File No: NA/960

August 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Lexmark Yellow Dye 415

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Director
Chemicals Notification and Assessment

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Lexmark Yellow Dye 415

1. APPLICANT

Lexmark International Inc. of 12A Rodborough Road FRENCHS FOREST NSW 2086 (ACN 050 148 466) has submitted a standard notification statement in support of their application for an assessment certificate for Lexmark Yellow Dye 415.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Lexmark Yellow Dye 415

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Orange solid

Boiling Point: Decomposed from 185°C
(Boiling temperature is estimated to be >360°C).

Relative Density: 1 310 kg/m^3 at 20°C

Surface Tension: 71.1 mN/m at 20.5°C

Vapour Pressure: $<7.6x10^{-8}$ kPa at 25°C

Water Solubility: 748 g/L at 20°C

Fat Solubility: $<1.25x10^{-3}$ g/kg at 37°C

Partition Co-efficient (n-octanol/water): $\log_{10} P_{ow} < -2.89$

Hydrolysis as a Function of pH: at pH 4.0 and 25°C, $t_{1/2} > 1$ year;

	at pH 7.0 and 25°C, $t_{1/2}$ > 1 year; at pH 9.0 and 25°C, $t_{1/2}$ > 1 year.
Adsorption/Desorption:	$\log_{10} K_{oc}$ < 1.25
Particle Size:	2% has size <100 μm
Dissociation Constant:	pK_a 9.34 ± 0.05
Flash Point:	Not determined.
Flammability Limits:	Tests were not conducted based on structure and known properties.
Autoignition Temperature:	> 186°C
Explosive Properties:	Less sensitive to shock or friction than m-dinitrobenzene.
Reactivity/Stability:	Not determined.

3.1 Comments on Physico-Chemical Properties

All tests were performed by Safepharm Laboratories Ltd (1998g and 1999c).

The vapour pressure was determined using a vapour pressure balance and Method A4 of Commission Directive 92/69/EEC. The notifier indicated that the balance readings were too low and variable for a best-line fit. Therefore, a limit value was determined from a single data point by imposing a gradient of –1500 K on the highest observed value. The low value determined indicates that the notified chemical is classified as being very slightly volatile.

The water solubility was determined using the shake flask method specified in Method A6 of Commission Directive 92/69/EEC. Known amounts of the notified chemical (7.5, 8, 8.5 and 9 g) were added to water (2.5, 2, 1.5 and 1 g, respectively) and the resulting suspensions were shaken for 72 h and then equilibrated at 20°C for 24 h. After this period, the extent of dissolution was assessed visually. The notifier concluded that because undissolved test material remained in the sample which originally contained 8 g of the notified chemical in 2 g water while there was no undissolved test material in the sample containing 7.5 g in 2.5 g water, the solubility of the notified chemical in water is > 748 g/L. The notified chemical is classified as being readily soluble which is consistent with its structure.

The partition coefficient was determined using the shake flask method specified in Method A8 of Commission Directive 92/69/EEC. A stock solution was prepared by dissolving a known amount of the notified chemical (2.5 g) in *n*-octanol saturated water (500 mL). Six partitions were performed in which a known volume of the stock solution (described above) was shaken with a known volume of *n*-octanol saturated water over a 5 min period. After separation, aliquots of both phases were analysed by HPLC. The log P_{ow} <-2.89 is characteristic of a compound which tends to partition into the aqueous phase. The high water

solubility is consistent with the low log P_{ow}, indicating a very low affinity for the organic component of soils and sediments. This is confirmed by the low log K_{oc} as determined by the OECD draft guideline (July 1997). As such, the notified chemical is classified as being hydrophilic and relatively mobile in soil.

The hydrolysis as a function of pH was determined by Method C7 of Commission Directive 92/69/EEC. The notified chemical is classified as slightly hydrolysing in the pH range of 4-9.

The dissociation constant for the hydroxyl functional group was determined using OECD TG 112.

The surface tension was determined using a ring method based on ISO 304 and method A6 of Commission Directive 92/69/EEC. The result indicates the notified chemical is not surface active.

