File No: LTD/1404

October 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Lexmark Magenta Ink

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800
FAX+ 61 2 8577 8888
Website: www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Lexmark International (Australia) Pty Ltd
Level 1, 13b Narabang Way,
Belrose NSW 2085

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, CAS name, Other names, Molecular formula, Structural formula, Molecular weight, Purity, Composition of impurities, Details of use, Import volume, Methods of detection and determination.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for: Dissociation constant and Flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU, USA.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lexmark Magenta Ink

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, UV/Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Red solid

Property	Value	Data Source/Justification
Melting Point, Freezing Point, Boiling temperature	>360°C at 101.91 kPa	Measured
Density	1451 kg/m^3 at 20°C	Measured
Vapour Pressure	<9.0 x 10^{-8} kPa at 25°C	Measured
Surface Tension	63.6 mN/m at 22°C	Measured for 1 g/L solution
Water Solubility	231 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Stable (half-life > 1 year at 25°C at pH 4, 7 and 9).	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = -2.49 at 20°C	Measured
Adsorption/Desorption	log K_{oc} < 1.25 at 30°C	Measured
Dissociation Constant	Expected to be dissociated at environmental pH.	Analogue data
Particle Size	Inhalable fraction (<100 μm): 9.17% Respirable fraction (<10 μm): 5.00%	Measured
Flash Point	----	Not applicable for solid
Solid flammability	Not highly flammable	Measured
Autoignition Temperature	369°C	Measured
Explosive Properties	Not explosive	Measured
Oxidizing Properties	Non-oxidising	Measured

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
Not expected to be reactive.

Dangerous Goods classification
Based on the available data, the notified chemical is not classified as a Dangerous Goods according to the Australian Dangerous Goods Code (NTC, 2007).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia and will be imported into Australia in the form of fully finished computer printer cartridges.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.35-0.75	0.35-0.75	0.35-0.75	0.35-0.75	0.35-0.75

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS
Lexmark International (Australia) Pty Ltd

PACKAGING AND TRANSPORTATION
The notified chemical is packaged in a plastic computer cartridge, which is then packaged in a foil wrapped bag, which is in turn inserted into a cardboard box. Cardboard overpacks (48 cartons/packs) are shipped from overseas and driven to receiving points for further distribution in trucks to individual retail stores. Some cartridges are packaged and sold with the associated printer.

USE
The notified chemical will be used as an ingredient of a conventional liquid ink filled computer printer cartridge at a concentration of <5%.

The major use (~99%) of the products containing the notified chemical will be for consumers (home/home offices) and remaining (~1%) for industrial printing such as screen printing, signs or use in photo or copy shops.

OPERATION DESCRIPTION
Fully finished computer printer cartridges containing the notified chemical will be imported and no reformulation or repackaging of the product containing the notified chemical will occur in Australia. The product is delivered to distributors as it is imported into Australia and then sold to customers (general public, office workers, and industrial workers).

The customer opens the cardboard box and then opens the foil containing the cartridge. The cartridge containing the notified chemical will be used to print on paper or other media. It will be installed and/or replaced by service technicians, office workers, general public, or industrial workers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS
As the major use (~99%) of the products containing the notified chemical is targeted at consumers (home/home offices), the number and category of workers involved in the use of cartridges is not available. However, it is expected that the cartridges would also be used by workers in offices, and a considerable number of workers are still expected to be involved in the transportation and distribution of cartridges containing the notified chemical.

EXPOSURE DETAILS
Worker exposure to the notified chemical during the importation, transport and storage of the printer cartridges is not expected, except in the unlikely event of an accident where the cartridge and its packaging may be breached.

Dermal and ocular exposure to the notified chemical may occur when refilling/replacing spent cartridges containing the notified chemical. Replacement of printing cartridges involves removal of the old printing cartridge from the printing machine and directly loading the new cartridge. Dermal and possible ocular exposure could also occur when handling faulty or ruptured cartridges.

However, as the concentration of the notified chemical in the ink is low (<5%), the ink is contained within the cartridge, refilling/replacement of spent cartridge is done infrequently, exposure to the notified chemical during refilling/replacement of cartridge is expected to be low. Users will avoid contact with the cartridge ink where possible, to avoid staining of their skin/or clothing.

