

File No: LTD/1241

3 April 2006

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

CIM-01

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 and Heritage.

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**Director
NICNAS**

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FULL PUBLIC REPORT

CIM-01

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

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(s)

Other Name(s)

CAS Number

Molecular Formula

Structural Formula

Molecular Weight

Spectral Data

Composition

Purity

Non-hazardous Impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Flash Point

Explosive properties

Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

NCE/12 (exemption advice on low volume)

NOTIFICATION IN OTHER COUNTRIES

US EPA PMN Notification, PMN No. P-04-0880 (Dec. 2004)

Canada, Ontario state Registration of New Chemical Substance (Oct. 2004)

Philippines Small quantity information clearance notification (Nov. 2004)

The notified chemical is not classified in Annex 1 of Directive 67/548/EEC. The notified chemical has not been reported by EU industry as an High Production Volume Chemical (HPVC) or Low Production Volume Chemical (LPVC). IUCLID and OECD Chemical Data Sheets are not available for the notified chemical. The notified chemical is not listed on a priority list (as foreseen under European Council Regulations (EEC) No 793/93 on the evaluation and control of the risks of existing chemicals.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Carbomonocyclic carboxylic salt

MARKETING NAME(S)
CIM-01

METHODS OF DETECTION AND DETERMINATION

METHOD The notified chemical can be characterised by IR spectroscopy, ¹H-Nuclear Magnetic Resonance (NMR) and ¹³C- NMR spectra.
Remarks Reference spectra were provided.
TEST FACILITY Canon Inc. (2004)

3. COMPOSITION

DEGREE OF PURITY
High

4. 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 of liquid ink in sealed ink-jet printer cartridges at a concentration of 0.5% or less (notified chemical).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 1	< 1	< 1	< 1	< 1

USE

The notified chemical acts as a component of (0.5% or less) of inkjet printer ink.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, New South Wales

IDENTITY OF MANUFACTURER/RECIPIENTS

No manufacture or reformulation of the notified chemical will occur in Australia. The ink cartridges containing the notified chemical will be imported and stored at the notifier's warehouse prior to distribution to offices nationwide and office equipment retailers.

TRANSPORTATION AND PACKAGING

The size of the imported ink cartridge will be 56 mm x 29 mm x 45 mm and 70 mm x 30 mm x 120 mm. Each cartridge contains 16 - 150 mL of ink. At port of entry, the cartridges are transferred by land to the notifiers warehouse and then distributed by road to end users. No repackaging occurs.

5.2. Operation description

No processing such as reformulation, repackaging, filling or refilling of the cartridges containing the notified chemical, or any other handling of the notified chemical is carried out in Australia. Sealed ink cartridges containing the notified chemical will be handled by service technicians, office workers or the public, who will replace spent cartridges in the printers as necessary. Office workers and the public will use the printers for varied printing work.

5.3. Occupational exposure

Number and Category of Workers

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

Exposure Details

Waterside, storage and transport workers will only handle the sealed cartridges containing the notified chemical, therefore, exposure is not expected unless the packaging is accidentally breached.

Service technicians may be exposed to the ink containing up to 0.5% notified chemical during repair and cleaning of ink jet printers. Exposure to the notified chemical may occur while removing cartridges if the ink is inadvertently handled. Due to the low volatility of the notified chemical, dermal exposure is expected to be the main potential route of exposure.

Office workers may be exposed to the ink when replacing the cartridge. Instructions on how to replace the cartridge safely are included with the cartridge. During the printing process, the ink turns into an extremely fine mist and is transferred to the paper. However, mist emission of the non-volatile components of the ink from the printer is expected to be low. 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, therefore, dermal exposure to the notified chemical from contact with the dried ink is not expected. Dermal exposure is also possible if non-absorbent substrates are inadvertently used for printing.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Printer ink is imported in ready-to-use cartridge. Release of the ink solution to the environment is not expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE

Environmental release of the substance is possible during paper recycling and from the disposal of used cartridge. Around 5% of the ink will remain in the empty cartridges. For this reason, the concentration of the remained notified chemical from empty cartridges is 5% of 1000 kg/year (50 kg/year maximum). Such a release will be extremely dispersed and hence predicted environmental concentration of the substance in Australia will be low. The substance will not be released from the printed paper. The ink remaining in the ink cartridges during the recycling process is not reused and disposed.