The fat solubility of the notified chemical was determined using OECD TG 116. The fat solubility of the notified chemical is considered to be low and is consistent with a chemical that has a high water solubility.

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 used as a component in an ink-jet printing cartridge for ink jet printers.

Less than 5 tonnes of the notified chemical will be imported for each of the first five years.

6. OCCUPATIONAL EXPOSURE

Printing inks containing the notified chemical will be imported in pre-packed cartridges, each containing a maximum of 3% 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 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

The notified chemical will not be manufactured, reformulated or packaged in Australia. The imported inkjet cartridges may be transported by air, ship, rail, or truck to their distribution location. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. The design also prevents leakage of ink. The public may be exposed to the notified chemical in the event of an accident during transport involving extensive breakage of cartridges.

The loading and removal of a cartridge into or from its containment area in a printer can be readily accomplished without any contact with ink. Skin contact with the ink may occur if an attempt is made to insert or remove a damaged cartridge or to correct a paper-jam.

The cartridges are not refilled. Spent cartridges contain on average 2-4 gm of remaining ink. The remaining ink is absorbed on foam contained within the cartridge and cannot be removed without breaking it. Ink on paper will be bound to the paper and is unlikely to be transferable to a person's skin.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release of the ink solution to the environment is not expected under normal use as the ink cartridge is designed to prevent leakage. However, if leakage does occur, the ink will be contained with absorbent material and that material will presumably be 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 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.

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 chemical. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, nitrogen and sulphur.

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.

A biodegradation study was conducted according to OECD TG 301B – Ready Biodegradability; CO_2 Evolution Test (Safepharm Laboratories Ltd, 1998h). Activated sludge, obtained from Severn Trent Water Plc sewage treatment plant in Derbyshire, was mixed with the test substance or standard material (sodium benzoate) to give final test concentrations of 10 mg carbon/L. The study was carried out in darkness at 21 °C. The sodium benzoate standard attained 100% biodegradation after 28 days, indicating the test conditions were valid. After 28 days, the biodegradation of the test substance was determined to be 68% and as such was not considered to be readily biodegradable under the conditions of OECD TG 301B. Although the notified chemical was close to satisfying the 60% requirement for ready biodegradability, this was not achieved within 10 days of the degradation exceeding 10%.

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

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Lexmark Yellow Dye 415

Test	*Species*	*Outcome*	Reference
acute oral toxicity	rat	LD50=134 mg/kg (female)	Safepharm Laboratories Ltd, 1998a
acute dermal toxicity	rat	LD50>2 000 mg/kg	Safepharm Laboratories Ltd, 1999a
skin irritation	rabbit	Slight irritant	Safepharm Laboratories Ltd, 1998b
eye irritation	rabbit	Slight to moderate irritant	Safepharm Laboratories Ltd, 1998c
skin sensitisation	guinea pig	Non sensitiser	Safepharm Laboratories Ltd, 1998d

9.1.1 Oral Toxicity (Safepharm Laboratories Ltd, 1998a)

Species/strain: Rat/Sprague-Dawley

Number/sex of animals: 3 female groups: 5 females each;
1 male group: 5 males.

Observation period: 14 days.

Method of administration: Oral by gavage at 71, 100 and 141 mg/kg in female groups, and at 71 mg/kg in the male group.

Vehicle: water.

Test method: OECD TG 401

Mortality:

	71 mg/kg	100 mg/kg	141 mg/kg
Female	0/5	1/5	3/5
Male	1/5		

All deaths occurred on day of dosing or day 1 post-dosing.

Clinical observations: At dose level of 71 mg/kg, animals exhibited ataxia, hunched posture, lethargy, ptosis, decreased respiratory rate, laboured respiration, staining around the eyes, mouth and snout, and splayed gait.

At dose level of 100 mg/kg, animal after dosing exhibited ataxia, hunched posture, lethargy, increased lacrimation, ptosis, decreased respiratory rate, laboured respiration, loss of righting reflex, increased salivation, staining around the mouth and snout, occasional body tremors, and prostration.

