemical, the risk to public health is expected to be very low.

13. RECOMMENDATIONS

To minimise occupational exposure to Lexmark Red Dye 93A the following guidelines and precautions should be observed:

- Protective eyewear, clothing and gloves should be worn when handling the notified chemical;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

No special precautions are required for the notified chemical when used at low quantities in inkjet printer cartridges. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Service personnel should wear cotton or disposable gloves when removing spent printer cartridges containing the notified chemical or when servicing printers.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998), or other internationally acceptable standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe