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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CIM-07

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 334-336 Illawarra Road, Marrickville NSW 2204.

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:

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Director
NICNAS

TABLE OF CONTENTS

Full Public Report

CIM-07

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd. (ABN 66 005 002 951)
1 Thomas Holt Drive
NORTH RYDE NSW 2113

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Impurities, Purity, Use Details, Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Flash Point, Reactivity, Acute Inhalation Toxicity, Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/745

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIM-07
C-M5
C-M5 Liq.
Magenta C-M5

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >70%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Purple powder

Property	Value	Data Source/Justification
Melting Point	≥300°C	Measured
Density	1680 kg/m^3 at 19.5 ± 0.5°C	Measured
Vapour Pressure	<1.7 x 10^{-8} kPa at 25°C	Measured
Water Solubility	380-390 g/L at 20 ± 0.5°C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ > 1 year at pH 4, 7 and 9 (25 °C)	Measured

Partition Coefficient (n-octanol/water)	log Pow < - 4.37 at 23.0 ± 0.5ºC	Measured
Adsorption/Desorption	log K_{oc} < 1.25 at 40°C	Measured
Dissociation Constant	pka_1 2.24±0.50 pka_2 1.81±0.50 pKa_3-pKa_{10} ≤ 0.00	Estimated. Predicted to be ionised throughout environmental pH range of 4-9 due to existence of ionisable functionalities
Particle Size	Inhalable fraction (<100 μm): 74.0% Respirable fraction (<10 μm): 2.1 %	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	381ºC	Measured
Explosive Properties	Not predicted to be explosive	Estimated

DISCUSSION OF PROPERTIES
The notified chemical is a powder with the majority of particles in the inhalable fraction. It is highly soluble in water and will ionise readily at environmental and physiological pH. It is not expected to be a physical hazard. For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
The notified chemical may decompose into nitrogen or sulfur oxides. However, it is predicted to be stable under normal environmental conditions.

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, but will be imported as a component (<7%) of inkjet printer ink contained within sealed ink cartridges.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Canon Australia Pty Ltd

TRANSPORTATION AND PACKAGING
Imported ink cartridges (5 mL – 900 mL) containing the notified chemical will be stored at the notifier's warehouse prior to distribution to offices and office equipment retailers nationwide.

USE
The notified chemical will be imported as an ink component (<7%) in ink cartridges for use in inkjet printers. Each cartridge will be individually sealed in a plastic bag and packaged in a box.

OPERATION DESCRIPTION
No manufacture or reformulation will occur in Australia. Sealed ink cartridges containing the notified chemical will be distributed to commercial and retail centres and handled by service technicians, office workers or the public, who will replace spent cartridges in printers as necessary.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Importation/ Waterside	50	<8	10-50
Storage and Transport	15	<8	10-50
Office worker/ consumer	2,000,000	10 seconds/day	2
Service Technicians	100	1	170

EXPOSURE DETAILS
Storage and transport workers will only handle the sealed cartridges containing the notified chemical and therefore exposure is not expected unless the packaging is accidentally breached.

Service technicians and office workers may be exposed to the ink containing the notified chemical (<7%) when replacing used ink cartridges and repairing and cleaning ink jet printers. Dermal exposure is expected to be the most likely route of exposure. Instructions on how to replace the cartridges safely are included with the cartridge to minimise exposure. However, occasional dermal exposure during use of the printer may occur if the printed pages were handled inadvertently before the ink had dried, or if ink-stained parts of the printer were touched. Once the ink dries, the chemical would be bonded to the printed paper, and therefore dermal exposure to the notified chemical from contact with dried ink is not expected.