At dose level of 141 mg/kg, animal after dosing exhibited ataxia, emaciation, hunched posture, lethargy, ptosis, decreased respiratory rate, laboured respiration, staining around the eyes and snout, occasional body tremors, splayed gait and prostration.

Recovery was observed in surviving rats.

Morphological findings: Haemorrhagic lungs, dark liver, dark kidneys, orange material presented in the small intestine and/or stomach and orange-coloured staining of the gastric mucosa and non-glandular epithelium of the stomach were observed in dead animals.

No abnormalities were noted at necropsy of surviving animals at the end of the study.

Comment:	The response of single male animal was not markedly more sensitive than the females.
LD_{50}:	134 mg/kg (female)
Result:	The notified chemical was of moderate acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Safepharm Laboratories Ltd, 1999a)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	A single dermal application at 2 000 mg/kg (moistened with water) under a semi-occlusive dressing for 24 hours.
Test method:	OECD TG 402
Mortality:	None.
Clinical observations:	Yellow-coloured staining was observed during the study. No signs of systemic toxicity or skin irritation were noted.
Morphological findings:	None.
Comment:	Draize score for erythema and oedema were zero for all animals during the study except yellow-coloured staining lasted up to 8 days.
LD_{50}:	> 2 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No inhalation study was provided for assessment.

9.1.4 Skin Irritation (Safepharm Laboratories Ltd, 1998b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 males.
Observation period:	72 hours

Method of administration: A dermal dose of 0.5 g notified chemical moistened with 0.7 mL water was applied under a semi-occlusive dressing to an intact skin area of each rabbit for 4 hours.

Test method: OECD TG 404

Draize scores:

Time after treatment	***Animal #***		
	1	***2***	*3*
Erythema			
1 hour	[a]1	0	1
24 hours	0	0	0
48 hours	0	0	0
72 hours	0	0	0
Oedema			
Draize scores for oedema were zero for all animals during the study.			

[a] see Attachment 1 for Draize scales

Comment: Yellow coloured staining was noted at all treated skin sites throughout the study. This staining did not interfere with evaluation of skin reactions.

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

9.1.5 Eye Irritation (Safepharm Laboratories Ltd, 1998c)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3 males.

Observation period: 72 hours

Method of administration: A dose of 0.1 mL (65 mg notified chemical) was applied to conjunctival sac of one eye. The untreated eye served as the control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	*1 hour*			*24 hours*			*48 hours*			*72 hours*		
Cornea												
	Draize scores for cornea (opacity and area) were zero for all animals during the study.											
Iris												
1		0			0			0			0	
2		0			0			0			0	
3		1			0			0			0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2	2	1	1	0	0	0	0	0	0	0
2	2	1	3	1	0	0	0	0	0	0	0	0
3	2	2	3	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Comment: Orange/yellow coloured staining of fur around the treated eye was observed in all animals throughout the study. Yellow coloured staining presented over nictitating membrane and part cornea in all treated eyes 1 hour after treatment. This staining did not affect evaluation of ocular effects.

Iridal inflammation was noted in one treated eye at the 1 hour observation.

Result: The notified chemical was a slight to moderate irritant to the eyes of rabbits.

9.1.6 Skin Sensitisation (Safepharm Laboratories Ltd, 1998d)

Species/strain: Male guineapig/Dunkin Hartley

Number of animals: 10 test and 5 control animals

Induction procedure:

test group:
day 0 Three pairs of intradermal injections (0.1 mL) were made in the shoulder regions:

- Freund's complete adjuvant (FCA) diluted 1:1 with distilled water

- 1% notified chemical in distilled water
- 1% notified chemical in a 1:1 preparation of FCA and water.

day 7 — 75% notified chemical in water was applied topically under occlusive dressings for 48 hours, to same skin area

control group: — Control animals were treated similarly to the test animals except without the notified chemical.

Challenge procedure:

day 21 — 50 and 75% notified chemical in water was applied topically to flanks separately for 24 hours under occlusive dressing.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
50%	**0/9	0/9	0/5	0/5
75%	0/9	0/9	0/5	0/5

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

Comment: One test animal was found dead on day 9. The cause of death was not determined.

