

File No: EX/199(LTD/1598)

April 2016

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

PUBLIC REPORT

Alcohol Ethoxylate in DNT Ink

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of the Environment.

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**

April 2016

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PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Alcohol Ethoxylate in DNT Ink (LTD/1598). Based on the submission of new information by the extension notifier, some sections of the original assessment report for Marubeni Australia Ltd have been modified. These modifications have been made under the heading "Extension Application" in the respective sections.

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
EX/199 (LTD/1598)	Ricoh Australia Pty Ltd.	Alcohol Ethoxylate in DNT Ink	Yes	≤ 1 tonne per annum	Component in inkjet printing ink

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data on an analogue chemical, the notified chemical should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrase:

R36: Irritating to eyes

and

The classification of the notified chemical using the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations 2009) is presented below.

	<i>Hazard category</i>	<i>Hazard statement</i>
Eye Irritation	Category 2	Irritating to eyes

Human health risk assessment

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

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

Environmental risk assessment

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified chemical:
R36 Irritating to eyes
- Use the following risk phrases for products/mixtures containing the notified chemical:
 - Conc ≥ 20%: Xi; R36

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in ink products:
 - Use of good natural or mechanical ventilation in the vicinity of printers.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in ink products
 - Avoid skin and eye contact

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

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent foil pouches/ 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 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 in inkjet printing ink contained within sealed cartridges or foil pouches, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne per annum, 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

Original notification

The MSDS 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 MSDS remains the responsibility of the applicant.

Extension Application

The extension applicant has provided an MSDS of the product containing the notified chemical which was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Holder of Original Assessment Certificate (LTD/1598)

Marubeni Australia Ltd (ABN 53 000 329 699)
Level 19, 367 Collins Street,
Melbourne VIC 3000

Applicant for an Extension of the Original Assessment Certificate

Ricoh Australia Pty Ltd (ABN 30 000 593 171)
8 Rodborough Road
Frenchs Forest NSW 2086

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, use details, analytical data and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: All physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, EU, Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Original Application

DNT Yellow Ink (contains the notified chemical at < 40%)

Extension Application

Pro Ink PackBlack L4160 (contains the notified chemical at < 25%)

MOLECULAR WEIGHT

< 500 Da

ANALYTICAL DATA

Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-68°C	Measured for analogue.
Boiling Point	229 °C at 101.3 kPa	Calculated (Adapted Stein and Brown Method). Analogue, 230°C (MSDS).
Density	950 kg/m ³ at 20°C	MSDS (analogue)
Vapour Pressure	3.48 x 10 ⁻³ kPa at 25°C	Calculated (Mean of Antoine and Grain Method). Analogue, 4 x 10 ⁻³ kPa at 20 °C (MSDS).
Water Solubility	405 g/L at 25°C	Estimated using WSKOW v1.42 (US EPA 2009) and assuming melting point of <25°C. The analogue is water soluble (MSDS)
Hydrolysis as a Function of pH	Not determined	No hydrolysable groups present
Partition Coefficient (n-octanol/water)	log Pow = 0.22	Estimated using KOWWIN v1.68 (US EPA 2009)
Adsorption/Desorption	log Koc = 1.00 (MCI method) log Koc = 0.45 (Kow method)	Estimated from MCI and Kow using KOCWIN v2.00 (US EPA, 2009)
Dissociation Constant	Not determined	Contains no dissociable functionality.
Flash Point	106°C at 101.3 kPa	MSDS (analogue)
Flammability	LEL 0.85% UEL 24.6 %	MSDS (analogue)
Autoignition Temperature	228°C	MSDS (analogue)
Explosive Properties	Not determined	Not expected to be explosive based on structure.
Oxidising Properties	Not determined	Not expected to have oxidising properties.

DISCUSSION OF PROPERTIES

Reactivity

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

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

Original application

The notified chemical will be imported as a component (< 40% concentration) in a finished inkjet ink formulation contained in 600 ml inkjet cartridges.

Extension application

The notified chemical will be imported as a component (< 25% concentration) in a finished inkjet ink formulation contained in 220 ml and 660 ml foil pouches which will be inserted into inkjet cartridges.

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

Original Application and Extension Application total import volume

<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 RECIPIENTS

Original application

Marubeni Australia Ltd

Extension application

Ricoh Australia Pty Ltd

TRANSPORTATION AND PACKAGING

Original application

The notified chemical will be imported as a component (<40% concentration) in a finished inkjet ink formulation contained in 600 ml inkjet cartridges. It will be transported by sea to the port and by road from the port to the warehouse facilities.

