File No: NA/930

July 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Lexmark Black Pigment

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Lexmark Black Pigment

1. APPLICANT

Lexmark International Inc of 12A Rodborough Rd 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 Black Pigment.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	Lexmark Black Pigment.
Molecular Weight:	Uncertain as the chemical is attached to a surface.
Method of Detection and Determination:	UV/Visual (UV/Vis) and Infrared (IR) spectroscopy.
Spectral Data:	UV/Vis and IR spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Black solid.
Melting Point:	> 360°C
Specific Gravity:	1.97 at 20°C
Vapour Pressure:	< 1.4×10^{-8} kPa at 25°C
Water Solubility:	< 0.8 mg/L (estimated).
Partition Co-efficient (n-octanol/water):	Not determined.
Hydrolysis as a Function of pH:	Not determined.

Adsorption/Desorption:	Not determined.
Dissociation Constant:	Not determined.
Particle Size:	44.7% < 100 μm; 11.4% < 10 μm.
Flash Point:	Not determined.
Flammability Limits:	Not highly flammable.
Autoignition Temperature:	300°C
Explosive Properties:	Not explosive.
Reactivity/Stability:	Non-oxidising.

3.1 Comments on Physico-Chemical Properties

All tests were performed by Safepharm Laboratories Ltd (2000a, b).

The vapour pressure provided was determined using a vapour pressure balance and Method A4 of Commission Directive 92/69/EEC. Linear regression analysis was used to calculate vapour pressure at 25°C. The low value determined indicates that the notified chemical is classified as being very slightly volatile.

The water solubility was determined using a visual assessment method because no method of analysis was available for the notified chemical. A known amount of the notified chemical (4×10^{-4} g) was added to water (5 L) and the resulting suspension was agitated in an ultrasonic bath for 15 minutes and then allowed to stand for 3 days at room temperature. After this period, the extent of dissolution was assessed visually. The notifier concluded that because undissolved test material remained in the sample, the solubility of the notified chemical in water is $< 8 \times 10^{-4}$ g/L. The notified chemical is classified as being very slightly to slightly soluble which is consistent with its predominantly carbon structure.

Measurements of hydrolytic stability, partition coefficient and adsorption/desorption were not determined because the notified chemical is insoluble in both aqueous and organic media.

4. PURITY OF THE CHEMICAL

Degree of Purity:	94% (89 – 99%)
Hazardous Impurities:	None.
Non-hazardous Impurities (> 1% by weight):	2 non-hazardous impurities at concentrations up to 5%.
Additives/Adjuvants:	None.

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a component (at a concentration of 2%) of an ink for use in inkjet printers. Less than 1 tonne of the notified chemical will be imported for each of the first five years. The notified chemical will be imported in an ink formulation in cartridges to be inserted in ink jet printers used with computers.

6. OCCUPATIONAL EXPOSURE

Printing inks containing the notified chemical will be imported in pre-packed cartridges, each containing a maximum of 2% w/w notified chemical.

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

Public exposure will only occur with rupture of ink cartridges as a result of an accident. According to the MSDS this spillage should be soaked up using cloth or paper towel and disposed of in accordance with standard regulations.

Emptied cartridges will contain very small quantities of the chemical. These cartidges will likely be disposed of in landfill. Disposal of the cartridges is unlikely to lead to public exposure.

Ink will be contained in cartridges and released by the printer. Over the life of a cartridge approximately 1 ml of the ink will be deposited on internal workings of the printer. Normal public exposure will occur with this residue during cartridge change (which occurs about every 600^{th} or 1200^{th} page depending on size of cartridge). The quantities of ink present on the printed page are extremely small, and as it is bound to the paper, public exposure is expected to be limited.

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 wiped up and the absorbent material 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 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 either in landfill or via incineration.

8.2 Fate

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

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, 2000c). 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 89% biodegradation after 28 days, indicating the test conditions were valid. After 28 days, the biodegradation of the test substance was determined to be 14% and as such was not considered to be readily biodegradable under the conditions of OECD TG 301B.

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 Black Pigment (solid)

Test	*Species*	*Outcome*	Reference
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Safepharm Laboratories Ltd, 2000d)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Safepharm Laboratories Ltd, 2000e)
skin irritation	rabbit	not irritant	(Safepharm Laboratories Ltd, 2000f)
eye irritation	rabbit	slight to moderate irritant	(Safepharm Laboratories Ltd, 2000g)
skin sensitisation	guinea pig	not sensitising	(Safepharm Laboratories Ltd, 2000h)

9.1.1 Oral Toxicity – Acute Toxic Class Method (Safepharm Laboratories Ltd, 2000d)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 3/sex.