Yellow coloured staining was observed on the applied sites, which prevented accurate evaluation of erythema.

Result: The notified chemical was non-sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Safepharm Laboratories Ltd, 1999b)

Species/strain: Rat/Sprague Dawley

Number/sex of animals: 5 sex/group

Method of administration: Oral (gavage)

Dose/Study duration: Control group: 0 mg/kg/day,
Low-dose group: 5 mg/kg/day,
Mid-dose group: 15 mg/kg/day,
High-dose group: 50 mg/kg/day (vehicle: water).

The notified chemical was administered for 28 consecutive days.

Test method: OECD TG 407

Clinical observations:
No deaths occurred during the study.

No abnormalities were observed in control, low and mid dose animals.

High-dose animals had increased salivation during dosing up to one hour after dosing and a reduced dietary intake. High-dose males had a reduced bodyweight gain and an increase in the percentage average of startle reflex response when compared with controls.

Clinical chemistry/Haematology
No treatment related haematological changes were detected.

High-dose females had increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels in plasma. An increase in plasmic ALT extended in females at mid and high doses.

Histopathology:
No treatment related changes were detected in organ weights.

High-dose males showed small seminal vesicles at terminal kill. Microscopic examination revealed that these animals had a reduction in secretory content of seminal vesicles.

Comment:
The increased plasmatic ALT levels in mid and high dose females were considered to be treatment related, and selected for the establishment of NOEL.

Result:
The NOEL level for the notified chemical in this repeat dose study is determined to be 5 mg/kg/day.

The NOAEL level for the notified chemical in this repeat dose study is determined to be 15 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Safepharm Laboratories Ltd, 1998e)

Strains: *S. typhimurium* TA1535, TA1537, TA98 and TA100; *E. coli* WP2*uvr*A.

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Concentration range:	Triplicate plates were prepared for each bacterial strain and dose level, in both the presence and the absence of S9-mix. Distilled water was used as the vehicle. Main study: 0, 50, 150, 500, 1 500 and 5 000 μg/plate in all strains. Positive controls: (without S9-mix) • N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG) for TA100, TA1535 and WP2*uvr*A; • 9-aminoacridine (9AA) for TA1537; • 4-nitroquinoline-1-oxide (4NQO) for TA98. (with S9-mix) • 2-aminoanthracene (2AA) for all strains.
Test method:	OECD TG 471
Comment:	No cytotoxicity was observed in the study. Under the conditions of the study, the notified chemical caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes. All positive controls responded appropriately.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung Cells (Safepharm Laboratories Ltd, 1998f)

Cells:	Chinese Hamster Lung (CHL) Cells
Metabolic activation system:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Dosing schedule:	Duplicates were performed at each concentration.

Metabolic Activation	*Experiment Number*	*Test concentration (μg/mL)*	*Controls*
-S9	1	12 hr continuous treatment 0, 78.1, 156.25, 312.5*, 625*, 1 250* and 1 875	Positive: Mitomycin C (MMC)
	2	12 hr continuous treatment 0, 156.25, 312.5*, 625*, 1 250* and 1 875 6 hr continuous treatment 0, 156.25, 312.5, 625, 1 250*, 2 500* and 5 000* 24 hr continuous treatment 0, 156.25, 312.5*, 625*, 1 250*, 1 875 and 2 500 48 hr continuous treatment 0, 156.25, 312.5*, 625*, 1 250*, 1 875 and 2 500	Negative: Eagle's Minimal Essential medium with Earle's salts (MEM)
+S9	1	4 hr treatment, 8 hr recovery 0, 156.25, 312.5, 625, 1 250*, 2 500* and 5 000*	Positive: CP
	2	4 hr treatment, 8 hr recovery 0, 625, 1 250*, 2 500* and 5 000* 6 hr treatment, 18 hr recovery 0, 156.25, 312.5, 625, 1 250*, 2 500* and 5 000*	Negative: Eagle's Minimal Essential medium with Earle's salts (MEM)

CP - cyclophosphamide
* - cultures selected for metaphase analysis

Test method: OECD TG

Comment: There was no clear evidence of a dose-related increase in cytotoxicity in any of the exposure cases.

