File No: LTD/1868

November 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

CIM-35

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

This Public Report is 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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1868	Canon Australia Pty. Ltd.	CIM-35	ND*	< 1 tonne per annum	Component of inkjet printing ink

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R36: Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 3:	H402 - Harmful to aquatic life

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 reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the ink product:
  - Avoid contact with eyes and skin

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the ink product:
  - Protective clothing and gloves if frequent exposure to the ink is expected

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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
  - the importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of inkjet printing ink, or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, 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 (M)SDS of the notified chemical and product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified chemical by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty. Ltd (ABN: 66 005 002 951)
Building A, The Park Estate
5 Talavera Road
MACQUARIE PARK NSW 2113

NOTIFICATION CATEGORY
Limited-small volume (reduced fee notification): Chemical other than polymer (1 tonne or less per year) – Assessed by comparable agency

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, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: flash point, oxidising properties and reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/928

NOTIFICATION IN OTHER COUNTRIES
US EPA (2014)
China (2014)
Japan (2013)
Korea (2014)
Philippines (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME
CIM-35

MOLECULAR WEIGHT
> 1,000 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Black powder

Property	Value	Data Source/Justification
Melting Point	> 400 °C	Measured

Property	Value	Data Source/Justification
Density	1,716 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.002 kPa at 20 °C	Measured
Water Solubility	186 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Hydrolytically stable at pH 4, 7 and 9	Measured
Partition Coefficient (n-octanol/water)	log Pow < - 4.5	Measured
Surface Tension	72.7 m/Nm	Measured
Adsorption/Desorption	log K_{oc} < 1.25	Measured
Dissociation Constant	Not dissociable	Measured
Particle Size	Respirable fraction (< 10 μm): 7.37% MMAD* = 89.65 μm	Measured
Solid Flammability	Not highly flammable	Measured
Autoignition Temperature	271.4 ± 7.8 °C	Measured
Explosive Properties	Non-explosive	Measured
Oxidising Properties	Predicted negative	Based on structure group evaluation, one group of the notified chemical was predicted to confer oxidising potential. However, the oxygen balance calculations estimated that the chemical was not potentially oxidising.

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties that have not been assessed by the US EPA, refer to Appendix A.

The notified chemical contains groups indicative of explosive potential; therefore, a study on the explosive properties of the chemical was conducted to the EC Council Regulation No 440/2008 A.14 Explosive Properties. The results of the study showed that the chemical was not explosive under the conditions of the tests.

Reactivity

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

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured or reformulated in Australia. The notified chemical will be imported into Australia as a component of ink formulations at a concentration up to 7% for inkjet printing systems to be used by commercial printing facilities and the public. The ink containing the notified chemical will not be repackaged and will be contained within purposely designed 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

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of inkjet printer ink in sealed cartridges in size ranging from 2.5 to 2,600 mL capacity. The ink cartridges containing the notified chemical at ≤ 7% concentration will be transported and distributed within Australia by road.

USE
The notified chemical will be used as a component of inkjet printing ink at a concentration ≤ 7%. The ink containing the notified chemical will be sealed in purposely designed ink cartridges which will be distributed Australia-wide for commercial and public use.

OPERATION DESCRIPTION
No manufacture, reformation or repackaging processes will occur for the notified chemical in Australia.

Sealed ink cartridges containing the notified chemical will be handled by service technicians, office workers or members of the public, who will use the inkjet printers and replace spent cartridges as necessary. The printers will be used for a variety of printing work.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Importation / Waterside	< 8	10 – 50
Storage and Transport	< 8	10 – 50
Office worker	< 0.5	2
Service Technicians	1	170

EXPOSURE DETAILS
During transport and storage, workers are unlikely to be exposed to the notified chemical (unless the packaging is accidentally breached).