6.1.2. Public exposure
Home users may encounter dermal exposure to the ink containing the notified chemical (<7%) when replacing used ink cartridges similar to the exposure experienced by office workers. However, home users are expected to handle ink cartridges and print less frequently, therefore exposure is expected to be less frequent when compared to that of office workers.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	low toxicity, LD50 >2000 mg/kg bw
Rat, acute dermal toxicity	low toxicity, LD50 >2000 mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation*	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days*.	NOEL = 150 mg/kg bw/day (females) NOEL = 25 mg/kg bw/day (males)
Mutagenicity – bacterial reverse mutation	non-mutagenic
Genotoxicity – *In vitro* chromosome aberration study	non-genotoxic

* Details of these studies can be found in Appendix B

Toxicokinetics
The notified chemical would not be expected to be absorbed across biological membranes given its high molecular weight and low log Pow (~-4). However, in the acute and 28-day repeat dose oral toxicity studies in rats, discolouration of tissues and red-coloured urine were observed. These effects suggest that absorption and distribution of either the notified chemical and/or its metabolites probably occurred but the mechanism is unknown.

The potential for dermal absorption is not known, however it is not expected given its high molecular weight and low log Pow.

Airborne particles of the notified chemical are likely to be inhaled (74% of the particles are in the inhalable range (<100 μm)). It is expected that these particles of the notified chemical will lodge in the lung, where they are expected to dissolve in mucus (given the high water solubility). However, absorption into systemic circulation through the alveoli is not expected given the high molecular weight and low log Pow of the notified chemical. Instead, the notified chemical in mucus may be ingested orally following mucociliary clearance from the lung.

Acute toxicity
The notified chemical was found to be of low acute oral toxicity in rats according to OECD TG 420 Fixed Dose Method (SafePharm Laboratories, 2007e). No mortality occurred during the study at a dose of 2000 mg/kg bw. However, purple stained faeces and urine were observed up to 4 days after dosing. Upon necropsy, red stained kidneys were observed in one. The oral LD50 was determined to be >2000 mg/kg bw.

The notified chemical, moistened with arachis oil BP, was found to be of low toxicity in a rat acute dermal toxicity study according to OECD TG 402 (SafePharm Laboratories, 2008b). No mortality occurred during the study. Dermal irritation was not able to be evaluated adequately due to red staining observed at the site of application for up to 2 days after dosing. However, in female rats crust formation was observed at the treatment sites between 3 to 6 days after dosing. The acute dermal median LD50 was determined to be >2000 mg/kg bw.

Irritation and Sensitisation
The notified chemical, moistened with distilled water, was found to be non-irritating in a rabbit skin irritation study according to OECD TG 404 (SafePharm Laboratories, 2007f). No evidence of skin irritation was observed in 3 male rabbits during the study. Red staining observed at the site of application up to 3 days after treatment did not affect the scoring of irritation. However, in the previously described acute dermal toxicity study conducted in female rats only, the notified chemical dissolved in arachis oil BP caused red staining preventing irritation scoring. However, crust formation was observed 3 to 6 days after treatment suggesting that the notified chemical produced some effects on the skin but their severity was insufficient for classification as a skin irritant according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Slight eye irritation in the form of conjunctival redness, conjunctival chemosis and slight discharge was observed in all animals up to 24 hours after treatment (see Appendix B for details). In addition, purple/pink stained fur was observed around the treated eye, persisting to 72 hours after treatment. These effects were not sufficient to classify the notified chemical as an eye irritant according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

The notified chemical, dissolved in dimethyl formamide at concentrations of 5%, 10% and 25%, was found to be non-sensitising in CBA/Ca mice in a local lymph node assay (LLNA) conducted according to OECD TG 429 (SafePharm Laboratories, 2007h).

Repeated Dose Toxicity
In a 28-day oral gavage repeat dose toxicity study in rats, the notified chemical was found to have a NOEL of 150 mg/kg bw/day in female rats and a NOEL of 25 mg/kg bw/day A.I. in males, on the basis of the staining of organs and effects observed in the liver, kidney, stomach and lymph node observed at higher doses (see Appendix B for details). For males, a NOAEL of 150 mg/kg bw/day was established.