5.5. Disposal

The notifier collects the used cartridges by setting up collection boxes in general merchandising stores and post offices, which are sent to the subcontractor.

The subcontractor disassembles the used cartridges and makes new raw material. The notifier does not recycle the used cartridges to be renewed as new cartridges by refilling the ink.

The other cartridges which are not collected are disposed of by landfill.

5.6. Public exposure

The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers (see section 5.3 above). However, it is expected that the public will be printing less frequently than office workers.

6. PHYSICAL AND CHEMICAL PROPERTIES

A number of properties were tested for two major components of the notified chemical. Due to confidentiality claims in chemical industry, these components are called “Component A” and “Component B” in the report.

Appearance at 20°C and 101.3 kPa White crystalline solid

Melting Point/Freezing Point 203.9 ± 0.5 °C

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks Determined by Differential Scanning Calorimetry. Test conducted in accordance with GLP standards. No protocol deviations reported.
TEST FACILITY Safe Pharm Laboratories (2005a)

Boiling Point 317.8 ± 0.5°C at 101.99 kPa

METHOD OECD TG 103 Boiling Point.
Remarks Determined by Differential Scanning Calorimetry. Test conducted in accordance with GLP standards. No protocol deviations reported.
TEST FACILITY Safe Pharm Laboratories (2005a)

Density 1.34 x 10³ kg/m³ at 20.0 ± 0.5 °C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Determined by gas comparison pycnometer. Test conducted in accordance with GLP standards. No protocol deviations reported.
TEST FACILITY Safe Pharm Laboratories (2005a)

Vapour Pressure 1.3 x 10⁻⁷ kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
Remarks EC Directive 92/69/EEC A.4 Vapour Pressure.
TEST FACILITY Safe Pharm Laboratories (2005b)

Water Solubility In the range 52.2 to 53.6% (w/w) at 20 ± 0.5 °C

METHOD OECD TG 105 Water Solubility.
Remarks Determined by Flask Method
Analytical Method: visual inspection (no analysis could be performed due to the high solubility producing unfilterable mixtures.)
Test conducted in accordance with GLP standards.
TEST FACILITY Safe Pharm Laboratories (2005a)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T (°C)</i>	<i>t</i> _{1/2} (<i>year</i>)
4	25	> 1 (Component A) > 1 (Component B)
7	25	> 1 (Component A) > 1 (Component B)
9	25	> 1 (Component A) > 1 (Component B)

Remarks	<p><u>Analytical Method: HPLC</u></p> <p>The nominal concentration of the test solutions was 2.0 g/L. Aliquots of sample solutions were taken at various times (0 and 120 hours) and the pH of the solution was recorded.</p> <p>In both analysis of the components (A and B), after 120 hours (5 days) at all pHs and at 50 °C it was found that less than 10% of the test substance had hydrolysed, thus indicating a half-life of greater than 1 year at 25 °C.</p> <p>Test conducted in accordance with GLP standards.</p>
TEST FACILITY	Safe Pharm Laboratories (2005a)
Partition Coefficient (n-octanol/water)	<p>log Pow at 22.4 ± 0.5 °C = -3.36 (Component A)</p> <p>log Pow at 22.4 ± 0.5 °C = -3.49 (Component B)</p>
METHOD	OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method
Remarks	<p>Analytical Method: HPLC. Six measured amounts of the test substance and water saturated n-octanol were shaken by inversion at 22.4 ± 0.5 °C for 5 minutes. Aliquots of both the water and n-octanol phases were taken for analysis.</p> <p>Partitioning coefficient analysis was done for the two components of the test item, Component A and Component B.</p> <p>Negligible hydrolysis of the sample solution was assumed based on the data from the pH and hydrolysis tests.</p> <p>Test conducted in accordance with GLP standards.</p>
TEST FACILITY	Safe Pharm Laboratories (2005a)
Adsorption/Desorption – screening test	<p>log K_{oc} < 1.25 (Component A)</p> <p>log K_{oc} < 1.25 (Component B)</p>
METHOD	OECD 121 Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography.
Remarks	<p>The HPLC screening method was used with the use of 12 reference standards with known adsorption coefficients. The retention time of the test substance was 1.81 minutes which was less than that for acetanilide (3.939 minutes) which has a known log K_{oc} of 1.25, therefore the log adsorption coefficient is less than 1.25.</p> <p>The adsorption coefficients was measured using a Genesis CN 120A 4 µm column and a mobile phase made of methanol:water (55:45 v/v).</p> <p>The test was done at pH 7 and therefore reflects the ionised test item. Testing the unionised form of the test item is not possible as it requires being done at pH 3 or below and greater than pH 11 for the acidic and basic functional groups respectively. As a consequence of this, one of the groups will always be present in its ionised form.</p> <p>The result indicates that the notified chemical will be mobile in soils and sediments.</p> <p>Test conducted in accordance with GLP standards.</p>
TEST FACILITY	Safe Pharm Laboratories (2005a)
Dissociation Constant	<p>pK_a = 9.42 at 20.0 ± 0.5 °C (Component B)</p> <p>pK_a = 5.13 at 20.0 ± 0.5 °C (Component A)</p> <p>pK_a = 2.81 at 20.0 ± 0.5 °C (Component A)</p>