Extension application

The notified chemical will be imported as a component (<25% concentration) in a finished inkjet ink formulation contained in 220 ml and 660 ml foil pouches. It will be transported by sea to the port and by road from the port to the warehouse facilities.

USE

Original application

The notified chemical will be used as a component in inkjet printing ink at a concentration up to 40%.

Extension application

The notified chemical will be used as a component in inkjet printing ink at a concentration up to 25%. This ink is used in wide-format commercial printers.

OPERATION DESCRIPTION

Original application

The notified chemical will not be manufactured, reformulated or repackaged in Australia.

The imported ink product containing the notified chemical in the sealed 600 ml cartridges will be stored in warehousing facilities for subsequent distribution to commercial printing equipment suppliers.

Distribution workers will not handle the opened packaging. Printer service staff and office workers will open the cardboard packaging and insert the cartridges within the printer according to the manufacturer's instructions. When empty, the spent cartridges will be removed from the printer and disposed of to landfill in domestic waste. Refilling of empty cartridges is not recommended by the manufacturer and the manufacturer does not supply refill kits. Spent cartridges are not recycled.

Extension application

The use in the extension application will be the same as in the original notification with the following exceptions;

- The concentration of the notified chemical in the ink is < 25% and

- The notified chemical will be imported in 220 ml and 660 ml foil pouch instead of 600 ml ink cartridge. These foil pouches (containing the notified chemical in a finished inkjet formulation) will be inserted into the ink cartridges and this will be followed by inserting the ink cartridges into the cartridge port of the printing machine.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport workers	2	50
Warehouse workers	2-6	260
Printer Service Staff	4	260
Office workers	8	260

EXPOSURE DETAILS

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Printer service staff and office workers may be exposed to the ink containing the notified chemical (< 40%) when replacing used ink cartridges (refilling of empty cartridges will not occur), clearing paper jams from the printer and during printer maintenance. Dermal and inhalation are expected to be the most likely routes of exposure. However, given the controlled release design of the cartridges, exposure (dermal or inhalation) to the notified chemical is expected to be limited. In addition, the notified chemical has a relatively low vapour pressure and printing equipment is supplied with a filter to capture any vapours/mists.

Users of the printers may also be exposed to the notified chemical during handling of printed paper. However, the notified chemical is adsorbed to the paper matrix and is not expected to be readily bioavailable except if the paper is handled before the ink has dried. The notifier has stated the drying time is 2-5 seconds.

Extension application

The nature of work done and worker exposure are similar to those described in the original application. The additional step of inserting the foil pouches containing the finished inkjet formulation into the inkjet cartridge is not expected to give rise to additional worker exposure.

6.1.2. Public Exposure

The notified chemical and products containing the notified chemical will not be sold to the public. The public may have dermal exposure to printed substrates containing the notified chemical. However, the notified chemical is adsorbed to the paper matrix and is not expected to be readily bioavailable except if the paper is handled before the ink has dried. The notifier has stated the drying time is 2-5 seconds.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified chemical. Toxicity data on the notified chemical is presented by the US National Library of Medicine and summarised in the following table:

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 4674 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	LD50 3382 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LCLo 6700 ppm/6 hour; low toxicity

In addition, published data/information on a structurally similar analogue of the notified chemical is available and, where relevant, is briefly discussed below (the identity of the analogue chemical and information sources are considered exempt information).

Toxicokinetics

The notified chemical is expected to be readily absorbed across biological membranes, given the low molecular weight (< 500 Da), relatively high water solubility and estimated low partition coefficient (log Pow = 0.22). However, dermal absorption may be limited due to the hydrophilic nature of the notified chemical, which may limit uptake into the lipid rich environment of the stratum corneum.

Acute toxicity

Based on the toxicity data presented by the US National Library of Medicine, the notified chemical is of low acute oral, dermal and inhalation toxicity.

Irritation and Sensitisation

An analogue of the notified chemical is not irritating or sensitising to the skin. However, the analogue is irritating to eyes and is classified as an eye irritant (R36). Hence, given the structural similarity with the analogue chemical, the notified chemical is also expected to be an eye irritant.

Repeated dose toxicity

The notified chemical contains a functional group of concern for repeated dose toxicity. No repeated dose toxicity data were provided for the notified chemical.