Printer technicians and office workers may be exposed to the ink containing the notified chemical (at ≤ 7% concentration) during normal operations including removal of empty ink cartridges to replace with new ones, printer maintenance/cleaning, and the handling of wet printed substrates. Dermal exposure is expected to be the main route, although incidental ocular exposure is possible. However, given the design of the ink cartridges, exposure to the notified chemical is expected to be limited if workers follow the safety instructions provided with the ink cartridges.

Occasional dermal exposure during printing may also occur if the wet printed substrates are handled inappropriately. Once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable. Inhalation exposure to the notified chemical is not expected given the low vapour pressure of the chemical and the low likelihood of aerosols being released from the cartridges and printers.

6.1.2. Public Exposure
The public may use inkjet printer cartridges containing the notified chemical (at ≤ 7% concentration) for printing purposes at home. Exposure of these users to the notified chemical is expected to be of a similar or lesser extent compared to the exposure experienced by office workers who use the commercial ink cartridges.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies covering irritation and genotoxicity endpoints, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation (*in vitro* reconstructed human *Epidermis* test)	Non-irritating
Rabbit, skin irritation	Non-irritating
Eye irritation (*in vitro* isolated chicken eyes test)	Irritating
Rabbit, eye irritation	Slightly to moderately irritating

Endpoint	*Result and Assessment Conclusion*
Mouse, skin sensitisation – Local lymph node assay	No evidence of sensitisation
Mutagenicity – bacterial reverse mutation (2 studies)	Non mutagenic
Genotoxicity – *in vitro* chromosome aberration test (2 studies)	Equivocal (1 positive / 1 negative)
Genotoxicity – *in vitro* micronucleus test	Non genotoxic
Genotoxicity – *in vivo* mouse micronucleus test	Non genotoxic

Toxicokinetics, metabolism and distribution
Many azo compounds are unlikely to be absorbed through the skin because of their size and polarity (Øllgaard, 1998). Given the high molecular weight (> 1,000 Da), high water solubility (186 g/L at 20 °C) and low partition coefficient (log Pow < -4.5) of the notified chemical, dermal absorption is expected to be limited. However, bacterial skin microflora have been reported to be able to break down azo compounds into smaller species, which may be more readily absorbed through azo reduction (SCCNFP, 2002).

Absorption through GI tract is also expected to be limited, based on the above physical/chemical properties. However, azo compound reduction in the small intestine with possible absorption of the reduction products through the GI tract cannot be ruled out.

Acute toxicity
The notified chemical is of low acute oral toxicity based on studies conducted in rats.

Irritation
The notified chemical was non-irritating to the skin in a study in rabbits. It showed eye irritation potential in both an *in vitro* and an *in vivo* study.

The *in vitro* isolated chicken eye test indicated that the notified chemical is not corrosive or a severe eye irritant but has the potential to cause eye irritation. In the *in vivo* eye irritation study conducted in rabbits, conjunctival irritation was observed that was fully resolved in all animals within 7-day observation. Due to intensive staining during the study, effects on the cornea, iris and conjunctival redness could not be accurately examined at the early observation times. Based on conservative assumptions, the study authors classified the chemical as eye irritation/reversible effects on the eye (Category 2B). This class of eye irritation is not adopted under the GHS in Australia. Using the precautionary scores assumed by the study authors, the chemical should be classified as R36 - Irritating to eyes, according to *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Sensitisation
The notified chemical was not found to be a sensitiser when tested at up to 25% concentration in a local lymph node assay (LLNA: BrdU-ELISA). A test concentration of 25% for the notified chemical (the highest dose tested) resulted in a stimulation index (SI) of 1.0 ± 0.1 (mean ± SD), compared with that of the vehicle control.

Repeated dose toxicity
No repeated dose toxicity data was submitted for the notified chemical.

Mutagenicity/Genotoxicity
The notified chemical showed negative results in two bacterial reverse mutation studies using both the standard and the Prival-Mitchell (Prival MJ and Mitchell VD, 1982) modified method.