Observation period: 14 days.

Method of administration: Arachis oil suspension via oral (gavage) route; dose 2000 mg/kg.

Test method: OECD TG 423

Mortality: None.

Clinical observations: Black coloured staining of the urine and faeces up to three days after dosing.

Morphological findings: None.

LD_{50}: > 2000 mg/kg.

Result: The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Safepharm Laboratories Ltd, 2000e)

Species/strain:	rat/Sprague-Dawley.
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	Semi-occluded 24-hour application to intact skin; dose 2000 mg/kg.
Test method:	OECD TG 402
Mortality:	None.
Clinical observations:	No signs of toxicity. Erythema could not be evaluated due to black staining of the skin one day after dosing and at 8 treatment sites 2 days after dosing. No evidence of skin irritation was noted for the remainder of the observation period.
Morphological findings:	None.
LD_{50}:	> 2000 mg/kg.
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No data provided.

9.1.3 Skin Irritation (Safepharm Laboratories Ltd, 2000f)

Species/strain:	rabbit/New Zealand White (NZW).
Number/sex of animals:	2 females/ 1 male.
Observation period:	72 hours.
Method of administration:	0.5 g test substance under semi-occluded dressing for 4 hours.
Test method:	OECD TG 404
Comment:	Grey coloured staining was observed in all animals at 1 hour and in one animal at 24 hours post-treatment but this did not affect scoring of irritative effects. No erythema or oedema was observed in any animal at any time point.
Result:	The notified chemical was not irritating to the skin of

rabbits.

9.1.5 Eye Irritation (Safepharm Laboratories Ltd, 2000g)

Species/strain: rabbit/NZW.

Number/sex of animals: 3 females.

Observation period: 72 hours.

Method of administration: 0.1 mL (43 mg) to the conjunctival sac of 1 eye. The other eye served as control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	***o***	***a***		***o***	***a***		***o***	***a***		***o***	***a***	
1	0[1]	0		0	0		0	0		0	0	
2	dull	2		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
Iris												
1	0			0			0			0		
2	1			0			0			0		
3	0			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	2	3	1	1	0	0	0	0	0	0	0
3	2	2	2	1	1	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

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

9.1.6 Skin Sensitisation (Safepharm Laboratories Ltd, 2000h)

Species/strain: guinea pig/Dunkin-Hartley.

Number of animals: 10 test, 5 control.

Induction procedure:

test group:

day 1 — Pairs of intradermal injections (0.1 mL) to the scapular region as follows:

- Freund's Complete Adjuvant (FCA), 1:1 in water;
- Lexmark Black Pigment, 5% distilled water;
- Lexmark Black Pigment, 5% in FCA, 1:1 in distilled water.

day 7 — 5% Lexmark Black Pigment in distilled water under occlusive dressing for 48 hours.

control group: As for test animals without the Lexmark Black Pigment.

Challenge procedure:

day 21 — 25% or 10% Lexmark Black Pigment in distilled water under occlusive dressing for 24 hours.

Test method: OECD TG 406

Challenge outcome:

Challenge concentration	• *Test animals* • *24 hours**	• *48 hours**	• *Control animals* • *24 hours*	• *48 hours*
25%	0/9**	0/9	0/5	0/5
10%	0/9	0/9	0/5	0/5

* time after patch removal

** number of animals exhibiting positive response

Comment: One animal in the test group died on day 21. Black staining prevented accurate evaluation of erythema at the intradermal induction sites of all test group animals 24 and 48 hours after dosing except in one animal which showed moderate and confluent erythema 48 hours after treatment. After topical induction black staining noted 24 hours after dressing removal did not affect evaluation of dermal reactions.

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

9.2 Repeated Dose Toxicity (Safepharm Laboratories Ltd, 2000i)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex/group.

Method of administration: Oral (gavage). Vehicle: distilled water.

Dose/Study duration: 0, 150, 500 and 1000 mg/kg/day for 28 consecutive days.

