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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

BS-1

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Director
NICNAS

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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 identity; Composition; Manufacture/import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Particle size; Boiling point; Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/297 (1998)
NCE/52 (2005)

NOTIFICATION IN OTHER COUNTRIES
Philippines (Small Quantity Importation Clearance (SQIC) Notification): 2005, 2006

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
BS-1
Glycol
Note: The notified chemical will be imported in "Ink Cartridge for Ink Jet Printer", eg. Magenta Ink Cartridge for Ink Jet Printer

METHODS OF DETECTION AND DETERMINATION

METHOD	The notified chemical can be characterised by IR spectroscopy.
TEST FACILITY	Canon Inc. (1998)

3. COMPOSITION

DEGREE OF PURITY
>99%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component (≤ 10%) of inkjet printer ink contained within print cartridges. The notified chemical will not be manufactured in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<0.1	<1	<1	<1	<1

USE
Ink jet cartridges containing the notified chemical (≤ 10%) will be used by office workers and the public for a variety of printing work. The notified chemical will be present in several different coloured inks, including black, cyan, magenta, yellow, etc.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney Airport and Sydney Harbour

IDENTITY OF MANUFACTURER/RECIPIENTS
The ink cartridges will be stored at the notifier's warehouse prior to distribution to offices nationwide and office equipment retailers.

TRANSPORTATION AND PACKAGING
The size of imported ink cartridges is as follows:

Size: 56 mm x 29 mm x 45 mm - 70 mm x 30 mm x 120 mm

Volume : 16 ml - 150 ml

Transport in Australia will be by road and no special transport requirements are necessary.

5.2. Operation description
The notified chemical is imported in sealed ink cartridges; therefore, no processing takes place in Australia. 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.

5.3. Occupational exposure
Number and Category of Workers

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

Exposure Details
Importation/waterside workers, storage and transport workers will handle sealed cartridges containing the notified chemical and exposure is not expected unless the packaging is accidentally breached.

Service technicians may be exposed to ink containing 10% or less of the notified chemical during repair and cleaning of ink jet printers. Due to the low volatility of the notified chemical, dermal exposure is expected to be the main potential route of exposure. Exposure to the notified chemical may occur while changing cartridges if the ink is inadvertently handled.

Office workers may be exposed to the ink when replacing the cartridge, however, exposure is expected to be low. Instructions on how to replace the cartridges 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 very low. Occasional dermal exposure to the notified chemical may occur during use of the printer if the printed pages are handled inadvertently before the ink dries, if ink-stained parts of the printer are touched, or if

the ink is mistakenly used on non-absorbent surfaces. Once the ink dries on the paper, the notified chemical would be bonded to the printed-paper, and therefore dermal exposure to the notified chemical from contact with dried ink is not expected.

5.4. Release

RELEASE OF CHEMICAL AT SITE

As the notified chemical is manufactured and packaged overseas, there will be no environmental release of chemical at site.

RELEASE OF CHEMICAL FROM USE

Environmental release of the notified chemical from use is summarised in the following table.

Source of release	% Annual Volume	Released to
Residual notified chemical remaining within used ink-jet cartridges as well as accidental spills.	≤5%	Landfill or Incinerator
Paper products containing the notified chemical.	≥95%	Landfill or Sewer

5.5. Disposal

Up to 5% of the total annual volume of notified chemical is expected to remain as residual within used ink-jet cartridges. A large proportion of these may be recycled, with the notified chemical being removed and disposed of to landfill or by incineration. Cartridges that are not recycled are expected to be disposed of directly to landfill.

The remaining 95% of the total annual volume of notified chemical is expected to be absorbed onto paper during the printing process, and it is claimed to remain associated with the paper during recycling on disposal. However, based on the notified chemical's physico-chemical properties (water solubility, partition coefficient, adsorption/desorption), release during paper recycling is likely to occur, with the notified chemical remaining within the effluent and not being removed. Paper containing the notified chemical that is not recycled is expected to be disposed of to landfill.

In the landfill environment, the notified chemical is expected to remain bound to paper and thus be relatively immobile. Over time, it is expected that the notified chemical will degrade via biotic and abiotic means to form simple oxides. Any notified chemical that is disposed of by incineration is similarly expected to form simple oxides.

Notified chemical that is released to sewer from paper recycling is expected to remain within the aquatic compartment. Over time, the notified chemical is expected to degrade via abiotic and biotic processes.

5.6. Public exposure

During normal usage, public exposure to the notified chemical will be negligible, given that it is present as a minor component (10% or less) in the final imported product (inkjet printer ink). Upon drying, the notified chemical will be bonded to the printed-paper, and dermal exposure to the notified chemical is not expected.