Metaphases presented at up to 5 000 μg/mL after 6 and 12 hour treatment (with S9-mix), and at up to 5 000 μg/mL after 6 hour treatment and up to 1 250 μg/mL after 12, 24 and 48 hour treatment (without S9-mix).

The notified chemical did not induce a significant increase in the frequency of cells with aberration or in the numbers of polyploid cells, either with or without metabolic activation.

	All positive controls responded appropriately. CP was used as the positive control in 6 hour treatment without S9-mix in Experiment 2. The report claimed this test was a control for the 6 hour treatment with S9-mix.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of moderate acute oral toxicity and low acute dermal toxicity in rats. No inhalation toxicity study was provided. It was a slight to moderate eye irritant and a slight skin irritant in 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 NOEL was established at 5 mg/kg/day based on the increase of plasmic ALT levels at the higher dose tested. The NOAEL for the notified chemical in this repeat dose study was determined to be 15 mg/kg/day.

The notified chemical was not mutagenic in the bacterial stains tested, nor clastogenic in a chromosome aberration study in Chinese hamster lung cells. No report of an *in vivo* micronucleus assay was provided.

Based on the acute oral toxicity data, the notified chemical, Lexmark Yellow Dye 415 is classified as a hazardous substance with a risk phrase R25 (Toxic if swallowed) according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies for Lexmark Yellow Dye 415 were provided by the notifier.

Test	***Species***	***Results***
Acute Toxicity	Rainbow Trout *Oncorhynchus mykiss*	LC_{50} (96 h) > 100 mg/L NOEC (96 h) = 100 mg/L
Acute Immobilisation	Water Flea *Daphnia magna*	EC_{50} (48 h) = 3.4 mg/L NOEC (48 h) = 1.8 mg/L
Chronic exposure/reproduction	Water Flea *Daphnia magna*	EC_{50} (21 d) = 1.9 mg/L NOEC (21 d) = 1.1 mg/L
Growth Inhibition [OECD 201]	Algae *Scenedesmus subspicatus*	EC_{50} (72 h) > 100 mg/L NOEC (72 h) =100 mg/L

* NOEC - no observable effect concentration

The tests on fish (Safepharm Laboratories Ltd, 1998i) were performed using a semi-static

methodology. Observations were performed at 3, 6, 24, 48, 72 and 96 hours. The test was performed in duplicate using ten specimen fish per duplicate at a temperature of 14ºC. Based on the results from the range finding study, the test was conducted at a nominal concentration of 100 mg/L. The nominal concentrations of the notified chemical used were validated by HPLC using an external standard technique. Analysis of the test solutions at 0, 24 and 96 h showed that the concentration of the test substance was within experimental error of the nominal concentration of 100 mg/L. The results of the definitive study showed that no mortalities or sublethal effects were observed at a concentration of 100 mg/L. The 96-hour LC_{50} for the notified chemical to *Oncorhynchus mykiss* is greater than 100 mg/L.

The immobilisation tests with Daphnia (Safepharm Laboratories Ltd, 1998j) were also performed under semi-static conditions with observations performed at 24 and 48 hours. The test was performed in duplicate using 10 daphnids per flask at a temperature of 21ºC. The tests were conducted at the nominal concentrations of 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.2, 10 and 18 mg/L. The nominal concentrations of the notified chemical used were validated by HPLC using an external standard technique. Analysis of the test solutions at 0 and 48 h showed that the concentration of the test substance was within experimental error of the nominal concentrations. After 48 h, no immobilised daphnids were observed in the test vessels with less than 1.8 mg/L, 50 and 90% mortality was observed at 3.2 and 5.6 mg/L, respectively, and 100 % mortality was observed at test concentrations above 10 mg/L. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is 3.4 mg/L as determined using a moving average method. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* as determined by probit analysis is 3.42 mg/L with 95% confidence limits of 2.93-3.98 mg/L.