Once the ink dries, the notified chemical would be trapped in the printed paper and is not expected to be readily bioavailable. Therefore, dermal exposure to the notified chemical from contact with the dried ink is expected to be low.

6.1.2. Public exposure

Dermal and ocular exposure to the notified chemical may occur when refilling/replacing spent cartridges. However, as the concentration of the notified chemical in the ink is low (<5%), the ink is contained within the cartridge, refilling/replacement of spent cartridge is done infrequently, exposure to the notified chemical during refilling/replacement of cartridge is expected to be low. Furthermore, users will avoid contact with the cartridge ink where possible, to avoid staining of their skin/or clothing.

Once the ink dries, the notified chemical would be trapped in the printed paper and is not expected to be bioavailable, therefore exposure to the notified chemical from dermal contact with the dried ink is also expected to be low.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro-human lymphocytes	non genotoxic

Toxicokinetics, metabolism and distribution.
No data was available to assess toxicokinetics, metabolism and distribution of the notified chemical. The low log Pow may limit the potential for dermal absorption. Although the particle size is low with inhalable and respirable fractions, the chemical is introduced in solution.

Acute toxicity.
The notified chemical was of low acute oral and dermal toxicity in rats. Acute inhalation toxicity was not tested.

Irritation and Sensitisation.
The notified chemical was not irritating to the skin of rabbits, but was severely irritating to the eyes of rabbits. The notified chemical was not a skin sensitiser in a guinea pig maximisation study.

Repeated Dose Toxicity (sub acute).
In an oral toxicity study in rats, the No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on no adverse treatment-related effects at the highest dose tested (1000 mg/kg bw/day). The stomach changes identified during the study at 1000 mg/kg bw/day probably represent an adaptive response to mild irritation and did not indicate systemic toxicity due to the notified chemical.

Mutagenicity.
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test and a genotoxicity assay in vitro. Therefore, the notified chemical is unlikely to be a genotoxic.

Carcinogenicity.
No data was available to assess the potential for carcinogenicity.

Toxicity for reproduction.
No data was available to assess the potential for toxicity for reproduction.

Health hazard classification
Based on the eye irritation effect, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with a risk phrase R41 - Risk of serious damage to eyes.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on available studies, the notified chemical was of low acute oral and dermal toxicity in rats. It was not irritating to the skin of rabbits, but was severely irritating to the eyes of rabbits. The notified chemical was not a skin sensitiser in guinea pigs. The notified chemical is not expected to be a genotoxic. In an oral 28 days toxicity study in rats, the NOAEL was established as 1000 mg/kg bw/day in this study.

The main acute risk from the use of notified chemical is eye irritation. The effects are expected to reduce in severity at lower concentrations. At the concentration of <5% in the imported ink, mild irritation only would be expected from inadvertent contact with the ink.

There is a risk for potential occupational exposure to the notified chemical during end use industrial printing applications (replacing ink cartridges, printing), servicing and maintenance. However, occupational exposure is expected to be low and for a brief period of time during replacement of ink cartridges and printing will mostly be carried out within a closed and automated system. Any exposure during servicing and maintenance is also expected to be low and for a brief period of time. Furthermore, printing machine operators and service and maintenance personnel are also expected to wear PPE, such as gloves, goggles, and overalls while performing different functions.

Therefore, considering the exposure level, low hazards of the notified chemical, and the use of PPE, the risk of acute occupational exposure is expected to be low and considered acceptable during printing, servicing and maintenance. Furthermore, considering the high NOAEL obtained in a 28 days repeat dose study, risk form the repeated use of the ink containing the notified chemical is also expected to be low and considered acceptable.

During transport and storage, the risk to workers is also minimal and acceptable as workers will only be exposed to the notified chemical in the case of an accident involving damage to the packaging and to wrapping.

6.3.2. Public health

There is a risk for potential public exposure to the notified chemical during printing applications such as replacing ink cartridges and printing. However, exposure is expected to be low and only for a brief period of time. Therefore, considering the exposure level and the low hazards of the notified chemical, the risk from acute occupational exposure is expected to be low and considered acceptable. Furthermore, considering the high NOAEL obtained in a 28 days repeat dose study, risk from the repeated use of the ink containing the notified chemical is also expected to be low and considered acceptable.