The possible chronic effects of inhalation of respirable or inhalable particles of the notified chemical in the inhalable range are not known.

Mutagenicity
The notified chemical was negative in a bacterial reverse mutation assay (Ames test), conducted both with and without metabolic activation according to OECD TG 471 (SafePharm Laboratories, 2007i). A pink colour was observed in all test plates from 50-5000 µg/plate, but this did not prevent scoring of revertant colonies. No precipitate of the notified chemical or visible reduction in the growth of the background lawn was observed at any dose level.

The notified chemical was found to be non-clastogenic in a chromosome aberration study in cultured Chinese hamster lung (CHL) cells, conducted according to OECD TG 473 (SafePharm Laboratories, 2007j). This study investigated 6-hour exposures in the absence and presence of S9, and 24-hour exposures in the absence of S9. Cytotoxicities of up to 32% occurred at the highest test concentration used (~5000 µg/mL for 6-hour exposures). The optimal level of 50% inhibition was not achieved but given the maximum test concentration was used this was considered acceptable. The optimal level of 50% inhibition was not achieved for 24-hour exposures. However, this was considered acceptable given dose levels beyond ~625 µg/mL were completely toxic. No notable increases in chromosomal aberration frequency were observed in cultures after 6 or 24 hours of exposure at any dose levels.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Ink containing the notified chemical (<7%) will be contained within a sealed ink cartridge and therefore, exposure via the oral or inhalation routes is not anticipated.

The level of dermal exposure for service technicians and office workers handling sealed cartridges of printing inks containing the notified chemical (7%) is not expected to be significant, compared to the NOEL of 25 mg/kg bw/day. Should dermal exposure occur, absorption is expected to be low.

The notified chemical has the potential to be slightly irritating to the eye based on an eye irritation study in rabbits. However, ocular exposure is not expected under normal circumstances, unless the ink residues containing the notified chemical are deposited on the fingers and then rubbed into the eyes. Overall, the risk presented by the notified chemical to the health and safety of workers is not expected to be unacceptable.

6.3.2. Public health
Dermal and ocular exposure patterns of home users to the notified chemical at 7% in printing inks contained in sealed cartridges are expected to be similar to, but less frequent than that of office workers described above. The level of public exposure to the notified chemical is not expected to present an unacceptable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported to Australia as a component of printer ink final product in ready-to-use cartridges. No manufacturing and reformulation of the notified chemical will take place in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE
The ink cartridges are designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. Workers at large businesses will undertake installation and replacement. If leakage or spillage does occur, the ink will be contained with absorbent material and disposed of to landfill in accordance with federal, state and local regulations.

Cartridges are contained within the printer until the contents are used up and then they are removed and sent for recycling or disposed of to landfill. Around 5% of the ink containing the notified chemical will remain in "empty" cartridges.

Most of the notified chemical (95%) will be bound to printed paper, which will be disposed of to landfill, recycled or possibly incinerated.

RELEASE OF CHEMICAL FROM DISPOSAL
Around 5% of the ink containing the notified chemical will remain in "empty" cartridges. The notifier will collect the used cartridges by setting up collection boxes in general merchandising stores and post offices, etc. The collected cartridges are sent to a subcontractor. The subcontractor disassembles the used cartridges and recycles the packaging as raw materials, for example a plastic material to be used to make plastic goods. The remaining ink separated from the used cartridges is disposed of under Australian regulations. The notifier will not refill cartridges with ink for resale. The other empty ink cartridges which are not collected will be disposed of to landfill.

Printed paper, having the notified chemical thereon will be disposed of to landfill, recycled or possibly incinerated.

7.1.2 Environmental fate

The majority of the notified chemical will enter the environment from disposal of paper products on which ink containing the notified chemical will be printed. During printing, ink containing the notified chemical will be bound to the printed paper. Approximately 45% of the notified chemical bound to printed waste paper will be disposed of to landfill, and will eventually degrade in-situ by abiotic and biotic processes into water, hydrogen sulphide, ammonia, and oxides of carbon, sulphur and nitrogen. Free notified chemical in landfill may leach due to the low K_{OC} and high water solubility.