Based on a study summary provided, the notified chemical gave negative results with and without metabolic activation in an *in vitro* micronucleus study. Two *in vitro* chromosomal aberration studies on the notified chemical in CHL cell lines were submitted. One study, using short-term and 24 h exposures, indicated that the notified chemical did not induce chromosome aberrations in either the absence or the presence of metabolic activation under the conditions of this test. In the other study, when CHL cells were exposed to the notified chemical in the absence of metabolic activation, a dose-related increase of structural chromosome aberrations was observed at dose levels ≥ 480 µg/mL at the 48 h exposure period. A review of the results of this study submitted by the notifier (Canon, 2015a) considered that the structural aberration might have been caused by the osmotic pressure or cytotoxicity of the relatively high concentrations of the notified chemical.

The notified chemical was also studied in an *in vivo* mouse micronucleus assay through the oral route at the dose levels up to 2,000 mg/kg bw/day and the results did not indicate any genotoxicity concern for the notified chemical under the conditions of the test. However, as the notified chemical did not render signs of toxicity at

the highest dose tested, it was not possible to determine whether the test substance had reached the bone marrow of the test animals.

Overall on the basis of the available information, while the notified chemical is not expected to be clastogenic *in vivo*, this cannot be completely ruled out given the positive chromosome aberration test result on the notified chemical.

Reproductive/Developmental Toxicity
No reproductive/developmental toxicity data were submitted for the notified chemical.

Carcinogenicity
The notified chemical is not expected to be reductively cleaved to release any of the aromatic amines with carcinogenic potential listed in EU SCCNFP/0495/01 (SCCNFP, 2002).

Health hazard classification
Based on the available information, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase:

R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information the notified chemical is expected to be a mild eye irritant. The notified chemical is not expected to be clastogenic *in vivo* based on the weight of evidence; however, the risk cannot be fully ruled out due to a positive *in vitro* chromosome aberration test. The notifier indicated in the submission that the overseas manufacturing process for the notified chemical has been improved by additional purification to reduce potential hazard related to impurities.

Dermal or possibly incidental ocular exposure to workers may occur during operations including replacing spent ink cartridges and printer maintenance/cleaning. Dermal exposure is also possible when handling printed substrates before the ink dries. However, the exposure is expected to be infrequent or only incidental in nature, given the containment of the notified chemical within purposely designed ink cartridges at a relatively low concentration (up to 7%). Once the ink dries, the notified chemical will be bound to the matrix of the substrates and is not expected to be bioavailable.

Therefore, although the potential risk of the notified chemical following prolonged or repeated exposure cannot be ruled out based on the available information, the risk is not expected to be of concern in the proposed use manner. The exposure and risk for workers with more frequent contact, such as printer technicians, would be further controlled through the use of personal protective equipment (PPE).

Overall, based on the limited expected exposure and dermal absorption potential, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health
The types of public exposure to the notified chemical during the use of inkjet printers is expected to be similar to that experienced by workers, but the exposure is expected to be much less frequent. The public may also come into contact with printed substrates containing the notified chemical. However, once dried the notified chemical is bound into the substrates and will not be bioavailable. Therefore, based on very low exposure potential, the risk of the notified chemical to the public 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 sealed ready-to-use ink cartridges. The notified chemical will not be manufactured, reformulated or repackaged in Australia; therefore, release of the notified chemical from these activities is not expected.

