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

PUBLIC REPORT

CIM-28

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 Sustainability, Environment, Water, Population and Communities.

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

This 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**

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1584	Canon Australia Pty Ltd	CIM-28	ND*	≤1 tonne per annum	Component of inkjet printer ink

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

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

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
 - Avoid contact with skin and eyes
- Service personnel should wear impervious 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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill. Emergency procedures
- Spills or accidental release of the notified chemical should be handled by 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/polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;
 - the proposed mode of introduction and/or usage scenario changes such that the level of exposure of workers and/or the public increases;
 - new information becomes available on the toxicity of the notified chemical.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of inkjet printer inks, or is likely to change significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

The MSDS of the notified chemical and a product 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.

ASSESSMENT DETAILS

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, adsorption/desorption and particle size.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Low volume chemical permit.

NOTIFICATION IN OTHER COUNTRIES

USA (2011)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIM-28

MOLECULAR WEIGHT
>1,000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, MS and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Black solid (granules)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	>400 °C	Measured
Density	1640 kg/m ³ at 20 °C	Measured
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
Water Solubility	>200 g/L at 25 °C	Measured
Hydrolysis as a Function of pH	t _{1/2} >1 year at 25 °C at pH 4,7 and 9	Measured
Partition Coefficient (n-octanol/water)	log Kow <-3.84 at 25 °C	Measured
Surface Tension	72.1 ± 0.6 mN/m at 25 °C	Measured
Adsorption/Desorption	Not determined	The notified chemical is expected to have a high mobility in soil based on its high water solubility and low log Kow
Dissociation Constant	pKa = 5.31	Measured. The notified chemical is expected to have multiple pKa values due to the presence of several ionisable groups.
Particle Size	Not determined	Introduced as a component of formulated products
Flammability	Not highly flammable	Measured
Autoignition Temperature	>400 °C	Measured
Explosive Properties	Predicted negative (no significant exotherms when heated to 500 °C)	Measured
Oxidising Properties	Predicted negative	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is expected to be stable under normal conditions of use.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table, the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component (≤7%) of inkjet printer ink.

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

PORT OF ENTRY

Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

Canon Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of inkjet printer ink in sealed cartridges. The cartridges will vary in size between 5-900 mL and will be packaged in sealed foil bags. The printer cartridges will be transported by road to the Canon Australia Pty Ltd warehouse and then distributed to retail outlets/end-users.

USE

The notified chemical will be used as component ($\leq 7\%$) of inkjet printer ink for commercial and household printers.

OPERATION DESCRIPTION

The notified chemical will be imported as a component of ink in sealed cartridges. Reformulation will not take place in Australia.

End-users (including service technicians, office workers and the general public) will remove the cartridge from the packaging and place the cartridge into the printer. The cartridge will be disposed of when empty.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration</i>	<i>Exposure Frequency (days/year)</i>
Import/waterside	<8 hours/day	10-50
Storage and transport	<8 hours/day	10-50
Office workers	10 seconds/day	2
Service technicians	1 hour/day	230

EXPOSURE DETAILS

Waterside, storage and transport workers may come into contact with the notified chemical, as a component of ink ($\leq 7\%$), only in the unlikely event of an accident.

Service technicians and office workers may be exposed to the ink containing $\leq 7\%$ of the notified chemical when replacing spent cartridges and during the repair and cleaning of ink jet printers. Dermal exposure is expected to be the main route of exposure, and it is expected to be minimised by users following instructions for replacing spent cartridges, which will be included with the cartridges.

Occasional dermal exposure during use of printers could also occur if the printed pages were touched before the ink had dried. Once the ink dries, the notified chemical will be bound to the paper, and is not expected to be bioavailable, thus further dermal contact should not lead to exposure. Inhalation exposure to the notified chemical is not expected under the proposed use scenario.

6.1.2. Public Exposure

Dermal exposure of the public to inks containing the notified chemical (at $\leq 7\%$) is expected to be similar, though less frequent, than that described above for office workers.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Absorption of the notified chemical across gastrointestinal tract and the skin is expected to be limited by the high molecular weight ($>1,000$ Da) and the low partition coefficient ($\log P_{ow} < -3.84$). However, the notified chemical contains identified impurities ($<5\%$), that are similarly structured but with a lower molecular weight, that may be absorbed. In addition, the notified chemical contains functional groups that are expected to be metabolised into lower molecular weight chemicals.

The notified chemical contains functional groups that have been associated with skin irritation, skin sensitisation and carcinogenic effects. The potential for these effects may be limited by the relatively high molecular weight of the notified chemical. However, they cannot be completely ruled out, particularly due to the presence of the lower molecular weight impurities and/or metabolic products.