Approximately 5% of the imported volume of the notified chemical will remain in empty ink cartridges and is expected to be disposed of to landfill, where it will degrade according to the same processes described above.

The other 50% is expected to be released to sewer, after the deinking of paper during recycling (NOLAN-ITU, 2001). Waste paper is re-pulped 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. A proportion of the ink is expected to be recovered during recycling by adsorption to sludge. Any chemical adsorbed to sludge during the recycling process will be disposed of to landfill. Assuming a worst case scenario based on the high water solubility, the entire amount of chemical from paper recycling will be released from sewage treatment plants into the aquatic environment.

The chemical is not readily biodegradable (for the details of the environmental fate studies please refer to Appendix C).

7.1.3 Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration arising from the industrial use pattern has been modelled for the worst case in which none of the notified chemical released in aqueous wastes from the recycling of paper is removed by (or is degraded in) on-site waste water treatment and sewage treatment plants. As the notified chemical is to be used in industrial applications at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The details of the calculation based on these parameters are presented below:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.45	µg/L
PEC - Ocean:	0.05	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	E_rC50 = 150 mg/L	Not harmful
Inhibition of Bacterial Respiration	EC50 > 1000mg/L	Not harmful

The notified chemical is not considered harmful to aquatic life based on the test results.

7.2.1 Predicted No-Effect Concentration

The Predicted No Effect Concentration (PNEC) was calculated using the worst-case value for the acute toxicity to fish (LC50) and using a safety factor of 100 (three trophic levels of aquatic species were supplied).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish)	> 100	mg/L
Assessment Factor	100	
Mitigation Factor	1	
PNEC	> 1,000	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Qs) have been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.24	> 1000	< 0.01
Q - Ocean:	0.02	> 1000	< 0.01

The Risk Quotient is less than 0.01 based on the worst case prediction. Therefore, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on the proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

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

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

CONTROL MEASURES

Occupational Health and Safety

- 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.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal

- The notified chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical 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
- imported in any form other than within a finished ink cartridge.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of printing ink contained within a sealed cartridge, or is likely to change significantly;
- the amount of chemical being introduced has increased from one tonne per annum, or is likely to increase, significantly;
- if 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 products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Decomposed without melting at 300ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry.
Test Facility SafePharm Laboratories (2007a)

Density 1680 kg/m^3 at 19.5 ± 0.5ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a gas comparison pycnometer.
Test Facility SafePharm Laboratories (2007b)

Vapour Pressure <1.7 x 10^{-5} kPa at 25ºC

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance. No statistical analyses were performed because the balance readings were too low and variable for a line of best fit to have any meaning. A regression slope was imposed on a chosen data point to provide an estimate of the maximum value for the vapour pressure at 25ºC.
Test Facility SafePharm Laboratories (2007c)

Water Solubility 380 to 390 g/L at 20.0 ± 0.5ºC

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method. Samples of concentrations ranging from 36.0 - 39% were prepared in the definitive test at pH 7.6-8.2. The standard A6 methodology could not be used; due to the chemical's high water solubility, it was not possible to prepare samples of 5× saturation level. No analysis performed due to the high solubility producing unfilterable mixtures. Visual inspection showed clear coloured solution up to 38% w/w. High solubility of the notified chemical is expected based on its highly hydrophilic structure containing many soluble inorganic salt groups.
Test Facility SafePharm Laboratories (2007a)

Hydrolysis as a Function of pH $t_{1/2}$ > 1 year at pH 4, 7 and 9, 25ºC.