RELEASE OF CHEMICAL FROM USE

The ready-to-use ink cartridges are designed to prevent leakage and will not be unsealed during transport, installation, use or replacement. Therefore, release of the printer ink containing the notified chemical to the environment is not expected under normal conditions. During use, the majority of the notified chemical will be cured within an inert ink matrix and bound to paper substrates, and is not expected to be mobile. In the event of accidental spills or leaks, the printer ink containing the notified chemical will be contained and collected with absorbents, and is expected to be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in printer ink for printing onto paper substrates. The majority of the notified chemical is expected to share the fate of the printed articles to which it is bound. It is assumed that 50% of the printed paper will be disposed of to landfill, and the rest will undergo paper recycling processes. Empty ink cartridges containing residues of the notified chemical are expected to be recycled or disposed of to landfill. The ink remaining in the ink cartridges during the recycling process is not expected to be reused but disposed of to landfill. Hence, the majority of the notified chemical is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments that results in ink detachment from the fibres. Waste water containing the notified chemical will be released to sewer.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable (0% degradation over 28 days). Based on its high water solubility and low partition coefficient (log Kow < -4.5), the notified chemical is not expected to bioaccumulate. The majority of the notified chemical is expected to enter the environment from disposal of printed paper products to which the printer ink containing the notified chemical is bound. Approximately 50% of the notified chemical is expected to be disposed of to landfill as part of printed waste paper. Notified chemical that is not cured and bound to paper in landfill may leach due to its high water solubility and low adsorption coefficient (log K_{OC} < 1.25), where it may enter surface waters.

The remaining 50% of the notified chemical has the potential to be released to sewer after the de-inking of printed paper during recycling processes. The notified chemical is not expected to be removed during sewage treatment plant (STP) processes due to its high water solubility and low adsorption coefficient. Therefore, the notified chemical from paper recycling may be released from STPs to surface waters. Notified chemical released to surface waters from STPs and landfill leachate is expected to disperse and eventually degrade. In landfill and in surface waters, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 50% of the paper products containing the notified chemical undergoing recycling, and the notified chemical to be released into sewers with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

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)	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	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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/m^3). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 2.835 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the 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 are summarised in the table below. Details of the daphnia and algal studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 18 mg/L	Harmful to algae

Based on the above acute ecotoxicological endpoints, the notified chemical is expected to be harmful to algae. Therefore, the notified chemical is formally classified as "Acute Category 3; Harmful to aquatic life" under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009). Although the notified chemical is not readily biodegradable, based on its acute toxicity and low bioaccumulation potential, the notified chemical is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 1000 was used, given that acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae, 72 h)	18	mg/L
Assessment Factor	1,000	
PNEC:	18	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.43	18	0.024
Q - Ocean	0.04	18	0.002

The Risk Quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Whilst the notified chemical is not readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in printing ink, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point > 400 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Capillary method was used (digital melting point apparatus). Melting of the test substance was not observed during the heating up to 400 °C. At approximately 385°C, a small proportion of the test material sublimated.
Test Facility	CiToxLAB (2014a)

Density 1,716 kg/m^3 at 20 °C

Method	EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	Chilworth Technology (2014a)

Vapour Pressure 0.002 kPa at 20 °C

Method	EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Static method was used with a U-tube manometer. The result was the mean of runs 2 and 3. The first run was discarded as curving was seen in the plot.
Test Facility	Chilworth Technology (2014b)

Surface Tension 72.7 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions. EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	The surface tension was observed to be higher than 60 mN/m, therefore, test item is not classified as surface active substance.
Test Facility	CiToxLAB (2014b)

Adsorption/Desorption – screening test $\log K_{OC} < 1.25$

Method	OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks	HPLC method
Test Facility	CiToxLAB (2014c)

Dissociation Constant Not dissociable in water

Method	OECD TG 112 Dissociation Constants in Water.
Remarks	The test item contains dissociable group, however the dissociation of these groups is very weak.
Test Facility	CiToxLAB (2014d)

Particle Size MMAD = 89.65 µm with 7.37% < 10 µm

Method	Chilworth Technology Ltd protocol CTL SOP No. 417 using ISO 13320:2009 and taking into consideration of OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Manual sieve analysis indicated that 12.2% by weight of the test substance had particles size > 2.000 µm. Subsequent laser diffraction analysis on the test substance with particle size ≤ 2,000 µm (87.8% by weight) produced the following results:

Results	*Average (µm)*
Volume weighted mean	99.148
Median (d.50)	68.440
Mode	121.128