Health hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical will be handled by workers at $\leq 7\%$ concentration. At such concentrations, skin irritation is not expected. However, skin sensitisation and carcinogenic effects cannot be ruled out following exposure to the notified chemical. Dermal exposure to the notified chemical may occur when replacing spent cartridges (and/or incidental exposure through the touching of wet ink on printed pages).

While significant dermal exposure of technicians to the notified chemical is not expected given the containment within cartridges, the performing of printer maintenance operations, in an industrial setting, may occur on a frequent basis. Therefore, measures should be taken to avoid exposure to the notified chemical (e.g. use of impervious gloves).

Dermal exposure of office workers to the notified chemical is expected to be infrequent and of a low level, given the containment of the chemical within cartridges and the provision of instructions for replacing the cartridges.

Therefore, provided that measures to protect technicians are being adhered to (i.e., use of impervious gloves and adequate ventilation when performing printer maintenance operations), and based on the expected low exposure of office workers to the notified chemical, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Public exposure to the notified chemical is expected to be similar, though less frequent than office workers. Therefore, the risk to the health of the public from use of the notified chemical is not considered to be unreasonable.

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 into Australia as a component of inkjet printer ink in ready-to-use cartridges. 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

The notified chemical will not be released from the printed paper. Approximately 5% of the ink containing the notified chemical will remain in spent cartridges. The ink remaining in the ink cartridges during the recycling process will not be reused and will be disposed of with the packaging. Environmental release of the notified chemical is possible during paper recycling and from the disposal of used print cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL

The notifier will collect the used cartridges from collection boxes in general merchandising stores and post offices, etc. The collected cartridges will be sent to a subcontractor who will disassemble the used cartridges and recycle them into raw materials such as plastics. The remaining ink separated from the used cartridges will be disposed of under State/Territory regulations. Uncollected cartridges will be disposed of to landfill.

Half of the paper to which the notified chemical will be applied is expected to be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, will enhance detachment of toner from the fibres.

7.1.2. Environmental Fate

In the MSDS for the notified chemical it is reported to be not readily biodegradable (OECD 301F; < 5% biodegradation after 28 days). The majority of the notified chemical is expected to enter the environment from disposal of printed paper products on which ink containing the notified chemical will be used. Approximately 45% of the notified chemical will be disposed of to landfill by binding on the printed waste paper, and eventually degrade *in-situ* by abiotic and biotic processes into water, inorganic salts and oxides of carbon, nitrogen and sulfur. Notified chemical not bound to paper in landfill may leach due to the expected low K_{oc} and high water solubility.

The remaining 50% of the notified chemical is expected to be released to sewer, after the de-inking of paper during recycling. Assuming a worst-case scenario, the entire amount of notified chemical from paper recycling will be released from sewage treatment plants into aquatic ecosystems, where the notified chemical is expected to be mobile. However, the notified chemical is not expected to bioaccumulate due to its very low K_{ow} and high solubility in water.

7.1.3. Predicted Environmental Concentration (PEC)

Under a worst case scenario, it was assumed that 50% of the paper products containing the notified chemical will be recycled and released into sewers with no removal of the notified chemical by the sewage treatment plant (STP). As the notified chemical is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The resultant Predicted Environmental Concentration (PEC) in sewage effluent nationwide is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	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	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.43	$\mu\text{g/L}$
PEC - Ocean:	0.043	$\mu\text{g/L}$

STP effluent re-use for irrigation 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 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.425 $\mu\text{g/L}$ may potentially result in a soil concentration of approximately 2.835 $\mu\text{g/kg}$. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the

concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 14.17 µg/kg and 28.35 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical and reported in the MSDS are outlined in the table below. Only a very brief summary of the tests was reported in the MSDS.

<i>Endpoint</i>	<i>Test Guideline</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	OECD 203	LC50 (96 h) >100 mg/L	Not harmful
Daphnia Toxicity	OECD 202	EC50 (48 h) >100 mg/L	Not harmful
Algal Toxicity	OECD 201*	EC50 (72 h) = 9.2 mg/L**	Potentially toxic
Inhibition of Bacterial Respiration	OECD 209	IC50 >1000 mg/L	Not inhibitory to bacterial respiration

*Conducted with the ETAD modification for coloured substances.