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½ (Hours)*
4	50±0.5	> 120
7	50±0.5	> 120
9	50±0.5	> 120

Remarks HPLC used for concentration determination. Preliminary test conducted only. Less than 10% hydrolysis was detected after 5 days for all the tests, which is equivalent to a half life greater than 1 year at 25ºC.
Test Facility SafePharm Laboratories (2007b)

Partition Coefficient (n-octanol/water) log Pow < - 4.37 at 23.0 ± 0.5ºC

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC was used for concentration determination. A P_{OW} value of < - 4.75 was estimated in the preliminary test. The definitive test was conducted at pH 7. An extremely low value of P_{OW} is expected based on the high water solubility in water
Test Facility SafePharm Laboratories (2007a)

Adsorption/Desorption – screening test log K_{OC} < 1.25 at 40°C

Method OECD 121, Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
EC Directive 2001/59/EC C.19, Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
Remarks The retention time of formamide was measured as the reference standard. The adsorption coefficient of the notified chemical has been determined to be K_{OC} < 17.8 ($logK_{OC}$ < 1.25) since the retention time is less than that for acetanilide.
Test Facility SafePharm Laboratories (2007b)

Dissociation Constant Ionized at environmental pH range of 4-9.

Method Not determined. Computer based estimation conducted.
Remarks Testing was not possible according to OECD TG 112 due to the absence of any dissociating functional groups within the pH range of the test methods.
Therefore, estimates were obtained using ACD/I-Lab Web Service (ACD/pKa 8.03), computer based estimation software, and the pKa values are as follows:

Dissociation constant	Result
pka_1	2.24±0.50
pka_2	1.81±0.50
pKa_3-pKa_{10}	≤ 0.00

From these results, it can be determined that the notified chemical would always be ionised at the environmental pH range of 4-9.
Test Facility SafePharm Laboratories (2007b)

Surface Tension 71.9 mN/m at 21.8± 0.2ºC

METHOD
Remarks Concentration: 1.01 g/L solution, 0.937g/L corrected for purity. Test was performed using the ISO 304 ring method. The notified chemical is not surface active based on the test result.
TEST FACILITY SafePharm Laboratories (2008a)

Particle Size

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

Range (μm)	*Mass (%)*
<100	74.0
<10.0	2.10
<5.5	0.327

Remarks The inhalable fraction (<100 μm) was determined by sieve. The fractions <10 μm and <5.5 μm were determined using a cascade impactor.
Test Facility Safepharm (2007b)

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The pile of the notified chemical failed to ignite during 2 minutes' application of a bunsen flame.
Test Facility SafePharm Laboratories (2007d)

Autoignition Temperature 381ºC

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	The cube contained a small amount of black charred remains after the test.
Test Facility	SafePharm Laboratories (2007c)

Explosive Properties Not highly explosive

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Determined by BAM fall hammer test, BAM friction test and Koenen steel tube test.
Test Facility	SafePharm Laboratories (2007c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. 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 M
Observation Period	72 hours
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			
Conjunctiva: redness	0.33	0.33	0.33	2	24 hours	0
Conjunctiva: chemosis	0.33	0.33	0.33	1	24 hours	0
Conjunctiva: discharge	0.33	0.33	0.33	2	24 hours	0
Corneal opacity	0	0	0	-	-	0
Iridial inflammation	0	0	0	-	-	0

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

Remarks - Results

Redness and chemosis of the conjunctivae were observed in all animals 1- and 24-hours after treatment. However, these reactions were absent 48 hours after treatment.
Purple/pink-stained fur was observed around the treated eye up to 72 hours after treatment in all animals.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: SafePharm Laboratories (2007g)

B.2. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Sprague-Dawley Crl:CD
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*		*Mortality*
		Nominal	*Actual*	
control	5 per sex	0	0	0
low dose	5 per sex	25	24.79	0
mid dose I	5 per sex	150	148.71	0
mid dose II	5 per sex	300	297.42	0
high dose	5 per sex	1000	991.41	0
control recovery	5 per sex	0	0	0
high dose recovery	5 per sex	1000	991.41	0

Mortality and Time to Death

No mortalities were observed during the study.