Results	*Average (µm)*
MMAD (Mass Median Aerodynamic Diameter)	89.65

Volume (%)	*Range (µm)*
10	< 12.112
50	< 68.440
90	< 235.090

Remarks Wet small volume dispersion system using silicone oil as dispersant was utilised. By volume of the sample, 7.37% was seen to be < 10 µm.
Test Facility Chilworth Technology (2014c)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks Two parallel independent test runs were conducted and showed negative results. As there were negative results in the preliminary test, a main test was not performed.
Test Facility CiToxLAB (2014e)

Autoignition Temperature 271.4 ± 7.8 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks Self-ignition was observed at temperatures between 268.3 and 274.6 °C in 3 test runs.
Test Facility CiToxLAB (2014f)

Explosive Properties Non-explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks The notified chemical was tested using following methods:

- BAM friction test
- BAM fall hammer test
- Koenen steel tube test

All results were negative under the conditions of the tests.
Test Facility Harlan (2015)

Oxidizing Properties Predicted negative

Method Structural group and oxygen balance evaluations were performed on the notified chemical.
Remarks One group of the notified chemical was predicted to confer oxidising potential. However, the oxygen balance calculations estimated that the chemical was not potentially oxidising.
Test Facility CSR (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – eye (*in vitro* isolated chicken eye test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 438 Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants
Vehicle	None
Remarks - Method	The purity of the test substance was reported as 95.2%. The test substance was directly administered to the isolated chicken eyes. The control eyes and test eyes were evaluated pre-treatment and at approximately 30, 75, 120, 180 and 240 minutes after the post-treatment rinse. Corneal thickness and corneal opacity were measured at all time points. Fluorescein retention was measured on two occasions, at base line (t = 0) and approximately 30 minutes after the post-treatment rinse. Positive control: imidazole Negative control: saline (0.9% w/w sodium chloride)

RESULTS

Test Substance

Observation	*Value*	*ICE Class*
Mean maximum corneal swelling at up to 75 min	1%	I
Mean maximum corneal swelling at up to 240 min	1%	I
Mean maximum corneal opacity	0.67	II
Mean fluorescein retention	1.00	II
Overall ICE Class	1 × I, 2 × II	

Positive Control

Observation	*Value*	*ICE Class*
Mean maximum corneal swelling at up to 75 min	1%	I
Mean maximum corneal swelling at up to 240 min	6%	II
Mean maximum corneal opacity	3.83	IV
Mean fluorescein retention	2.67	IV
Overall ICE Class	1 × II, 2 × IV	

Negative Control

Observation	*Value*	*ICE Class*
Mean maximum corneal swelling at up to 75 min	0%	I
Mean maximum corneal swelling at up to 240 min	0%	I
Mean maximum corneal opacity	0.00	I
Mean fluorescein retention	0.00	I
Overall ICE Class	3 × I	

Remarks - Results	The test substance and the positive control (imidazole) were stuck on the surface of the cornea. Gentle rinsing with 20 mL saline was performed at each observation time point. The surface of the cornea was not cleared 240 minutes after the post-treatment rinse.
CONCLUSION	The notified chemical was not corrosive or a severe eye irritant under the conditions of the test. The notified chemical also was not considered as a non-irritant and an *in vivo* study was required for classification.
TEST FACILITY	CiToxLAB (2014g)

B.2. Irritation – eye

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Observation Period	72 hours for two animals and 1 week for one animal
Remarks - Method	The purity of the test substance was reported as 95.2%. The test substance was directly administered.

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[#]	1.33	1.67	1.33	3	< 72 h	0
Conjunctiva: chemosis	0.00	0.00	0.33	1	< 48 h	0
Conjunctiva: discharge	0.00	1.00	0.67	1	< 7 d	0
Corneal opacity[^]	< 2.00	0.00	< 2.00	< 2	< 48 h	0
Iridial inflammation[&]	0.00	0.00	0.00	0	-	0

***** Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal
[#] Assumed a maximum of 3 at 24 hours when the scoring was impossible due to staining
[^] Assumed < 2 when the scoring was impossible due to staining
[&] Assumed no effects when the scoring was impossible due to staining