Two repeated dose oral toxicity studies have been conducted in rats with an analogue of the notified chemical. The analogue caused effects in the liver, spleen, kidneys and on haematological parameters establishing a NOAEL of < 891 mg/kg bw/day in a 6 week study using only male rats and a NOAEL of < 51-65 mg/kg bw/day in a 90 day study on both sexes. In the 6 week study, it was noted that the systemic effects observed at the LOAEL were limited to minor liver effects. Both studies have been reported to have limitations: the 6-week study was performed with males only, and the 13-week study suffers from a high mortality rate at the highest dose level. Furthermore, the effects observed (decrease in white blood cell count and lymphocytes) in the 13 week study for the low (51-69 mg/kg bw/day) and mid (1270-1630 mg/kg bw/day) dose group in females were not observed at all dose levels in the 90 day study with males only. Given the doubts on the quality of the 13 week study, the NOAEL for the notified chemical has been considered by the authors in the European Union risk assessment for the analogue chemical to be 891 mg/kg bw/day, given only minor liver effects were observed at this dose level.

In 13-week repeated dose dermal studies on an analogue, dose levels up to 2000 mg/kg bw day caused no systemic effects in rats. However, some local irritation was observed.

In a 90-day repeated dose inhalation (whole body) study in rats at doses up to 94 mg/m³ for 6 hr/day, no treatment related effects were observed. The NOAEL was therefore established as 94 mg/m³ in this study. However, in a 5-week study in rats, the NOAEL was established as 39 mg/m³ based on liver effects observed at the highest dose of 117 mg/m³. The NOAEL for the analogue for repeated dose inhalation toxicity is therefore considered to be 94 mg/m³.

Mutagenicity

An analogue of the notified chemical was not mutagenic in a bacterial reverse mutation study, and was not genotoxic in an *in vitro* chromosome aberration study in CHO cells. It was not genotoxic in an *in vivo* mammalian micronucleus test.

Reproduction and developmental toxicity

In a one generation gavage reproduction study in rats the NOAEL for fertility was > 1000 mg/kg bw/day. For developmental effects the NOAEL was 500 mg/kg bw/day based on reduced body weight gain at the higher dose. There were no teratogenic effects following oral exposure. In a dermal one-generation study at doses up to 2000 mg/kg bw/day in rats no effects were observed as was the case in a dermal study in rabbits at doses up to 1000 mg/kg bw/day.

Health hazard classification

Based on the data on an analogue chemical, the notified chemical should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (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 reported data on the notified chemical and an analogue, the notified chemical is an eye irritant and there is evidence for systemic toxicity via the oral and inhalation routes. There is also potential for irritation effects from repeated dermal exposure.

The notified chemical will not be manufactured, reformulated or repackaged in Australia. The notified chemical will be contained within a sealed ink cartridge and therefore, exposure to the oral and inhalation routes is not anticipated.

The level of repeat dermal exposure for service technicians and office workers handling sealed cartridges of printing inks containing the notified chemical at < 40% is not expected to be significant. Service personnel are expected to wear disposable gloves when removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs, to further minimise exposure. Hence, provided that adequate PPE is worn (i.e., disposable gloves) the risk of skin irritation to service technicians from repeated exposure is not expected.

The risk of eye irritation is not expected under normal circumstances, unless the ink residues containing the notified chemical are deposited on the fingers and then rubbed into the eyes, in the absence of adequate PPE.

Overall, provided that adequate PPE is worn, the risk to workers associated with handling of the notified chemical contained within sealed cartridges is not considered to be unreasonable.

6.3.2. Public Health

The public will only come into contact with the dried ink on printed substrate. The notified chemical will be trapped within the dried ink matrix or paper matrix and will not be available for exposure. Therefore, the risk of the notified chemical to the health of the public under the assessed use 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 to Australia as a component of printer ink in ready-to-use cartridges. No manufacturing and reformulation of the notified chemical will take place in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and are not expected to be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. If leakage or spillage does occur, the ink is expected to be contained with absorbent material and disposed of to landfill in accordance with federal, state and local regulations. Cartridges are contained within the printer until the contents are consumed and then they are removed and disposed of to landfill. Around 1% of the ink containing the notified chemical will remain in "empty" cartridges.

Most of the notified chemical will be bound to printed paper, which is expected to be disposed of to landfill, or subjected to recycling processes.

Extension application

The notified chemical will be imported as a component in finished inkjet printing ink formulation in foil pouches. The additional step of inserting the foil pouches containing the finished inkjet formulation into the inkjet cartridge is not expected to give rise to additional exposure scenarios affecting the risk assessment. Once the content of the foil pouch is depleted, it is removed and replaced by a new foil pouch. The cartridge is then closed and fitted in the printer. The foil pouches are designed to prevent leakage during transport, installation and removal.

Around 1% of the ink containing the notified chemical will remain in “empty” foil pouches. The empty foil pouches will be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Around 1% of the ink containing the notified chemical will remain in “empty” cartridges. The empty cartridges will be disposed of to landfill.