Public will be exposed to the paper or other types of material printed with cartridge ink containing the notified chemical. In this case, the exposure will be minimal as the notified chemical will be bound to the paper or other print substrates once the ink has dried. Therefore, the risk is not considered unacceptable, given that exposure is expected to be very low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be manufactured overseas and imported in sealed cartridges.

RELEASE OF CHEMICAL FROM USE
Environmental exposure will result from the disposal of printed paper (estimated at 95%) and discarded cartridges, which are estimated to contain 2–4 mL of ink (~5%), as well as the possibility of accidental leakage of the cartridges during use.

Ink residues contained in the emptied cartridges are expected to remain within these containers after disposal, although release could occur from deterioration of the discarded spent cartridge.

Release of the ink solution to the environment is not expected under normal use 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 landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified chemical is expected to be disposed of to landfill, as residues in cartridges, spillages, and printed paper.

Waste paper may also be recycled or thermally decomposed. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The wastes are expected to go to trade waste sewers.

7.1.2 Environmental fate

The notified chemical is water soluble and not readily biodegradable, and could therefore be expected to pass through recycling processes and sewage treatment works without substantial removal through sorption and degradation. However, some removal may be expected with sludge as insoluble calcium salts, for example. Residues entering aquatic environments are expected to disperse and slowly degrade, with bioaccumulation precluded by the water solubility.

Predicted Environmental Concentration (PEC)

The PECs can be determined based on the assumption of 50% release from paper recycling via sewage treatment works to receiving waters, as outlined below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	750	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	375	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.03	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	0%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.24	µg/L
PEC - Ocean:	0.024	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 > 100 mg/L	Not harmful
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful
Algal Toxicity	EC50 > 160 mg/L	Not harmful
Inhibition of Bacterial Respiration	EC50 > 1000 mg/L	Not harmful

Test results indicate that the notified chemical is not harmful to aquatic life. The results are considered reliable, as exposure concentrations were confirmed by analysis.

7.2.1 Predicted No-Effect Concentration

The PNEC can be calculated by application of a hundred fold assessment factor, as data for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Acute aquatic toxicity	100	mg/L
Assessment Factor	100	
PNEC:	1000	µg/L

7.3. Environmental risk assessment

The Risk Quotients (Q = PEC/PNEC) are tabulated below

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.24	1000	**0.00024**
Q - Ocean	0.024	1000	**0.000024**

The risk quotients are well below 1, indicating that the notified chemical will not pose a risk to the environment when it is used as proposed.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R41 - Risk of serious damage to eyes

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is as follows. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Eye irritation	1	Danger: Causes serious eye damage

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R41: May cause serious eye damage

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥10%: R41 May cause serious damage to eyes
  - 5%≤ conc ≤10%: R36 Irritating to eyes

CONTROL MEASURES
Occupational Health and Safety

- Based on the information provided, no specific engineering controls or personal protective equipment are required for the safe use of the chemical as introduced at <5% in cartridges, however these should be selected on the basis of all ingredients in the formulation.

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.
  Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if

- the function or use of the notified chemical has changed from a component of printer ink at <5%, or is likely to change significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical properties were conducted on notified chemical with a purity of >90%.

Melting Point, Freezing Point, Boiling Temperature >360°C at 101.91 kPa

Method	EC Directive 92/69/EEC A.1 & A.2 Melting/Freezing Temperature. ASTM E537-86
Remarks	Determination was carried out by differential scanning calorimetry (DSC). Similar thermographic profiles were obtained using air and nitrogen atmospheres; this indicates that the observed decomposition in both determinations is probably thermal and not oxidative. Decomposed without boiling from 360°C
Test Facility	SafePharm Laboratories Ltd (2000a)

Density 1451 kg/m^3 at 20°C

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a gas comparison pycnometer.
Test Facility	SafePharm Laboratories Ltd (2000b)

Vapour Pressure <9.0 x 10^{-8} kPa at 25°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined using a vapour pressure balance.
Test Facility	SafePharm Laboratories Ltd (2000c)

Water Solubility 231 g/L at 20°C

Method	EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method
Test Facility	SafePharm Laboratories Ltd (2000a)

Hydrolysis as a Function of pH

Method EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*Half-life*
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks	The notified chemical is stable to hydrolysis (half-life more than a year at 25°C) as less than 10% degradation was recorded after 120 hours at 50°C.
Test Facility	SafePharm Laboratories Ltd (2000b)

Partition Coefficient (n-octanol/water) log Pow = -2.49 at 20°C

Method	EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Shake Flask Method
Test Facility	SafePharm Laboratories Ltd (2000a)

Adsorption/Desorption – screening test log K_{oc} < 1.25 at 30°C

Method	OECD TG 121 Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge Using HPLC.
Remarks	Testing was carried out at approximately neutral pH.