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Determined by potentiometric titration method.

Dissociation constant analysis was done for the each component of the test item. Test item is fully ionised under neutral pH. Deprotonation of the cationic component starts at ~pH 8.40 achieving completion at ~pH 10.70. The anionic component is fully ionised at neutral pH accepting two protons to neutralise. The first protonation starts at ~pH 6.0 achieving completion at ~pH 4.0. The second protonation starts at ~pH 3.70 achieving completion at ~pH 2.50.

TEST FACILITY Test conducted in accordance with GLP standards.
Safe Pharm Laboratories (2005a)

Particle Size

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

<i>Range (μm)</i>	<i>Mass (%)</i>
An inhalable particle size less than 100 μm	61.00
A thoracic particle size less than 10.2 μm	4.24
A respirable particle size less than 5.4 μm	0.51

Remarks Test conducted in accordance with GLP standards. No protocol deviations reported.

TEST FACILITY Safe Pharm Laboratories (2005a)

Flash Point Not determined

METHOD
Remarks A high melting point solid. The notified chemical is not flammable.
TEST FACILITY

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks In the preliminary test the notified chemical did not propagate combustion over the 200 mm. Test conducted in accordance with GLP standards. No protocol deviations reported.
TEST FACILITY Safe Pharm Laboratories (2005b)

Autoignition Temperature None below its melting temperature

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Test conducted in accordance with GLP standards. No protocol deviations reported.
TEST FACILITY Safe Pharm Laboratories (2005b)

Explosive Properties Predicted negative

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The structure of the notified chemical was examined for groups that would imply that it could possess explosive properties. There are no chemical groups that would imply explosive properties, therefore the result has been predicted negative.
TEST FACILITY Safe Pharm Laboratories (2005b)

Reactivity

Remarks The notified chemical is not expected to be reactive under normal environmental conditions.

Oxidising Properties

Predicted negative

METHOD	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	The structure of the notified chemical was examined for groups that would imply that it could possess oxidising properties. There are no chemical groups that would imply oxidising properties, therefore the result has been predicted negative.
TEST FACILITY	Safe Pharm Laboratories (2005b)

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Unspecified method. Consistent with OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100. <i>E. coli</i> : WP2 uvrA (pKM101).
Species/Strain	
Metabolic Activation System	Phenobarbital (PB) and 5,6-Benzoflavone (BF) induced rat liver S9 fraction.
Concentration Range in Main Test Vehicle	a) With metabolic activation: 312.5 - 5000µg/plate. b) Without metabolic activation: 312.5 - 5000µg/plate. Sterilized pure water (with and without metabolic activation)
Remarks – Method	1. A dose range finding test (Test 1, with doses 19.53 – 5000 µg/plate) with and without metabolic activation. 2. Main test (Test 2, with doses 312.5 – 5000 µg/plate) were conducted with and without metabolic activation. 3. Positive controls were used. 4. Statement of GLP. No protocol deviations reported.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Present</i>				
Test 1	>5000	>5000	>5000	negative
Test 2	>5000	>5000	>5000	negative
<i>Absent</i>				
Test 1	>5000	>5000	>5000	negative
Test 2	>5000	>5000	>5000	negative

