File No: STD/1561

October 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

iPDG

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
STD/1561	Kao Australia Pty Ltd	iPDG	ND*	≤ 10 tonnes per annum	Component of inkjet printing 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 *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Provided that the recommended controls are being adhered to, 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

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the ink products:
  - Local exhaust ventilation and adequate general ventilation (as specified in Safe Work Australia Guidance Control guidance sheet *P39 Wide-format inkjet printing with solvent-borne inks*)

- 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 products:
  - Avoid contact with skin and eyes
  - Avoid breathing in vapours
  - Compliance with Safe Work Australia Guidance Control guidance sheet *P39 Wide-format inkjet printing with solvent-borne inks*

- 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 products:
  - Protective clothing
  - Disposable gloves if dermal exposure to the ink may occur
  - Respiratory protection if engineering controls are inadequate

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 notified chemical is imported in any form other than as a component of printing ink used by commercial facilities;
  - additional information has become available to the person as to the repeated dose toxicity and/or reproductive/developmental toxicity of the 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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kao Australia Pty Ltd (ABN: 59 054 708 299)
Level 1, 19–23 Prospect Street
BOX HILL VIC 3128

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne 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, import volume and chemical identities of analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: All physico-chemical and toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China, 2013
EU, 2010
Korea, 1997
New Zealand, 2006

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
iPDG

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Freezing Point	< -70 °C	MSDS
Boiling Point	207 °C at 101.3 kPa	MSDS
Density	963 kg/m^3 at 20 °C	MSDS
Vapour Pressure	0.066 kPa at 20 °C	MSDS
Water Solubility	Soluble	MSDS
Hydrolysis as a Function of pH	Not determined	Not expected to be hydrolysed in the environmental pH range (4–9)
Partition Coefficient (n-octanol/water)	log Pow = -0.27 at 25 °C	Calculated (KOWWIN v1.68)
Adsorption/Desorption	log K_{oc} = 0.025 at 25 °C	Calculated (KOCWIN v2.00)

Property	Value	Data Source/Justification
Dissociation Constant	Not determined	Does not contain dissociable functional groups
Flash Point	98 °C	MSDS
Flammability	Upper: 20% Lower: 1.7%	MSDS
Autoignition Temperature	Not determined	MSDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

DISCUSSION OF PROPERTIES
No details of tests on physical and chemical properties were provided. The MSDS for the notified chemical indicates that vapour-air mixtures are explosive above the flash point.

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. It will be imported as a component of finished ink products for inkjet printing at concentrations ≤ 10%. The notified chemical will be present in several ink colours.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 1	5	5	10

PORT OF ENTRY
Sydney, Melbourne, Perth and Brisbane

IDENTITY OF RECIPIENTS
The notifier

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of printing ink products in 20 kg plastic bags inside a cardboard box. The packaged ink products containing the notified chemical at up to 10% concentration will be distributed by road to commercial printing facilities around Australia.

USE
The notified chemical will be used as a component of inkjet printing ink for commercial facilities at concentrations ≤ 10%. The printing substrate will normally be paper.

OPERATION DESCRIPTION
At the commercial printing sites, printer operators will open the ink packages and connect tubes to the ink bags which will remain in the original protective outer cardboard boxes. The printers are expected to be fully automated and required little intervention from the operators. The notifier states that the printers are supplied with local fume extraction to remove any vapours and aerosols formed during the printing. Once the ink bag is empty, it will be removed and replaced with a new one. Operators will also seal the waste ink bags for off-site disposal.

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)*
Storage & transport personnel	0	24
Printer operators	0	200
Service technicians	0.2	50

EXPOSURE DETAILS

Transport and storage
Exposure of workers to the ink formulations containing the notified chemical is not expected to occur except in the unlikely event of an accident where the packaging is breached.

Printer operators
When handling the ink products containing the notified chemical, printer operators may be exposed mainly via the dermal route to the notified chemical at concentrations up to 10% during opening the containers, inserting tubing or removing waste containers. The notifier states that workers will wear protective gloves during the handling.