Remarks - Results	The test substance has staining properties. Based on the observations on the test animals, there was no permanent staining, but due to the intense colour of the test substance, it was impossible to score redness, opacity or iris effects at the early time points. The colour cleared by 48 or 72 hours and there were no observed effects on corneal opacity and iridial inflammation at these time points. The study authors assumed that there were no iris effects and no effects exceeding an opacity score of 2 at any time of the study. Where redness scoring was not possible, the study authors estimated that the score was a maximum of 3 at 24 hours after exposure. When applied to rabbit eye mucosa, the test substance caused significant colouration, preventing full scoring of all endpoints at the early time points. The study authors considered that it was evident that there no significant or persistent conjunctival or corneal irritant effects during the early time points. The observed effects were fully reversible within 7 days.
CONCLUSION	The notified chemical is slightly to moderately irritating to the eye.
TEST FACILITY	CiToxLAB (2014h)

B.3. Genotoxicity – bacterial reverse mutation test (1)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Pre incubation procedure – Prival and Mitchell modification
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Hamster liver homogenate metabolising system (S9 in modified co-factors)
Concentration Range in Main Test	a) With metabolic activation: 50 – 5,000 µg/plate b) Without metabolic activation: 50 – 5,000 µg/plate
Vehicle	Water

Remarks - Method	The purity of the test substance was reported as 92.2%. The test method was designed to assess the mutagenic activity of azo compounds derived from mutagenic or potentially mutagenic aromatic amines. Modifications to the standard method include the use of Flavin Mononucleotide (FMN) rather than riboflavin to reduce the azo compounds to free amines, un-induced hamster liver S9 rather than rat liver S9 for metabolic activation and a 30 minute pre-incubation step before addition of top agar.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	-	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative
Present				
Test 1	> 5,000	-	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative

Remarks - Results	Intense test substance induced coloration was observed at the dose levels ≥ 1,500 µg/plate. In the preliminary test, small but statistically significant increases in TA100 revertant colony frequency were observed in the presence of metabolic activation at 15 and 1,500 µg/plate. These increases were not considered to be of biological relevance because there was no evidence of a dose-response relationship or reproducibility in the second test.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2014a)

B.4. Genotoxicity – bacterial reverse mutation test (2)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure
Species/Strain	<u>*Used for standard Ames test*</u> *S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA <u>*Used for modified azo compound test*</u> *S. typhimurium*: TA98, TA100
Metabolic Activation System	<u>*Standard test*</u> S9 mix (no further details provided) <u>*Modified azo compound test*</u> Hamster liver homogenate metabolising system (containing no enzyme inducers)
Concentration Range in Main Test	a) With metabolic activation: 313 – 5,000 µg/plate b) Without metabolic activation: 313 – 5,000 µg/plate
Vehicle	
Remarks - Method	Full details of the tests were not provided (summary only). The Prival and Mitchell modification for azo compounds was used to evaluate the test substance for two strains only, and the standard Ames method was used for all strains. Test 1 was also the preliminary test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	-	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative
Present				
Test 1	> 5,000	-	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative

Remarks - Results: No details of study were provided. Tables of the test results were provided. The positive controls performed as expected, confirming the validity of the test system.

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

TEST FACILITY: Canon (2015b)

B.5. Genotoxicity – *in vitro* chromosome aberration test (1)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Commission Regulation 440/2008 B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test

Species/Strain: Chinese hamster
Cell Type/Cell Line: Chinese Hamster Lung (CHL) Cell Line
Metabolic Activation System: S9 mix prepared from phenobarbitone/β-naphthoflavone induced male rat liver
Vehicle: Minimal Essential Medium
Remarks - Method: The purity of the test substance was reported as 93.76% and was adjusted in the test formulations. S9 mix was used at 5% in Test 1 and 2% in Test 2.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 156.25, 312.5, 625*, 1250*, 2500* and 5000*	6 h	24 h
Test 2	0*, 9.76, 19.53, 39.06, 78.13*, 156.25*, 312.5*, 625* and 1250	24 h	24 h
Present			
Test 1 (5% S9)	0*, 156.25, 312.5, 625*, 1250*, 2500* and 5000*	6 h	24 h
Test 2 (2% S9)	0*, 156.25, 312.5, 625*, 1250*, 2500* and 5000*	6 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 5,000	> 5,000	Negative
Test 2	≥ 1,250	≥ 1,250*	Negative
Present			
Test 1	≥ 5,000	> 5,000	Negative
Test 2	≥ 5,000	> 5,000	Negative