Members of the public may come into contact with ink cartridges when they need to be replaced in the printer. The cartridge has an aperture to deliver ink to the printer and accidental dermal exposure can occur to fingers (mainly). Instructions on how to replace the cartridges safely are included with the cartridge. Mist emission of the non-volatile components of the ink from the printer is expected to be very low. Occasional dermal exposure to the notified chemical may occur during use of the printer if the printed pages are handled inadvertently before the ink dries, if ink-stained parts of the printer are touched, or if the ink is mistakenly used on non-absorbent surfaces.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White solid block

Melting Point/Freezing Point (30 – 50) ± 0.5°C

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks Determined by Differential Scanning Calorimetry.
TEST FACILITY SafePharm Laboratories (2002a)

Boiling Point Test not conducted. Estimated to be >200°C based upon observations in the flash point test.

Density 1.54 x 10^3 kg/m^3 at 20 ± 0.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Determined by gas comparison pycnometer.
TEST FACILITY SafePharm Laboratories (2002a)

Vapour Pressure <7.8 x 10^{-7} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined by an effusion method: vapour pressure balance
TEST FACILITY SafePharm Laboratories (2006a)

Water Solubility Miscible in all proportions at 20.0 ± 0.5°C

METHOD Based on OECD TG 105
Remarks Mixtures of test material and glass double-distilled water were prepared. After shaking for 24 h at ~30°C and standing for 24 h at 20°C, the extent of dissolution was assessed visually. The standard flask method specified in the test guideline was not applicable because the test material showed no upper limit for saturation mass concentration in water.
TEST FACILITY SafePharm Laboratories (2002a)

Hydrolysis as a Function of pH Hydrolytically stable.

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	25	>1 year
7	25	>1 year
9	25	>1 year

Remarks Standard and sample solutions were analysed by HPLC.
TEST FACILITY SafePharm Laboratories (2002a)

Partition Coefficient (n-octanol/water) log Pow = -2.06 at 21.5 ± 0.5°C

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks Shake-Flask Method. The concentration of test material in the sample solutions was determined by HPLC.
TEST FACILITY SafePharm Laboratories (2002a)

Adsorption/Desorption – screening test log K_{oc} <1.25

METHOD OECD TG 106 Adsorption – Desorption (HPLC Method)
Remarks The test material eluted before the reference substance Acetanilide, which was the first to elute of 11 reference substances.
TEST FACILITY SafePharm Laboratories (2002a)

Dissociation Constant pKa 1= 14.06 ± 0.10

pKa 2= 13.35 ± 0.10

METHOD ACD/I-Lab Web Service, ACD/pKa 8.03 (software)
Remarks Testing was not possible according to OECD Guidelines No.112 due to the absence of any dissociating functional groups within the pH range of the test methods.
TEST FACILITY SafePharm Laboratories (2006b)

Particle Size Not determined, as the notified chemical exists as a solid block.

Flash Point No flash point below its boiling temperature

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Determined using a closed cup equilibrium method
TEST FACILITY SafePharm Laboratories (2006a)

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical did not propagate combustion over a length of 200 mm when loosely fitted into a mould 250x20x10mm in size.
TEST FACILITY SafePharm Laboratories (2006a)

Autoignition Temperature 394 ± 5°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY SafePharm Laboratories (2006a)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Fall hammer shock test, Friction test, Koenen steel tube test (thermal sensitivity) and Moisture content were performed.
TEST FACILITY SafePharm Laboratories (2002b)

Reactivity

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

Oxidising Properties Predicted to be negative.

METHOD Predicted using EC Directive 92/69/EEC A.17 Oxidising Properties (Solids).
Remarks Based on the chemical structure, the notified chemical is expected to be non-oxidising.
TEST FACILITY SafePharm Laboratories (2006a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Genotoxicity - bacteria

TEST SUBSTANCE BS-1 (65 % aqueous solution)

METHOD Method similar to OECD 471 Bacterial Reverse Mutation Test.

	Pre incubation procedure
Species/Strain	Study A: *Salmonella typhimurium:* TA98, TA100. Study B: *Salmonella typhimurium:* TA1535, TA1537. *Escherichia coli*: WP2 *uvr*A (pKM101).
Metabolic Activation System	S9 fraction from Phenobarbital (PB) and 5,6-Benzoflavone (BF) induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 0.625 - 10 µL/plate. b) Without metabolic activation: 0.625 - 10 µL/plate.
Vehicle	Sterilised pure water
Remarks - Method	The results were reported as two separate studies by the test facility. No significant protocol deviations were noted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>10µL/plate	>10µL/plate	>10µL/plate	Negative
Present	>10µL/plate	>10µL/plate	>10µL/plate	Negative