Test method: OECD TG 407

Clinical observations:
None. Animals from all treatment groups exhibited dark faeces from day 2 onwards. No changes in behavioural, functional or sensory assessments were noted. Black staining of fur from day 4 onwards in the 1000 mg/kg/day group was an occasional finding in other treatment groups.

Clinical chemistry/Haematology
No findings.

Macroscopic findings/Organ weights
No findings.

Histopathology:
No findings.

Comment:
Animals in the 500 and 1000 mg/kg/day groups exhibited dark contents of the g.i. tract at terminal kill.

Result:
The No Observed Adverse Effect Level (NOAEL) for Lexmark Black Pigment was the top dose of 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Safepharm Laboratories Ltd, 2000j)

Strains: *S. typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100; *Escherichia coli* strain WP2*uvrA*.

Metabolic activation: Induced rat liver microsomal fraction (S9).

Concentration range: 0, 50, 150, 500, 1500 or 5000 microgram/plate.

Test method: OECD TG 471

Comment: The negative controls were within normal limits and the positive controls (N-ethyl-N'-nitro-N-nitrosoguanidine, 4-nitroquinoline-1-oxide and 9-aminoacridine (-S9); 2-aminoanthracene and benzo(a)pyrene (+S9) demonstrated the sensitivity of the test. Precipitation was observed at 5000 microgram/plate and a black colour at 500 microgram/plate and above. Neither interfered with scoring.

Result: The notified chemical was non mutagenic under the conditions of the test as no increases in the numbers of revertant colonies above background were observed.

9.3.2 Chromosomal Aberration Assay in human lymphocytes in vitro (Safepharm Laboratories Ltd, 2000k)

Cells: Human lymphocytes.

Metabolic activation system: Induced rat liver microsomal fraction.

Dosing schedule:

• *Metabolic Activation*	• ***Experiment Number***	• *Test concentration (μg/mL)*	• *Controls*
-S9	1	Treatment time = 4 hours; expression time = 16 hours. Test concentration = 0*, 39.06, 78.13, 156.25, 312.5, 625*, 1250*, 2500* and 5000 microgram/mL.	Positive: EMS Negative: Vehicle = minimal essential medium
	2	Treatment time = 20 hours. Test concentration = 0, 78.13, 156.25, 312.5, 625*, 1250*, and 2500* microgram/mL.	
+S9	1 (S9 = 1%)	Treatment time = 4 hours; expression time = 16 hours. Test concentration = 0*, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*, 2500 and 5000 microgram/mL.	Positive: CP Negative: Vehicle = minimal essential medium
	2 (S9 = 2%)	Treatment time = 4 hours; expression time = 16 hours. Test concentration = 0*, 78.13, 156.25, 312.5, 625*, 1250*, and 2500* microgram/mL.	

EMS = ethylmethanesulphonate; CP = cyclophosphamide

* - cultures selected for metaphase analysis

Test method:	OECD TG 473
Comment:	Positive controls demonstrated the sensitivity of the test and negative controls were within historical limits. Precipitation was observed at all dose levels and there was no treatment-related reduction in mitotic index at any dose. No statistically significant increase in the frequency of chromosomal aberrations was seen at any dose level.
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 very low acute oral toxicity and low acute dermal toxicity in rats (each LD50 > 2000 mg/kg). It was not a skin irritant in rabbits, was a slight to moderate eye irritant in rabbits and was not a skin sensitiser in guinea pigs. No systemic toxicity was observed in a 28-day oral repeated dose study in rats (NOAEL = 1000 mg/kg/day) and neither mutagenicity in bacteria nor clastogenicity in human lymphocytes was observed.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	*Species*	*Results*
Acute toxicity	Rainbow trout	96 h LC_{50} > 1.2 mg/L NOEC = 1.2 mg/L
Acute toxicity	*Daphnia magna*	48 h EC_{50} > 2.4 mg/L NOEC = 2.4 mg/L
Algal Inhibition	*Scenedesmus subspicatus*	72 h EC_{50} > 0.82 mg/L NOEC = 0.82 mg/L

* NOEC - no observable effect concentration

The ecotoxicity tests were performed on a saturated solution of the notified chemical. The required amount of the notified chemical was added to dechlorinated tap water to a final concentration of 100 mg/L and the resulting suspension was stirred for 23 hours. The heterogeneous solution was allowed to stand for 1 hour prior to the removal of undissolved test material by filtration.