Remarks – Results	The test substance did not cause a marked increase in the number of revertants per plate of any of the bacterial strains either in the presence or absence of metabolic activation in both dose range finding test and the
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main test. The negative controls were within historical limits. The positive controls confirmed the activity of the activation system and the sensitivity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Canon Inc. (2004b)

8. ENVIRONMENT

8.1. Environmental fate

No test data for environmental fate endpoints were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity test data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will not be manufactured in Australia, but will be imported as a component in the inkjet printer ink at a concentration of 0.5% or less. No release of the notified substance is expected during transportation, except in the event of an accidental spill. The MSDS contains suitable procedures for containing spills. The notified chemical is an ink component for use by the general public in printer's cartridges for producing quality prints.

The notified chemical is not volatile, and therefore, does not dissipate into air from the paper. It is water-soluble and is expected to remain within the aquatic environment, but will not fully hydrolyse in natural waters at environmental pH values. The low log Kow and log Koc is consistent with the high water solubility indicating a low affinity for the organic phases and component of soils and sediments, suggesting accumulation in water compartments and high mobility in soils. The notified chemical is unlikely to be bioaccumulate due to its low log Kow and log Koc and ionised stage at environmental pH.

Environmental exposure of the notified chemical will result from the disposal of cartridges, printed-paper and any leaked ink containing the chemical during the use of the cartridges. The total import volume of the notified chemical will ultimately be either disposed of to landfill, incinerated or recycled with paper.

Recycling may take place in a number of centres throughout Australia. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30-60% of the total amount of ink

Using a worst case scenario, based on the assumption that the entire imported volume (maximum of 1000 kg) will end up on paper, 50 % of the paper will be recycled (500 kg of the notified chemical), and assuming that 60% de-inking occurred during the recycling process.

Predicted Environmental Concentration (PEC) in the aquatic compartment can be estimated, as shown below.

Amount released to sewer a year	300 kg (0.6 × 500)
Number of days used	365 days
Australia population	20 million people
Water consumption:	Average 200 L/person/day

Nation level	4000 ML/day for total population
Chemical concentration in Australian sewerage network concentration	2.1×10^{-4} mg/L (ie. 300×10^6 mg \div 365 days/year \div 4000×10^6 L = 2.1×10^{-4} mg/L)

The following PECs are determined:

PEC _{sewer}	0.21 µg/L
PEC _{ocean}	0.02 µg/L
PEC _{river}	0.21 µg/L

Based on dilution factors of 0 and 10 for inland and ocean discharges of STP-treated effluents, the predicted environmental concentrations (PECs) of the notified chemical in fresh water and marine surface waters may approximate 2.1×10^{-4} mg/L and 2.1×10^{-5} mg/L, respectively.

Using the SIMPLETREAT model for modelling partitioning and losses in sewage treatment plants [STP] (European Commission, 1996), the percentage removal from solution by STP may potentially approximate 0% through volatilisation and in sludge. Virtually all of the inflow concentration of the notified chemical may potentially remain in solution, passing through the STP. Thus the PEC concentrations in treated effluents and irrigation re-use waters may actually be 100% of that estimated with allowance for potential STP removal (ie estimated average effluent concentration of 2.1×10^{-4} and 2.1×10^{-5} mg/L for freshwater and marine waters, respectively).

The effluent re-use (eg. irrigation purposes) concentration of the notified chemical may potentially approximate 2.1×10^{-4} mg/L, assuming 100% remaining in solution during the STP process. STP effluent re-use for irrigation in Australia occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m³). Using these assumptions, irrigation with a concentration of 2.1×10^{-4} mg/L may potentially result in a soil concentration of approximately 2.1×10^{-2} mg/kg assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus, 2.1×10^{-2} mg/kg is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

9.1.2. Environment – effects assessment

While a PEC/PNEC calculation is not possible as no toxicity data were provided, modelling indicates the notified chemical is of low toxicity to fish, toad and midge (EPI Suite v3.12 © 2000, US Environmental Protection Agency).