While printers are running, printer operators monitor the operation and keep the substrate feeders stocked and attend to substrate jams. After the ink is applied to the substrate, the notified chemical will evaporate from the matrix of the ink. The notifier states that the printers are supplied with local fume extraction to remove any vapours and aerosols formed during printing. Thus, significant inhalation exposure to the notified chemical is not expected to occur. After printing onto the substrate, the ink will dry rapidly and significant exposure to the notified chemical is not expected to occur from handling the printed substrate.

Service technicians
Service technicians will be involved in maintaining the printing machines. Any residual ink within printing equipment will be wiped clean using rags and solvents. Used rags and solvents are normally disposed of through licensed waste disposal contractors. Service technicians may come into contact with the inks containing the notified chemical at up to 10% concentration mainly via the dermal route. The notifier states that these workers will wear appropriate personal protective equipment (PPE) during maintenance operations.

6.1.2. Public Exposure
The ink products containing the notified chemical will only be used for commercial purposes and will not be available for use by the public.

The general public may come into contact with the printed substrate. However, the notified chemical is expected to evaporate from the printed substrate at the time of printing and after the ink is dry it would no longer be available for further exposure.

6.2. Human Health Effects Assessment

No toxicity study reports were submitted for the notified chemical. Summary reports of toxicological investigations conducted on analogues of the notified chemical were submitted (analogues A, B and C) and are summarised in the following table. An additional analogue chemical identified by NICNAS, analogue D, was used to evaluate the repeated dose toxicity of the notified chemical. The notified chemical and analogue chemicals are all ethoxylated alcohols substituted with short chain alkyl groups.

Endpoint	*Result and Assessment Conclusion*	*Data Source*
Rat, acute oral toxicity	LD50 = 11,300 mg/kg bw; low toxicity	Notified chemical (RTECS)
Rabbit, acute dermal toxicity	LD50 = 16,000 mg/kg bw; low toxicity	Notified chemical (RTECS)

Endpoint	*Result and Assessment Conclusion*	*Data Source*
Rat, acute inhalation toxicity	LC50 = 6,700 ppm/6 hour; low toxicity	analogue C
Skin irritation	Irritating	analogue D
Eye irritation	Severely irritating	analogue B
Guinea pig, skin sensitisation	No evidence of sensitisation	analogues A, B and D
Rat, repeat dose toxicity	Oral:	
	NOAEL < 891 mg/kg bw/day	analogue A
	NOAEL < 30 mg/kg bw/day	analogue D
	Dermal:	
	NOAEL < 200 mg/kg bw/day (local effects)	analogue A
	NOAEL ≥ 2,000 mg/kg bw/day (systemic effects)	analogue A
	Inhalation:	
	NOAEC = 39 mg/m^3 (6 h/day, 5 d/wk for 5 wks)	analogue A
	NOAEL = 30 ppm (6 h/day, 5 day/wk for 4 wks)	analogue D
Rat, reproductive and developmental toxicity	Oral: NOAEL = 500 mg/kg bw/day for developmental effects NOAEL = 1,000 mg/kg bw/day for parental toxicity and fertility	analogue A
	Dermal: NOAEL = 1,000 mg/kg bw/day for systemic maternal toxicity and developmental effects	analogue A
	Inhalation: NOAEL ≥ 100 ppm for maternal toxicity NOAEL ≥ 300 ppm for developmental toxicity	analogue D
Mutagenicity – bacterial reverse mutation	Non mutagenic	analogues A and D
Genotoxicity – *in vitro*	Non genotoxic	analogues A and D

Toxicokinetics, metabolism and distribution

The notified chemical has a molecular weight < 500 Da and is highly water soluble. Based on its chemical and physical characteristics and information on the analogue chemicals, it is expected that the notified chemical would be readily absorbed through biomembranes via all routes, distributed within the body and metabolised. It has been reported that dermal absorption of ethoxylated alcohol derivatives in both liquid and vapour forms is very high (CICAD, 2002). Based on the studies on analogue D, the metabolism and excretion of the notified chemical is expected to be rapid with a large portion excreted from the body within 1 day, mainly through kidneys. A certain portion of the metabolites may be excreted via the lungs as carbon dioxide. The notified chemical is an ethoxylated alcohol and, therefore, is expected to have faster metabolism rate than bis-glycol ether derivatives (i.e. glymes).