Clinical Observations

Pink/red-coloured faeces and stains on the cage tray liners were observed throughout the treatment in animals of either sex treated with ≥150 mg/kg bw/day as treatment-related effects. These effects were also observed intermittently in animals treated with 25 mg/kg bw/day.

Staining of faeces and cage tray liners persisted in recovery animals of either sex treated with 1000 mg/kg bw/day throughout the recovery period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Treatment-related increases in plasma albumin, aspartate aminotransferase and creatinine were observed in animals of either sex treated with 1000 mg/kg bw/day. Females from this group also showed increases in total protein, albumin/globulin ratio and calcium concentration. Males from this group showed an increase in plasma cholesterol.

Red-coloured urine was also observed in animals of both sexes treated with 1000 mg/kg bw/day.

Effects in Organs

Upon gross necropsy, discolouration was observed in the majority of tissues in animals of either sex treated with ≥150 mg/kg bw/day.

Liver:

Increased absolute and relative liver weight was observed in females treated with 1000 mg/kg bw/day and in females of the recovery group. No significant histopathological effects were observed.

Kidney:

Increased absolute and relative kidney weights were observed in the females in the high dose recovery group. Tubular basophilia/degeneration and karyomegaly of the proximal tubular epithelial nuclei were observed in animals of either sex treated with 1000 mg/kg bw/day. Vacuolation of the proximal tubular epithelium was also observed in 3 females of this group. All of these effects were also observed in 3 females treated with 300 mg/kg bw/day.

All kidney effects regressed over the recovery period, in animals of either sex, except for karyomegaly (which remained in both sexes) and tubular basophilia (observed in females).

Stomach:

Agglomeration of secretion was observed in animals of either sex treated with ≥300 mg/kg bw/day and in males treated with 150 mg/kg bw/day. Animals of either sex treated with ≥150 mg/kg bw/day showed signs of acanthosis and hyperkeratosis of the limiting ridge. Mucous cell hyperplasia was observed in animals of either sex treated with ≥300 mg/kg bw/day and at the highest dose of 1000 mg/kg bw/day mucosal basophilia/atrophy was observed in animals of either sex.

Regression of the incidence and severity of these effects was observed in animals of either sex at the end of the recovery period.

Lymph nodes:

Vacuolation of histiocytes in the cervical and mesenteric lymph nodes was observed in animals of either sex

treated with 1000 mg/kg bw/day and in 2 males and 1 female treated with 300 mg/kg bw/day.

Regression in the severity but not in the incidence of these conditions was observed in recovery animals of either sex.

Remarks – Results

The pink/red-coloured faeces and stains on the cage tray liners observed throughout the study in animals treated with ≥150 mg/kg bw/day were treatment-related and consistent with the excretion of a coloured compound.

The increases in plasma albumin, aspartate aminotransferase and creatinine levels in both sexes treated with 1000 mg/kg bw/day as well as the increase in total protein, albumin/globulin ratio and calcium concentration in females and cholesterol in males were considered to have been adaptive responses.

Modest increases in absolute (9.2%) and relative (14.4%) liver weights in animals treated with 1000 mg/kg bw/day were treatment-related. However, no significant histopathological correlates were found, so this effect may merely be an adaptive change.

All effects observed in the kidney (tubular basophilia/degeneration and karyomegaly of proximal tubular epithelial nuclei) at 1000 mg/kg bw/day for males and ≥300 mg/kg bw/day for females were considered related to treatment and adverse. The signs of kidney toxicity and dysfunction are consistent with the observed elevated creatinine levels.

The treatment-related effects in the glandular stomach were observed in animals of either sex. The effects are considered to be adverse given the observed concordance between various effects observed in the stomach and the apparent dose-dependent nature of the effects.

Acanthosis and hyperkeratosis of the limiting ridge of the glandular stomach were considered to be local irritant effects caused by the notified chemical.