* Precipitation of test substance was observed on the slides of the 24-hour exposure group at and above this dose level.

Remarks - Results	The culture media were coloured purple at all test dose levels at the end of the exposure period. The positive controls performed as expected and confirmed the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to CHL cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Harlan (2014b)

B.6. Genotoxicity – *in vitro* chromosome aberration test (2)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test (Translated report provided)
Species/Strain	Chinese hamster
Cell Type/Cell Line	CHL/IU cells
Metabolic Activation System	S9 fraction from phenobarbital/5,6-benzoflavone induced male rat liver
Vehicle	Water
Remarks - Method	The purity of the test substance was report as 93.3% with 6.7% waster.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 1250, 2500 and 5000	6 h	24 h
Test 2	0, 350, 700, 1400 and 2800	24 h	24 h
Test 3	0, 120, 240, 480 and 960	48 h	48 h
Present			
Test 1	0, 1250, 2500 and 5000	6 h	24 h

All cultures were selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	Negative
Test 2	≥ 1,250	≥ 1,400	> 5,000	Negative
Test 3	≥ 625	≥ 480	> 5,000	Positive
Present				
Test 1	> 5,000	> 5,000	> 5,000	Negative

Remarks - Results	In the 48-hour exposure test, the frequency of cells carrying structural chromosome aberrations was 8.5% at 480 μg/mL and 19.5% at 960 μg/mL. Dose-response of frequency increase was observed.
CONCLUSION	The notified chemical was clastogenic to CHL/IU treated *in vitro* under the conditions of the test.
TEST FACILITY	BML (2014)

B.7. Genotoxicity – *in vitro* micronucleus test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 487 *In vitro* Mammalian Cell Micronucleus Test
Species/Strain	Human lymphoblastoid
Cell Type/Cell Line	TK6 cells
Metabolic Activation System	S9 mix
Vehicle	10% HS-RPMI (supplemented with sodium pyruvate and 10% horse

serum)

Remarks - Method: No details of the study were provided (summary only).

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39.1*, 78.1*, 156*, 313*, 625*, 1250*, 2500* and 5000*	3 h	24 h
Test 2	0*, 36.4*, 72.9*, 146, 292 and 583	24 h	24 h
Test 3	0*, 9.77*, 19.5*, 39.1*, 78.1*, 156*, 313, 625, 1250, 2500 and 5000	24 h	48 h
Present			
Test 1	0*, 39.1*, 78.1*, 156*, 313*, 625*, 1250*, 2500* and 5000*	3 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5,000	> 5,000	Negative
Test 2	≥ 146	> 5,000	Negative
Test 3	≥ 313	> 5,000	Negative
Present			
Test 1	> 5,000	> 5,000	Negative

Remarks - Results: No details of study were provided. Tables of the test results were provided.

CONCLUSION: The notified chemical was not clastogenic to human lympholastoid TK6 cells treated *in vitro* under the conditions of the test.

TEST FACILITY: Canon (2014)

B.8. Genotoxicity – *in vivo* micronucleus assay

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test

Species/Strain: Mouse/Crlj:CD1(ICR), SPF

Route of Administration: Oral – gavage

Vehicle: Water

Remarks - Method: The purity of the test substance was reported as 93.3% with 6.7% water. Mitomycin C was administered intraperitoneally at 2 mg/kg bw/day once as positive control.