The reproduction tests with Daphnia (Safepharm Laboratories Ltd, 1998k) were also performed under semi-static conditions for a period of 21 days. The tests were conducted at nominal concentrations of 0.034, 0.11, 0.34, 1.1 and 3.4 mg/L with 10 daphnids per concentration at a temperature of 21ºC. The nominal concentrations of the notified chemical used were validated by HPLC using an external standard technique. Analysis of the fresh media at 0 and 7 d, old media at 2, 5 d and 21 d and old and fresh media at 7, 9, 12, 14, 16 and 19 d showed that the concentration of the test substance was near to the nominal concentrations in most solutions. After 21 days, there was no immobilisation in either the adult or young daphnid populations in concentrations of the notified chemical of below 1.1 mg/L. There was 100% immobilisation observed in the adult daphnid population after day 5 in the 3.4 mg/L group. Therefore, the notified chemical does not impair the reproduction of daphnids that survive until day 21. The 21-day EC_{50} (immobilisation and reproduction) for the notified chemical to *Daphnia magna* is 1.9 mg/L.

Algae were exposed to the test substance at a concentration of 100 mg/L for 72 h at 24˚C under constant illumination and shaking (Safepharm Laboratories Ltd, 1998l). The nominal concentrations of the notified chemical used were validated by HPLC using an external standard technique. Analysis of the test solutions at 0 and 72 h showed that the concentration of the test substance was within experimental error of the nominal concentrations. 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 the growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance, giving a 72 h EC_{50} of greater than 100 mg/L and NOEC is 100 mg/L.

The ecotoxicity data indicates the notified chemical is practically non-toxic to fish and algae, but appears to be moderately toxic to daphnia.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

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 spent cartridges at landfill sites. Based on 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 which is released to the sewer.

Although it is not considered to be readily biodegradable, significant biodegradation of the notified chemical is expected to occur. Degradation of the notified chemical by abiotic processes should also occur. 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 fish and algae. The notified chemical is moderately toxic to daphnia, however there will be limited release to water. In addition, bioaccumulation is not expected due to the notified chemicals low log P_{ow}, indicating low lipid solubility, and high molecular weight which inhibits 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 was of moderate acute oral and low acute dermal toxicity. It is not likely to be a skin sensitiser or genotoxic. However, it is likely to be a slight to moderate eye irritant and slight skin irritant. The NOEL from a repeat oral dose study was 5 mg/kg/day. The NOAEL level for the notified chemical in this repeat dose study was determined to be 15 mg/kg/day. Based on the acute oral toxicity data, the notified chemical, Lexmark Yellow Dye 415 is classified as a hazardous substance with a risk phrase R25 (Toxic if swallowed) according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety
Exposure to printing inks containing the notified chemical during transport of pre-filled cartridges is not anticipated except in the event of accidental spillage.

The notified chemical will be in imported inkjet cartridges at a maximum of 3%. Dermal exposure of office workers to the notified chemical may 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, printer personnel should wear cotton disposable gloves.

Based on the low concentration of the notified chemical in the ink, the design of cartridge, and the limited duration of exposure, 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 and eye contamination because it can cause slight topical effects and has staining properties.

Public Health
Lexmark Yellow Dye 415 is a component of ink in inkjet printer cartridges. The design of the cartridge ensures that the ink is virtually inaccessible to those who handle cartridges. In those circumstances where exposure to the ink occurs, the very low concentration of Lexmark Yellow Dye 415 in the ink will further minimise the effects of any exposure.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R25 Toxic if swallowed

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥25% Toxic if swallowed
  - 3%≤conc<25% harmful if swallowed

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid skin and eye contact when removing spent cartridges.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Protective eyewear
  - Protective clothing
  - Cotton or disposable gloves – when servicing printers and removing spent cartridges.

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.

13.1 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.

14. MATERIAL SAFETY DATA SHEET

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

These MSDS were provided by the applicant as part of the notification statement. The MSDS for the product containing the notified chemical is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. 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

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