Acute toxicity

No study reports on acute toxicity of the notified chemical were submitted. Based on the information available for both the notified chemical and analogue C, the notified chemical is expected to be of low acute toxicity via oral, dermal or inhalation routes.

Irritation and sensitisation

Based on the information available for analogues B and D, the notified chemical is likely to be irritating to skin and eyes.

Available information on skin sensitisation studies using Guinea pig did not report any evidence of sensitising potential for analogues A, B and D under the conditions tested. The test concentration for analogue D was reported at 1% as the maximum non-irritating concentration suitable for the test. Test concentrations for analogues A and B were unknown.

Repeated dose toxicity

No repeated dose toxicity data were submitted for the notified chemical. Based on the information available for analogues A and D, the toxicity following repeated exposure is likely to be low, but with a significant degree of uncertainty.

Oral
In oral repeated dose studies using rats, analogue A caused effects in liver, spleen, kidneys, and haematological parameters. However, there were inconsistencies in effects between the studies and clear conclusions on the target organ of the analogue after repeated oral administration could not be established. The effects observed in one study were not consistent with the toxicity profile of glycol ethers. Given the uncertainty on the quality of the studies, a NOAEL of < 891 mg/kg bw/day derived from a 6-week study in male rats was proposed for analogue A. It was noted that effects observed in females in a 13-week study at dose levels of 51 and 254 mg should be considered in the weight of evidence.

In a repeated dose oral toxicity study with analogue D using rats, the effects observed included: occult blood and bilirubin in urinalysis, anaemia like changes in haematology, increase of erythroid cells and decrease of myeloid cells in bone marrow myelogram, increased weight of spleen, histopathological findings in spleen and bone marrow. These findings were observed in male and female groups at 500 mg/kg bw/day, and some were also found at 125 mg/kg bw/day. The findings in bone marrow myelogram were observed in both sex groups even at 30 mg/kg bw/day. Therefore, a NOAEL < 30 mg/kg bw/day was established for analogue D.

Dermal
No systemic effects were observed in dermal repeated dose studies with analogue A using rats. Local effects induced by repeated dosing included erythema at the application sites. Incidence, severity and time of onset of the effects were concentration dependent. Necrosis and eschar formation were also seen in female animals and were less severe with later onset in the males. The NOAEL for local skin and systemic effects was established at < 200 mg/kg bw/day and ≥ 2,000 mg/kg bw/day respectively for analogue A.

Inhalation
In repeated dose inhalation studies with analogue A using rats, liver effects were observed in the high dose group including an increased hepatocyte vacuolisation consistent with fatty change in female rats. The liver was considered as a potential target organ after inhalation. Pale livers in female rats were also recorded with relative liver weight increase. In male rats the relative liver weight had a dose-related decrease; however, this effect was not accompanied by microscopic changes. Dose-related reduction in spleen weight in the male rats was also noted. Local lung effects observed in the studies included perivascular and peribronchial accumulation of granulocytes and a decrease of body weight gain. The lowest NOAEC reported for analogue A in the studies was 39 mg/m^3.

In a repeated dose inhalation study with analogue D in rats, at concentrations of 0, 10, 30, or 100 ppm for 4 weeks, 6 h/day, 5 day/wk (with 5 rats/sex/group kept for a 14-day recovery period), mild haemolytic anaemia was observed in female rats exposed to 100 ppm, but had disappeared after the 14-day recovery period. Extramedullary haematopoiesis was observed in the spleen of rats in the 10, 30 and 100 ppm groups and in controls. A NOAEL of 30 ppm in male and female rats was established for analogue D.