9.1.3. Environment – risk characterisation

On the basis of the low expected aquatic toxicity and reported use pattern, the notified chemical is unlikely to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

Office workers may be exposed to the notified chemical, while changing spent cartridges or during normal printing processes and service technicians while removing cartridges, repairing and cleaning, primarily through dermal contact. Ocular and inhalation exposure are not expected due to sealed cartridges and low volatility of the notified chemical. Service technicians are expected to have the highest potential occupational exposure. However, for all workers, due to the design of the cartridge dermal exposure is likely to occur only occasionally and to small quantities of the notified chemical at a concentration of < 0.5%. Therefore, dermal exposure is expected to be low. Exposure will be minimised by the use of disposable gloves by service personnel.

Exposure to the notified chemical on printed-paper is low as the ink is bound to the paper matrix. Some intermittent exposure may occur if printing onto a non-absorbent substrate occurs and the ink does not dry in a short time.

9.2.2. Public health – exposure assessment

Similarly to office workers, exposure to the notified chemical is considered to be limited by the dermal route. The public may intermittently be exposed to the notified chemical when replacing spent cartridges and during use of printers. However, as it is expected that the public will be using the printer less frequently than workers, exposure is also expected to be lower.

Overall, exposure of the public is expected to be low, due to the small quantity of notified chemical in each cartridge, sealed cartridge and the controlled release during printing.

9.2.3. Human health – effects assessment

Toxicological data for the notified chemical was submitted for mutagenicity.

A reverse mutation test in *Salmonella typhimurium* (with and without activation) indicated the notified chemical was not mutagenic to bacteria.

Based on the available data, the notified chemical is not classified for mutagenicity as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

9.2.4. Occupational health and safety – risk characterisation

Due to the low concentration of the notified chemical as introduced (< 0.5% notified chemical) and limited exposure to the notified chemical expected during usual conditions of use in the office environment, the risk of adverse effects is considered to be low.

9.2.5. Public health – risk characterisation

As with office workers, due the low and intermittent exposure expected, the risk of adverse effects is also considered to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified for mutagenicity as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On basis of the reported use pattern, the chemical is not considered to pose a risk to the environment.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of an ink product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety*

Data Sheets (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for an ink product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls or work practices are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.
- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing printer cartridges containing the notified chemical and during routine maintenance and repairs.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed following the procedure describe bellow:
Dispose the used cartridges in the collection boxes set up in general merchandising stores and post offices, which would be collected by the notifier.

Emergency procedures

- Accidental spills/release of the notified chemical should be handled by the following method of treatment.
- Recovery:
Collect the ink by means of an industrial vacuum machine or similar and dispose of waste material in accordance with local regulations by incineration or landfill. Recovery of the substance for re-use is not recommended.
- Containment:
In case of spillage, do not release the substance to sewer, surface water or ground water. Use containment techniques appropriate to the size of the spillage.
- Neutralisation:
Dilute with plenty of water.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act; if
 - any of the circumstances listed in the subsection arise; and
 - the importation volume exceeds one tonne per annum notified chemical.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Canon Inc. (2004a) Reference Spectrum [Notified Chemical] Canon Australia Pty. Ltd 1 Thomas Holt Drive NORTH RYDE NSW 2113.

Canon (2004b) Report of Mutagenicity Test Using Microorganisms, Report No. 708, Canon Inc., Tokyo, Japan (Unpublished report submitted by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

SafePharm Laboratories (2005a) [Notified Chemical]: Determination of General Physico-Chemical Properties (SPL Project Number 345/821, 11 OCT 2005), SafePharm Laboratories Limited Derbyshire UK. (Unpublished report submitted by notifier).

SafePharm Laboratories (2005b) [Notified Chemical]: Determination of Hazardous Physico-Chemical Properties (SPL Project Number 345/822, 17 OCT 2005), SafePharm Laboratories Limited Derbyshire UK. (Unpublished report submitted by notifier).