Test Facility SafePharm Laboratories Ltd (2000b)

Dissociation Constant Not measured

Remarks The notified chemical is a water soluble salt that is expected to dissociate in the environmental pH range of 4-9.

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Method*	*Result*
Proportion of test material having an inhalable particle size less than 100 μm	Sieve	9.17%
Proportion of test material having a thoracic particle size less than 10 μm	Cascade Impactor	5.0%

Remarks Screening test (sieve method) and definitive test (cascade impactor method) were used.
Test Facility SafePharm Laboratories Ltd (2000b)

Solid Flammability Not highly flammable.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The test material failed to support combustion in the preliminary screening test.
Test Facility SafePharm Laboratories Ltd (2000d)

Autoignition Temperature 369°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test material was heated in an oven and the relative self ignition temperature determined
Test Facility SafePharm Laboratories Ltd (2000e)

Explosive Properties Determined not to have explosive properties.

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The test material was subjected to BAM fall hammer test, BAM friction test, and Koenen steel tube test for the determination of explosive properties.
Test Facility SafePharm Laboratories Ltd (2000e)

Surface Tension 63.6 mN/m at 22°C

Method EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension of a 1.0 g/L solution was determined. The notified chemical is not considered to be surface active.
Test Facility SafePharm Laboratories Ltd (2000b)

Oxidizing Properties Non-oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks The test material/cellulose mixtures failed to propagate combustion over the full 200 mm of the test.
Test Facility SafePharm Laboratories Ltd (2000e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Toxicological investigations were conducted on notified chemical with a purity of >90%.

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 (F)	2000	0
2	3 (M)	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity noted were dark red-coloured diarrhoea and red-coloured staining of the urine and faeces. Animals recovered two or four days after dosing. There were no deaths.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed an expected gain in bodyweight during the study.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories Ltd (2000f)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Test material was moistened with distilled water.
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The animals were observed for fourteen days after the day of treatment and were then killed for gross pathological examination.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5	2000	0
2	5	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation were noted during the study. Pink-coloured staining was noted at the treatment sites of all animals one to three days after dosing. The staining prevented the accurate evaluation of erythema at the treatment sites of all animals one day after dosing.

Signs of Toxicity - Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed an expected gain in bodyweight during the study.

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

TEST FACILITY SafePharm Laboratories Ltd (2000g)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test material was moistened with distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	0	0
Oedema	0	0	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	No evidence of skin irritation was noted during the study. Light pink-coloured staining was noted at all treated skin sites throughout the study. This staining did not effect evaluation of skin responses.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY SafePharm Laboratories Ltd (2007h)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	21 days
Remarks - Method	Additional observations were made on Days 7, 14 and 21 to assess the reversibility of the ocular effects.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect***	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2	3	3	Day 7	0 (Day 21)
Conjunctiva: chemosis	1.67	2	2	2	Day 7	0 (Day 21)
Conjunctiva: discharge	1.33	2	2	2	Day 7	0 (Day 21)
Corneal opacity	2	2	2	2	Day 7	0 (Day 21)
Iridial inflammation	0.67	0.67	1	1	48 hours	0 (Day 21)

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal. The animal number 3 was humanely killed after observation at 72 hours.
**The effect was absent on Days 14 and 21 with respect to corneal opacity, at 72 hours with respect to iridial inflammation, and on Days 14 and 21 with respect to redness, chemosis, and discharge. As animal number 3 was killed at 72 hours, these observations were only based on animal numbers 1 and 2.