Vacuolation of histiocytes in the cervical and mesenteric lymph nodes was observed in animals of either sex treated with 1000 mg/kg bw/day and 2 males and one female treated with 300 mg/kg bw/day and were considered to be treatment-related but not adverse.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 150 mg/kg bw/day in females and 25 mg/kg bw/day in males in this study and the No Observed Adverse Effect Level (NOAEL) was established as 25 mg/kg bw/day for either sex in this study.

TEST FACILITY SafePharm Laboratories (2008c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Purified water
Analytical Monitoring	Measurement of biochemical oxygen demand (BOD) with a closed system oxygen consumption measuring apparatus, determination of dissolved organic carbon (DOC) by a total organic carbon analysis (TOC), and determination of test item by HPLC were conducted.
Remarks - Method	On-site sludge sampling was carried out at the 10 locations in Japan by collecting return sludge, surface water and surface soil that were in contact with atmosphere. Test conducted at 25±1°C. The test concentration was 100 mg/L for the notified chemical and 30 mg/L for activated sludge.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation*
7	0.3	7	59
14	0.0	14	74
21	1.3	21	79
28	2.3	28	79

Remarks - Results	All the validity criteria of the test are satisfied. Percentage of biodegradation at 28 days was 2.3% by BOD, 0% by DOC and 0% by HPLC.
CONCLUSION	The notified chemical is not readily biodegradable by microorganisms.
TEST FACILITY	CERI (2007)

C.1.2. Bioaccumulation

	Test not conducted because of low partition coefficient of notified chemical.
CONCLUSION	The notified chemical is not considered to have potential for bioaccumulation as a result of its high water solubility.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi-static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static.
Species	*Rainbow Trout* (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	HPLC. The limit of quantitation has been assessed down to 0.93 mg/L.

Remarks – Method	The test water used for both the range-finding and definitive tests was laboratory tap water after being dechlorinated by passage through an activated carbon filter (Pure Series 500) and partly softened, and adjusted to required temperature. Following a preliminary range-finding test fish were exposed, in two groups of ten, to an aqueous solution of the test material, at a single concentration of 100 mg/L for a period of 96 hours at a temperature of approximately 14°C under semi-static test conditions. The number of mortalities and any sub-lethal effects of exposure in each test and control vessel were determined 3 and 6 hours after the start of exposure and then daily throughout the test until termination after 96 hours. pH: 6.0-8.5 Dissolved oxygen: > 9.0 mg O_2/L Light 16 hours light, 8 hours dark with 20 minute transition.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3h*	*24h*	*48h*	*72h*	*96h*
Control	< limit of quantitation	10	0	0	0	0	0
$100R_1$*1	97.7(0 h), 99.6(24 h), 104(96 h)	10	0	0	0	0	0
$100R_2$*1	103(0 h), 101(24 h), 105(96 h)	10	0	0	0	0	0

*1: R_1 and R_2 = Replicates 1 and 2

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	Verification of test concentration throughout the test period shows that the notified chemical is stable in the test medium. The recovery of solutions was 99% of the nominal concentration. There were no sub-lethal effects of exposure observed in 20 fish exposed to a test concentration of 100 mg/L for a period of 96 hours.

CONCLUSION	The notified chemical is not harmful to *Oncorhynchus mykiss.*
TEST FACILITY	SafePharm Laboratories (2007k)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
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	Visual Observation; HPLC
Remarks - Method	No significant protocol deviations. Following a preliminary range-finding test, 4 replicates of 5 daphnids were exposed to 100 mg/L of the notified chemical for 48 hours at 21.2-21.6°C. Positive control test was conducted using potassium dichromate as the reference material at concentrations of 0.32, 0.56, 1.0, 1.8 and 3.2 mg/L. The EC50 was determined to be 1.2 mg/L at 24 hours and 0.85 mg/L at 48 hours.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal	*Actual*		*24 h*	*48 h*
Control	0	5×4	0	0
100	96-100	5×4	0	0

LC50 > 100 mg/L at 48 hours
NOEC 100 mg/L at 48 hours
Remarks - Results Verification of test concentration at 0 and 48 hours shows that the notified chemical is stable in the test medium. The recovery of solutions was between 96-100% of the nominal concentration. No immobilisation was reported throughout the 48 hours test at 100 mg/L.