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day × doses*	*Sacrifice Time hours*
I (vehicle control)	6 M*	0 × 2	24
II (low dose)	6 M*	500 × 2	24
III (mid dose)	6 M*	100 × 2	24
IV (high dose)	6 M*	2,000 × 2	24
V (positive control)	6 M*	2 × 2 (intraperitoneally)	24

* 6 male mice were administered but only 5 of them were tested for micronucleus.

RESULTS

Doses Producing Toxicity: > 2,000 mg/kg bw/day

Genotoxic Effects: The frequencies of micronucleated polychromatic erythrocytes were not increased by administering the test substance.

Remarks - Results: No clinical signs of toxicity were noted up to the highest dose (2,000 mg/kg bw/day) tested. It was not possible to determine whether the test substance had reached the bone marrow of the test animals.

CONCLUSION	The notified chemical was not clastogenic under the conditions of this *in vivo* micronucleus test.
TEST FACILITY	CERI (2014a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202, *Daphnia sp.* Acute Immobilisation Test – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	39 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Geometric mean*		*24 h*	*48 h*
Control	Control	20	0	0
100	98.6	20	0	0

LC50	98.6 mg/L at 48 hours
NOEC	Not determined
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The 48 h EC50 value was reported based on nominal concentrations.
CONCLUSION	The notified chemical is not considered to be harmful to the aquatic invertebrates
TEST FACILITY	CERI (2014b)

C.1.2. Algal growth inhibition test

A 72-hour growth inhibition test in green algae (*Pseudokirchneriella subcapitata*) was conducted with the notified chemical (purity: 95.2% w/w) under static conditions. This study was reported to follow OECD test guideline No. 203 and OECD Guidance Document No. 23. Additionally, it was conducted according to "Algal Growth Inhibition Test" stipulated in the "Testing Methods for New Chemical Substances" (March 31, 2011, No. 0331-7, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; March 29, 2011, No. 5, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry; No. 110331009, Environmental Policy Bureau, Ministry of the Environment, Japan). The water solubility of the test substance was reported to be ≥ 150 g/L. A preliminary study was conducted at the 100 mg/L with normal and reduced test system volume to determine the effect of shading on the test system; the authors concluded that shading was not a factor in the outcome of the study. In the main study, three replicates of *P. subcapitata* (0.75×10^4 cells/mL) were exposed to the test substance at nominal concentrations of 0.10, 0.32, 1.0, 3.2, 10, 32 or 100 mg/L. The corresponding geometric mean measured concentrations were 0.10, 0.35, 1.1, 3.5, 11, 35 or 110 mg/L, respectively, as determined via HPLC with UV-VIS detection (LOD = 0.0250 mg/L). Six replicates of *P. subcapitata* were exposed to an OECD medium control. The algae were illuminated at a light intensity ranging from 94 – 98 µE·m-2·s-1 with constant shaking. The required test sample and medium were stirred and dissolved to prepare a stock solution. The required volume of stock solution was mixed and stirred with medium to prepare the test solution in the preparation container, and divided into each test vessel. At the start of exposure, test solutions of all exposure levels were dose-dependently navy-blue and clear. At the end of exposure, the appearances of test solutions in 0.32 – 100 mg/L levels were dose-dependently navy-blue, and those of 0.10 – 1.0 mg/L were green due to the algae growth. The 3.2 mg/L test solution was not green due to algae growth; however, the cells were visually confirmed. Over the course of testing, temperature ranged from 22.1 – 22.5 °C and pH ranged from 7.8 – 7.9. The submitter provided results as nominal concentrations;

considering that mean measured concentrations better represent exposure, effect levels were recalculated as mean measured. The mean cell density of control cultures increased by a factor 133 after 72 hours. The 72-hour algae EC50 based on yield calculations (as provided in OECD guidelines) was 7.3 mg/L. Based on mean measured concentrations, the 72-hour NOEC and LOEC values were 1.1 and 3.5 mg/L, respectively. The 72-hour ChV was calculated to be 2.0 mg/L. The study was considered acceptable.

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