Remarks - Results	Purple coloured staining of the fur around the treated eye was noted in all animals throughout the study. Pale appearance of the nictitating membrane was noted in animal 1 and 3 up to 72 hours. Petechial haemorrhages scattered over the nictitating membrane was noted in all treated eyes at the 24 and 48-hour observations and in animal 1 and 2 at the 72-hour observation. Two areas of haemorrhages, approximately 2 mm x 2 mm in size, on the nictitating membrane were noted in animal 3 at the 72-hour observation. Diffuse corneal opacity was noted in one eye at the 7-day observation in animal 2. Vascularisation (localised ingrowth of vessels of approximately 1-2 mm) was also noted in the same eye at the 14 and 21-day observations. The persistence of vascularisation at the 21-day observation was considered to be an irreversible effect and the classification of a severe eye irritant was warranted. It is also noted that the animal number 3 was killed at 72-hour observation due to signs of pain and discomfort.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	SafePharm Laboratories Ltd (2000i)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Adjuvant test. EC Directive 96/54/EC B.6 Skin Sensitisation - Adjuvant test.
Species/Strain	Guinea pig/Hartley-derived albino
PRELIMINARY STUDY	Maximum induction Concentration: Intradermal: 1% in distilled water Topical: 50% in arachis oil BP Maximum Non-irritating Concentration: Topical challenge: 50% and 25% in arachis oil BP
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 1% in distilled water topical: 50% in arachis oil BP
CHALLENGE PHASE	
1st challenge	topical: 50% and 25% in arachis oil BP
2nd challenge	Not performed
Remarks - Method	No significant protocol deviations. The

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50%	0/10	0/10	Not performed	
	25%	0/10	0/10	Not performed	
Control Group	50%	0/5	0/5	Not performed	
	25%	0/5	0/5	Not performed	

Remarks - Results 2-mercaptobenzothiazole was used as a positive control in the laboratory.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY SafePharm Laboratories Ltd (2000j)

B.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain Rats/Sprague-Dawley
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: Nil
Vehicle Distilled water
Remarks - Method Clinical signs, functional observations, body weight development and food and water consumptions were monitored during the study. Haematology and blood chemistry were evaluated for all animals at the end of the study. All animals were subjected to gross necropsy examination and histopathological evaluation of selected tissue was performed. The dose levels were chosen based on the results of the range-finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5M/5F	0	0
II (low dose)	5M/5F	15	0
III (mid dose)	5M/5F	150	0
IV (high dose)	5M/5F	1000	0

Mortality and Time to Death
There was no mortality.

Clinical Observations
Animals of either sex treated with 1000 mg/kg bw/day showed pink staining of the external body surfaces together with increased salivation up to ten minutes after dosing together with intermittent incidents of short-lived respiration throughout the study. Purple faeces and staining of the cage tray-liners was detected throughout the study. Animals from 150 mg/kg bw/day also showed purple faces and staining of the cage tray-liners. No such colouration was detected at 15 mg/kg bw/day.
No treatment related changes were detected in functional performance tests, sensory reactivity assessments, dietary intake, water consumption and bodyweight development.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment related haematological and blood chemical changes were detected.

Effects in Organs

Macroscopy:

No treatment-related organ weights changes were noted.

Animals of either sex treated with 1000 mg/kg bw/day showed red gastro-intestinal tract and stomach contents and pink discolouration of the glandular and/or non-glandular region of the stomach and limiting ridge. No such changes were seen in animals from 15 to 150 mg/kg bw/day treatment groups.

Microscopy:

Treatment-related changes were only observed in stomach. An increased incidence and severity of agglomeration of secretion, occasionally with associated goblet cell hyperplasia, was observed in the mucosa of the glandular stomach for rats of either sex at 1000 mg/kg bw/day, but not at either of the two remaining dose levels. Such changes are generally considered to be adaptive in nature.

Remarks – Results

The stomach changes identified during the study probably represent an adaptive response to mild irritation due to method of administration of the notified chemical and do not indicate systemic toxicity.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on no adverse treatment-related effects noted at the highest dose tested (1000 mg/kg bw/day).

TEST FACILITY SafePharm Laboratories Ltd (2000k)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbital/5,6-benzoflavone
Concentration Range in Main Test	a) With metabolic activation: 313, 625, 1250 & 5000 µg/plate b) Without metabolic activation: 313, 625, 1250 & 5000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	Negative
Test 2	Not performed	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	Not performed	>5000	>5000	Negative

Remarks - Results

In the two main tests, neither an increase in the number of revertant colonies or a dose-related response was observed with or without metabolic activation.