Printed paper containing the notified chemical will be disposed of to landfill or recycled. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is re-pulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The aqueous wastes are expected to be released to sewers. Approximately 50% of the printed paper will enter paper recycling and a minor proportion of the ink may be recovered during recycling in the sludge. Any quantity of notified chemical recovered with sludge during the recycling process is expected to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. Notified chemical applied to paper as a component of ink will be bound within the print matrix and is not expected to be readily bioavailable. When disposed of to landfill, the notified chemical will slowly degrade by biotic and abiotic processes to form water and oxides of carbon. Notified chemical that is not physically incorporated into ink matrix may leach due to the expected low soil adsorption coefficient (K_{oc}) and high water solubility.

Approximately half of the paper to which the ink containing the notified chemical is applied will be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents that enhance detachment of ink from the fibres. The notified chemical is expected to partition to the supernatant water, and these aqueous wastes are expected to be released to sewer. The notified chemical is likely to be largely removed during sewage treatment as it is expected to be biodegradable. Although, due to its high water solubility, it may remain in the water column and be released to receiving waters. In surface water, the notified chemical is expected to disperse and degrade. Further, the notified chemical is not likely to bioaccumulate based on its high water solubility and predicted low bioconcentration factor ($\log BCF = 0.5$, regression-based estimate using BCFBAF v3.01, US EPA 2009).

7.1.3. Predicted Environmental Concentration (PEC)

Predicted Environmental Concentration (PEC) for both river and ocean compartment have been calculated assuming that all of the imported notified chemical will be applied to paper and half of this amount will be recycled. In this worst-case scenario it is assumed that the notified chemical will be released in recycling effluent from the de-inking process, that there would be no removal of the notified chemical by sewage treatment plants (STPs) and that release of the notified chemical will occur over 260 days per annum corresponding to release only on working days.

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)	22.61	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

The notified chemical is likely to be significantly removed from STP influent due to partitioning to sludge. However, for this worst-case scenario it is assumed the notified chemical is released to the environment only in

STP effluent. 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 0.42 µg/L may potentially result in a soil concentration of approximately 2.84 µg/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

No measured ecotoxicity data were submitted. As there is the potential for aquatic exposure from the release of the notified chemical from recycling processes, modelled estimates for ecotoxicological endpoints for the notified chemical have been calculated and are tabulated below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Acute Toxicity		
Fish	96 h LC50 > 100 mg/L ¹	Not harmful to fish
Daphnia	48 h EC50 > 100 mg/L ¹	Not harmful to aquatic invertebrates
Algal	96 h EC50 > 100 mg/L ¹	Not harmful to algae
Chronic Toxicity		
Fish	30 d ChV > 100 mg/L ¹	Not harmful to fish
Daphnia	ChV > 100 mg/L ¹	Not harmful to aquatic invertebrates
Algal	ChV > 100 mg/L ¹	Not harmful to algae

¹ Modelled estimates (ECOSAR v1.00, class – neutral organics, US EPA, 2011).

This predicted toxicity is supported by the acute toxicity data of a close analogue of the notified chemical with 96 h LC50s of 2000 and 1300 mg/L for Silverside minnow and bluegill, respectively.

The ecotoxicity endpoints of the notified chemical were generated using validated quantitative structure activity relationships (QSARs) and the notified chemical is considered to be within the domain of the model and selected class. Therefore, the calculated QSAR results are considered reliable for the purposes of classification under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). The notified chemical is not harmful to fish, aquatic invertebrates and algae, and is therefore not classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the estimated acute and chronic toxicity of the notified chemical for fish, aquatic invertebrates and algae using an assessment factor of 10.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish, Daphnia, Algae	>100	mg/L
Assessment Factor	10	
PNEC:	>10,000	µg/L

7.3. Environmental Risk Assessment

The Risk Quotients, Q, for riverine and marine environments have been calculated for the notified chemical and are tabulated below. Note that the following risk assessment is conservative, as it assumes that all the notified chemical is released into aquatic ecosystems when paper is recycled, with no removal during sewage treatment.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.43	>10,000	<0.001
Q - Ocean	0.04	>10,000	<0.001

The Risk Quotient (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be <<1 for both river and ocean compartment. This indicates that the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern.

8. RISK ASSESSMENT FOR EXTENSION APPLICATION

The notified chemical will be imported as a component in finished inkjet printing ink formulation in foil pouches (at a concentration up to 25%), and will not be reformulated in Australia. The use scenario is covered under the original notification (LTD/1598). The additional step of inserting the foil pouches containing the finished inkjet formulation into the inkjet cartridge is not expected to give rise to additional exposure scenarios. The total import volume (Extension applicant and original applicant) will not exceed 1 tonne/year. The proposed fate of the notified chemical will not change under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

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