Mutagenicity/Genotoxicity
Analogue A was tested for mutagenic potential in several genotoxicity studies. The results showed that analogue A did not induce reverse mutations in *Salmonella typhimurium* with and without metabolic activation, or chromosomal aberrations in Chinese hamster ovary cells *in vitro*. Analogue A was negative in an unscheduled DNA synthesis test with primary cultures of rat hepatocytes without metabolic activation and was also negative in an *in vitro* mouse lymphoma assay in the presence of metabolic activation but weakly positive without metabolic activation at toxic dose levels. Analogue A did not induce: sex-linked recessive lethality in *Drosophila,* forward mutations at the HGPRT locus in Chinese hamster ovary cells with and without metabolic activation, and micronuclei in bone marrow of mice after administration of a single oral dose up to 3,300 mg/kg. Based on the above information, it was concluded that analogue A is not mutagenic.

In a mammalian chromosome aberration test with analogue D, using Chinese Hamster Lung/IU cells, no increase in clastogenicity (structural chromosome aberration) or polyploidy was observed in the treatments up to 1,050 µg/mL of the chemical with or without metabolic activation. In a bacterial reverse mutation assay with analogue D, at concentrations up to 5,000 µg/plate with or without metabolic activation, there was no observed mutagenic activity in any *Salmonella typhimurium* and *Escherichia coli* strains.

Based on the above information, the notified chemical is not expected to have genotoxicity potential under normal conditions.

Toxicity for reproduction
The US EPA issued a Significant New Use Rule (SNUR, US EPA, 2014) on 7 commercially available ethylene glycol ethers regarding reproductive hazard concerns for this group of chemicals. According to the US EPA, based on both toxicity data and structure-activity relationships, ethylene glycol ethers that consist of 1, 2 or 3 glycol ether groups and terminal alkyl groups of 1 to 4 carbons can be anticipated to cause developmental and reproductive toxicity and/or haemolytic toxicity. Based on the structure of the notified chemical, it is considered to be similar to the category of ethylene glycol ethers for which the US EPA raised concerns. According to the US EPA SNUR documents, ethylene glycol ethers have been shown to cause damage to reproductive organs as well as toxicity to blood and blood forming organs. Exposure to this group of chemicals can pose risks to consumers, workers and children because of potential birth defects due to damage of reproductive organs.

However, in a study designed to assess the potential for testicular toxicity of analogue D, rats were exposed by inhalation for two weeks at concentrations up to 1,000 ppm. Whilst there were marked signs of toxicity in the high dose group animals with reduced weight gain and haematological effects, there were no effects observed on the male testes.

For analogue A, in a one-generation gavage study with rats the NOAEL for fertility was established at 1,000 mg/kg bw/day (highest dose level tested). For developmental effects, the oral NOAEL was established at 500 mg/kg bw/day. The effect observed at the next higher dose level tested was reduced body weight gain of the pups. Analogue A was not considered to cause teratogenic effects after oral administration. In addition, no developmental effects were recorded in a dermal one-generation study in rats on analogue A at doses up to 2,000 mg/kg bw/day. Neither systemic maternal toxicity nor developmental or teratogenic effects were observed in rabbits dermally exposed to analogue A at dose levels up to 1,000 mg/kg bw/day.

Based on the information available, reproductive toxicity following repeated exposure is likely to be low, but with a significant degree of uncertainty.

Health hazard classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the information available, the notified chemical is expected to be irritating to the skin and eye. However, the enclosed nature of the ink packaging containing the notified chemical at a concentration ≤ 10% and computerised automatic printing processes would limit the dermal/ocular exposure and thus limit the irritation effects. The notifier stated that service technicians and printer operators are required to wear protective clothing and gloves during operations to minimise the potential for exposure.