No inhibition in the growth of the test strains was observed with or without metabolic activation. No precipitate was observed on any of the concentration levels, with or without metabolic activation.

The revertant colonies of the positive controls showed an increase of more than twice that of the negative controls, indicating that the study performed properly.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BML, Inc (1999)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Lymphocyte
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone-induced rat liver.
Vehicle	Minimal Essential Media
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 625, 1250*, 2500*, 5000*, MMC 0.4*	4 hrs	20 hrs
Test 2	0*, 78.13, 156.25*, 312.5*, 468.75*, 625*, 1250*, MMC 0.2*	24 hrs	24 hrs
Present			
Test 1	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*, CP 25*	4 hrs	20 hrs
Test 2	0*, 312.5, 625, 1250*, 2500*, 5000*, CP 25*	4 hrs	20 hrs

*Cultures selected for metaphase analysis.
MMC = Mitomycin C, CP = Cyclophosphamide

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	Negative
Test 2	≥625	>1250	>1250	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	Not performed	>5000	>5000	Negative

Remarks - Results	All vehicle (solvent) controls gave frequencies of cells with aberrations within the range expected for normal human lymphocytes. The test material did not induce a significant increase in the number of polyploid cells at any dose level in either of the treatment cases. All the positive control treatments gave statistically significant increases in the frequency of cells with aberrations, indicating the satisfactory performance of the test and of the activity of the metabolising system.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd (2000l)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Mixed population of sewage treatment microorganisms from sewage treatment plant treating predominantly domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Oxygen depletion
Remarks - Method	

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	2	3	51
9	18	9	56
18	27	18	86
28	27	28	97

Remarks - Results	No inhibitory effects were seen in the toxicity control.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	SafePharm Laboratories Ltd (2000m)

C.1.2. Bioaccumulation

Remarks	The test was not conducted as the notified chemical is a water soluble salt that is not expected to bioconcentrate in fish.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.
Species	Rainbow trout
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS spectroscopy.
Remarks – Method	The analytical method is considered reliable based on the chemical structure and the consistent profile of the spectra obtained.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		20	0	0	0	0	0
100	105	20	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	There was no evidence of insolubility or adherence of the test substance

to the glass.

CONCLUSION The notified chemical is not harmful to fish.

TEST FACILITY SafePharm Laboratories Ltd (2000n)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	UV/VIS spectroscopy.
Remarks - Method	The analytical method is considered reliable based on the chemical structure and the consistent profile of the spectra obtained.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
100	100	40	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	

CONCLUSION The notified chemical is not harmful to daphnids.

TEST FACILITY SafePharm Laboratories Ltd (2000o)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 10, 20, 40, 80, 160 mg/L Measured concentrations at 0 and 72 hours were between 90% and 100% of nominal.
Auxiliary Solvent	None
Water Hardness	Typical algal culture medium (soft water)
Analytical Monitoring	UV/VIS spectroscopy.
Remarks - Method	The analytical method is considered reliable based on the chemical structure and the consistent profile of the spectra obtained. Two separate bioassays were performed so as to distinguish the effects of light reduction from the toxic effects of the notified chemical.

RESULTS

Biomass	*Growth*

E_bC50 mg/L at 72 h	NOEC mg/L	E_rC50 mg/L at 72 h	NOEC mg/L
> 160	20	> 160	20
> 160	80	> 160	80
> 160	20	> 160	20

Remarks - Results: Microscopic examination found no abnormalities in any test or control culture. The first row in the table above reports the effects in the presence of the test substance, and the second the effects of light reduction by the test substance. The third row reports the effects of test material toxicity as determined after subtraction of the effects due to light reduction alone.

CONCLUSION: The notified chemical is not harmful to green algae.

TEST FACILITY: SafePharm Laboratories Ltd (2000p)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sewage sludge
Exposure Period: 3 hours
Concentration Range: Nominal: 1.0, 3.2,10, 32 and 100 mg/L

RESULTS

IC50: > 100 mg/L
NOEC: 10 mg/L
Remarks – Results: Results from the preliminary range finding test indicate that the IC50 exceeds 1000 mg/L.

CONCLUSION: The notified chemical is not harmful to sewage treatment microorganisms.

TEST FACILITY: SafePharm Laboratories Ltd (2000q)

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