**Not clear if this was an endpoint based on biomass or growth rate.

The ecotoxicity endpoints from the notified chemical's MSDS summarised above are considered acceptable to characterise the hazard of the notified chemical for risk assessment purposes. However, as the full study reports on which the endpoints are based are not available, the endpoints are considered insufficient to formally classify the notified chemical under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

In the algal study the Ecological and Toxicological Association of Dyes and Organic Pigments (ETAD) method was used to distinguish the effect of shading by the coloured test substance and toxic inhibition effects. It was reported that the observed algal growth inhibition effect of the test substance is caused by an indirect effect, namely the light absorption in the coloured test solution. However, this method is considered too simplistic to allow evaluation of both toxic and light absorption effects of coloured substances (EC, 2006). Furthermore, it is ambiguous if the reported endpoints in the MSDS are for biomass or growth. In the absence of a full study report, the most conservative algal endpoint provided in the MSDS is utilised for risk characterisation of the notified chemical.

7.2.1. Predicted No-Effect Concentration

The endpoint from the most sensitive species from the results reported in the MSDS was used to calculate the Predicted No-Effect Concentration (PNEC). A conservative assessment factor of 500 was used as although acute toxicity endpoints were available for effects of the notified chemical on aquatic species from three trophic levels, full study reports were not provided.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
72 h Algae EC50	9.2	mg/L
Assessment Factor	500	
PNEC:	18.4	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.43	18.4	0.023
Q - Ocean	0.043	18.4	0.0023

The Risk Quotients ($Q = \text{PEC}/\text{PNEC}$) for the worst case discharge scenario have been calculated to be $\ll 1$ for the river and ocean compartments. This indicates that the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point >400 °C

Method EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
 Remarks Determined using a Buchi Melting Point Apparatus B-545. No melting transition was observed (up to 400 °C).
 Test Facility Intertek (2011)

Density 1640 kg/m³ at 20 °C

Method EC Directive 92/69/EEC A.3 Relative Density.
 Remarks Determined using a Micromeritics Pycnometer 1330 TC.
 Test Facility Intertek (2011)

Water Solubility >200 g/L at 25 °C

Method In house method
 Remarks A series of solutions was prepared with increasing concentrations of test substance. Each sample was sonicated for 5 minutes and placed in a water bath at 25 ± 1 °C. The solubility of the test substance was determined by visual inspection of the samples.
 Test Facility Intertek (2011)

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

Method EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

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

Remarks Test solutions, at pH 4, 7 and 9, were prepared in duplicate and the pH was measured prior to storage at 50 ± 1 °C. Analysis of the test solutions by HPLC was carried out initially and at intervals over 5 days. There was less than 10% hydrolysis at pH 4, 7 and 9 after 5 days at 50 °C.

Test Facility Intertek (2011)

Partition Coefficient (n-octanol/water) log K_{ow} < -3.84 at 25 °C

Method EC Council Regulation No 440/2008 A.8 Partition Coefficient.
 Remarks Shake Flask Method. Test solutions were prepared in n-octanol saturated water and were centrifuged for 10 min at 2000 rpm and allowed to stand for at least an hour at 25 ± 1 °C. The concentration of test substance in the water and octanol phases was measured spectrophotometrically at 606 nm. The mean result from six measurements was reported.
 Test Facility Intertek (2011)

Surface Tension 72.1 ± 0.6 mN/m at 25 °C

Method EC Council Regulation No 440/2008 A.5 Surface Tension.
 Remarks Concentration: 0.1% solution.
 The test substance was not considered to be surface active material.
 Test Facility Intertek (2011)

Dissociation Constant pK_a = 5.31 at 22 °C

Method In house method
 Remarks The pK_a was determined by titration with 0.1 M HCl using a potentiometric titrator fitted

with a pH electrode. The titration was performed at three weights and the pKa was estimated by extrapolation to infinite dilution.

Test Facility Intertek (2011)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks Determined by measuring the burning rate of the test material. The test material failed to ignite following application of a Bunsen burner flame for a period of two minutes.
Test Facility Harlan (2011)

Autoignition Temperature >400 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature (Solids)
Remarks Determined by heating aliquots of the test substance in an oven (up to 400 °C) and observing for any signs of ignition.
Test Facility Harlan (2011)

Explosive Properties Predicted negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks Following the observation of functional groups in the notified chemical that imply explosive properties, thermal analysis was conducted using differential scanning calorimetry (DSC) (25-500 °C temperature program at a rate of 5 °C/min, in an air atmosphere). Under the conditions of the test, there were no significant exotherms.
Test Facility Harlan (2011)

Oxidizing Properties Predicted negative

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks The structure of the notified chemical was assessed for chemical groups that imply oxidising properties.
Test Facility Harlan (2011)

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