CONCLUSION The notified chemical is not harmful to *Daphnia magna*.

TEST FACILITY SafePharm Laboratories (2007l)

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 *Desmodesmus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal: 3.2, 10, 32, 100 and 320 mg/L
Actual: 3.83, 10.4, 32, 102 and 321 mg/L
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring HPLC. The detection system was found to have acceptable linearity. The analytical procedure had acceptable recoveries of test material in test medium. A method of analysis was validated and proven to be suitable for use.
A Coulter® Multisizer Particle Counter was used for the analysis of algal cell concentrations.
Remarks - Method Following a preliminary range-finding test, parallel experiments A and B were conducted by exposing algae to the notified for 72 hours at 24ºC under constant illumination and shaking. In experiment A, algae were directly exposed to test material solution and covered by glass Petri dishes above the test vessels containing culture medium. In experiment B, algae were exposed to culture medium alone and covered by glass Petri dishes above the test vessels containing the test material solutions.

A positive control test was conducted using potassium dichromate as the reference material at concentrations of 0.0625, 0.125, 0.25, 0.5 and 1.0 mg/L, giving an E_rC50 (0-72 h) of 0.58 mg/L (95% CI 0.47-0.71 mg/L), an E_bC50 (0-72 h) of 0.20 mg/L (95% CI 0.17-0.24 mg/L).

RESULTS

	Biomass		*Growth*	
	E_bC50 mg/L at 72 h	*NOEC mg/L*	*ErC50 mg/L at 0-72 h*	*NOEC mg/L*
A	31 (95% CI 24-40 mg/L)	3.2	150*	10
B	110 (95% CI 90-130 mg/L)	32	260*	32

* CI for the E_rC50 could not be calculated since the data generated did not fit the models available for calculation of confidence limits.

Remarks - Results All test validation criteria were met. Verification of test concentrations at 0 hour and 72 hours show that the notified chemical is stable under the test conditions.

	The significant differences between experiments A and B indicate that the effects of the notified chemical on algae were not only due to a reduction in light intensity, but also due to the intrinsic toxic properties of the notified chemical. Test results from experiment A were used for toxicity classification.
CONCLUSION	The notified chemical is not harmful to *Desmodesmus subspicatus* based on the test result ErC50.
TEST FACILITY	SafePharm Laboratories (2007m)

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	A mixed population of activated sewage sludge micro-organisms from the aeration stage of the Severn Trent Water Plc sewage treatment plant (UK) which treats predominantly domestic sewage.
Exposure Period	3 hours
Concentration Range	Nominal: 100 – 1000 mg/L
Remarks – Method	The water used in the test was laboratory tap water dechlorinated by passage through an activated carbon filter (Purite Series 500) and partly softened (Elga Nimbus 1248D Duplex water softener). The water had a total hardness of approximately 140 mg/L and was adjusted to the required temperature before use. For preparation of the test solution, the notified chemical was dissolved directly in water. A range finding test was conducted by subjecting sewage sludge to 100 and 1,000 mg/L solutions of the notified chemical. On the basis of the range finding test a limit test was conducted by exposing triplicate samples of sewage sludge to 1,000 mg/L of the notified chemical. In the control test, 3,5-dichlorophenol was used as reference material at 3.2 and 32 mg/L in control test.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The IC50 of 3,5-dichlorophenol was 10 mg/L. Observations made throughout the test period showed that all test vessels contained a very dark red dispersion with no visible undissolved notified chemical.
CONCLUSION	The notified chemical is not inhibitory to sewage sludge mircoorganisms.
TEST FACILITY	SafePharm Laboratories (2008d)

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