The tests on fish (Safepharm Laboratories Ltd, 2000l) were performed using a semi-static methodology in which test preparations were renewed daily to ensure that concentrations of test material were maintained near nominal and to prevent the accumulation of nitrogenous wastes. Observations were performed at 3, 6, 24, 48, 72 and 96 hours. The definitive test was

performed at a temperature of 14ºC on a solution saturated with the test material using ten specimen fish per test solution. The saturated solution was prepared from an initial dispersion at a concentration of 100 mg/L. Dissolved organic carbon (DOC) analysis of the saturated solutions at 0, 24, 72 and 96 h showed measured carbon concentrations to be below the limit of quantification (1 mg carbon/L). The limit of quantification equates to a test material concentration of 1.2 mg/L. As no mortalities or sublethal effects were observed in any test vessel, the 96 h LC_{50} and NOEC were >1.2 mg/L indicating that the notified chemical is not toxic to trout up to the limit of its solubility.

The immobilisation tests with daphnia (Safepharm Laboratories Ltd, 2000m) were performed under semi-static conditions in quadruplicate using 10 daphnids per flask at a temperature of 21ºC. Observations were made at 24 and 48 hours. The definitive test was performed on a solution saturated with the test material prepared from an initial dispersion at a concentration of 100 mg/L. The time weighted mean measured test concentration was > 2.4 mg/L. No immobilisation or adverse effects were observed in any test vessel giving a 48-h EC_{50} and NOEC of > 2.4 mg/L. Therefore the notified chemical is considered not to be toxic to daphnids up to the limit of its solubility.

Algae were exposed to a saturated solution of the test substance dispersed at 100 mg/L for 72 h at 24˚C under constant illumination and shaking (Safepharm Laboratories Ltd, 2000n). Six replicate test flasks were prepared for the test substance with three controls. The time weighted mean measured test concentration was > 0.82 mg/L. No abnormalities were detected in any of the replicate test samples. Neither biomass nor growth rate of *Scenedesmus subspicatus* was adversely affected by the test substance, giving a 72 h EC_{50} of greater than 0.82 mg/L and NOEC of 0.82 mg/L.

The ecotoxicity data indicates the notified chemical is not toxic to fish, daphnia and algae up to the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will enter environmental compartments indirectly via 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 of the notified chemical in printer 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 very little of the notified chemical will partition to the supernatant water which is released to the sewer.

Abiotic or slow biotic processes would be largely responsible for the degradation of the notified chemical as it was not found to be readily biodegradable. As a consequence of its low water solubility, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments.

Any released chemical is not expected to adversely affect aquatic organisms, since it is not toxic to fish, daphnia and algae up to the limit of its water solubility. Furthermore, bioaccumulation of the notified chemical is not expected due to its low water solubility and large molecular weight which 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 the oral or dermal routes. It is not likely to be a skin sensitiser or to be genotoxic. It is not likely to be a skin irritant but could be a slight to moderate eye 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 2%. 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, maintenance and printer personnel should wear cotton or disposable gloves.

It is concluded that the risk of 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 has staining properties.

Public Health

Exposure of the public as a result of transport and disposal of products containing the notified chemical is 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 low.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical 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. Spillage should be cleaned up promptly and 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 personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved 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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Safepharm Laboratories Ltd (2000f) Lexmark Black Pigment: Acute Dermal Irritation Test in the Rabbit. SPL Project Number 697/113. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000g) Lexmark Black Pigment: Acute Eye Irritation Test in the Rabbit. SPL Project Number 697/114. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

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Safepharm Laboratories Ltd (2000i) Lexmark Black Pigment: Twenty-Eight Day Repeated Dose Oral (Gavage) Toxicity Study in the Rat. SPL Project Number 697/117. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000j) Lexmark Black Pigment: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* and *Escherichia coli*. SPL Project Number

697/103. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000k) Lexmark Black Pigment: Chromosome Aberration Test in Human Lymphocytes in vitro. SPL Project Number 697/104. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000l) Acute Toxicity to Rainbow Trout. SPL Project Number 697/118. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000m) Acute Toxicity to *Daphnia Magna*. SPL Project Number 697/105. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

Safepharm Laboratories Ltd (2000n) Algal Growth Inhibition Test. SPL Project Number 697/105. Safepharm Laboratories Ltd, Derby, UK, (unpublished report submitted by Lexmark International Inc).

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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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