Remarks - Results	Study A and B: No cytotoxicity (as measured by a decrease in the bacterial background lawn) or precipitation was observed at any concentration. The positive controls (2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide, sodium azide and 9-aminoacridine (-S9); 2-aminoanthracene and benzo[a]pyrene (+S9)) demonstrated the sensitivity of the test system. Study A: No substantial increases in the number of revertant colonies were seen in any strain either in the presence or absence of metabolic activation in the dose range finding test and the main test. Study B: In the dose range finding test there was a slight increase in the number of revertant colonies observed in TA1535+S9Mix and TA1537-S9Mix. In the main test the number of revertant colonies increased twice or more over that in the negative control in TA1535+S9Mix, and there was a slight increase in the number of revertant colonies observed in TA1537-S9Mix. A confirmatory test using TA1535+S9Mix and TA1537-S9Mix was also performed. In this test, the number of revertant colonies did not increase twice or more over that in the negative control test strains.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Canon Inc. (2006a, 2006b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Sewage treatment micro-organisms from secondary treatment stage of a domestic STP.
Exposure Period	28 d
Auxiliary Solvent	Nil
Analytical Monitoring	Temperature, pH, Dissolved Oxygen.
Remarks - Method	The test material was exposed at a concentration of 4 mg/L with culture medium in sealed culture vessels in the dark at 21°C. The degradation of the test material was assessed by the determination of the amount of oxygen consumed. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	5	3	60
9	8	9	81
21	13	21	93
28	14	28	100

Remarks - Results	The toxicity control attained 80% degradation after 28 days thereby confirming that the test material was not toxic to the sewage treatment micro-organisms used in the study. The standard material, sodium benzoate, attained 100% degradation after 28 days thereby confirming the suitability of the test method and culture conditions.
CONCLUSION	The test material attained 14% degradation after 28 days and therefore cannot be considered to be readily biodegradable under the strict terms and conditions of OECD TG 301D.
TEST FACILITY	Safepharm (1998a).

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is manufactured and packaged overseas, and thus environmental exposure in Australia will not occur from manufacturing or reformulation. It is expected that notified chemical applied to paper in the printing process will adsorb to that paper and is likely to subsequently release in water, should the paper be recycled. Assuming 100% of paper is recycled in Australia, and that all notified chemical is removed during the recycling process, the following Predicted Environmental Concentration has been calculated.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	95.000%	
Annual quantity of chemical released to sewer	950.000	kg/year

Days per year where release occurs	365	days/year
Daily chemical release:	2.60	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.63	µg/L
PEC - Ocean:	0.06	µg/L

It is expected that the majority of paper that is not recycled will be disposed of to landfill, with only a small proportion potentially being incinerated. In landfill the notified chemical is expected to remain with the paper substrate and be immobile, eventually degrading to simple oxides.

9.1.2. Environment – effects assessment

Ecotoxicity data have not been submitted. Toxicity will be limited due to the notified chemical's high solubility in water and very low partition coefficient values. Its potential for bioaccumulation is also low, given the low and diffuse expected release to the aquatic environment.

9.1.3. Environment – risk characterisation

Based on the proposed use volume and patterns, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The maximum concentration of the notified chemical in inkjet printer cartridges is 10%. Occasional dermal exposure to the notified chemical may occur during use of inkjet printer cartridges containing the notified chemical. Printer service technicians may be exposed during repair and service of printers or while changing cartridges. Office workers may be exposed when replacing ink cartridges, handling printed pages before ink has dried, or touching ink-stained parts of the printer. Worker exposure to the notified chemical is expected to be low, particularly after ink has dried onto the paper, and is thus bonded to the paper.

9.2.2. Public health – exposure assessment

Members of the public may come into contact with materials printed with inks containing the notified chemical at concentrations up to 10%. Dermal exposure to the notified chemical in such circumstances is not expected to occur, given that the ink will be dried and the notified chemical bonded to the paper. Exposure to the notified chemical may occur when replacing ink cartridges. However, exposure should be low and limited to several times a year at most. Overall, public exposure to the notified chemical is expected to be low, particularly after the ink has dried onto the paper, and is thus bonded to the paper.

9.2.3. Human health – effects assessment

The notified chemical was not mutagenic in a bacterial reverse mutation assay. No other toxicity data was provided for this assessment.

Based on the available data, the notified chemical cannot be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The risk to workers from exposure to the notified chemical should be minimised by containment of the notified chemical within cartridges, and dermal exposure to ink containing the notified chemical will occur infrequently and be of small amounts. It should be noted that dermal absorption is not expected, given that the notified chemical is highly miscible in water and has low lipophilicity. However, given the concentration at which the notified chemical will be

present in final ink products (maximum 10%) and the limited toxicity information, adverse effects resulting from exposure to the notified chemical cannot be ruled out. Therefore, precautionary control measures should be in place to ensure safe use of the notified chemical in the printer inks if there is a possibility of exposure to ink in greater quantities or with greater frequency.

9.2.5. Public health – risk characterisation

The risk to the public is considered to be low, based on the low and intermittent dermal exposure, and its expected binding onto the printed paper.

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

10.1. Hazard classification

Based on the available data the notified chemical cannot be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

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 No Significant 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

- Workers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical itself:
  - Avoid contact with eyes and skin.

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent 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.

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

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

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(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 any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

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