The health effects of repeated or prolonged exposure to the notified chemical are uncertain. The notified chemical has potential for developmental/reproductive toxicity and organ damage based on the US EPA SNUR and analogue chemical data. Since the notified chemical is likely to volatilise during printing and drying, repeated inhalation exposure for workers is possible if vapour of the notified chemical is formed in workplaces. The notifier has stated that local exhaust ventilation will be used at the printing machines at all sites. In addition to the proposed local exhaust ventilation, the Safe Work Australia (SWA) guidance document, *P39 –Wide-format inkjet printing with solvent-borne inks*, recommends providing a good standard of general ventilation, and that ventilation equipment is maintained and working effectively. In order to provide fresh air, powered wall- or window-mounted fans, with five to ten air changes per hour and a through draught, are recommended in this guidance document. Safe work practices and use of appropriate PPE (SWA, 2012) would further reduce exposure. Given the potential hazard profile of the notified chemical, risk controls (i.e., engineering, work practices and personal protective equipment) should be implemented and their effectiveness monitored.

Overall, provided that adequate workplace controls are in place to reduce exposure to the ink containing the notified chemical, the risk to workers is not considered unreasonable.

6.3.2. Public Health
The ink containing the notified chemical will not be sold to the public. The public may have contact with dry printed materials. However, the notified chemical is expected to be evaporated during the printing and not to be

available for exposure after drying. Therefore, based on the use scenario, the risk of the notified chemical to the health of 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 not be manufactured or reformulated in Australia. It will be imported in sealed plastic bags (concentration of up to 10%) packed in cardboard boxes. The ink formulations containing the notified chemical are not expected to release to the environment except in the unlikely event of an accident where the packaging is breached. Accidental spills of the notified chemical during transportation and storage are expected to be disposed of according to State/Territory legislation.

RELEASE OF CHEMICAL FROM USE

Some release is expected to occur during the printing process via cleaning and maintenance operations and small spills. It is expected these residues will be disposed of to landfill. The formulated products containing the notified chemical will be applied to paper using industrial inkjet printers. The applied notified chemical is semi-volatile (VP = 0.066 kPa at 25 °C) and it is expected to evaporate from the ink matrix during heat-drying before the substrate leaves the printer.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be released to the atmosphere during drying. However, a very small amount may remain within the dried ink matrix and will be disposed of to landfill and is expected to remain associated with the substrate to which it has been applied. Of the notified chemical applied to paper 50% is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres.

7.1.2. Environmental Fate

Fate studies were provided for an acceptable analogue (analogue A) of the notified chemical. Analogue A was found to be readily biodegradable. Therefore the notified chemical is likely to be readily biodegradable and is not expected to persist in the environment.

The majority of the notified chemical is expected to be released to the atmosphere. The notified chemical is semi-volatile with a vapour pressure of 0.066 kPa at 25 °C. Thus, the notified chemical's potential for persistence in air and long range transport was assessed using AOP Program (v1.92) within the US EPA EpiSuite. This estimates the half-life of the notified chemical in air, based on a 12 hour day, as 3.44 h, which indicates that the notified chemical is expected to react rapidly with OH-radicals and therefore will not have the potential for long-range transport.

Notified chemical trapped in the ink matrices is expected to be disposed of to landfill with the substrate to which it is applied. Given the high water solubility and low log Koc, the notified chemical may leach from landfill and enter surface waters. A small proportion of the notified chemical may be released to sewer during paper recycling. Given the high water solubility and low log Koc, the notified chemical is not expected to partition to sludge during waste water treatment processes in sewage treatment plants (STPs). Therefore, the notified chemical is expected to remain in waste water and be released to aquatic environments.

Based on its high water solubility and low log Pow, the notified chemical is not expected to bioaccumulate. Ultimately, the notified chemical is expected to degrade via biotic and abiotic processes in the atmosphere and surface waters to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on its use in printing, it is conservatively assumed that 100% of the total import volume of the notified chemical was used in paper printing. Further, it is assumed that 50% of the paper products containing the notified chemical will be recycled and released to the sewer with no removal during recycling or STP processes. 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 estimate

for the predicted environmental concentration (PEC) in sewage effluent nationwide is summarised in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	50 %	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	19.23	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:	4.25	µg/L
PEC - Ocean:	0.43	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 12.75 µg/L may potentially result in a soil concentration of approximately 0.085 mg/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 0.142 mg/kg and 0.284 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on analogue A are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96h) > 1000 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 (48h) >100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96h) >100 mg/L NOEC (8d) = 53 mg/L	Not harmful to algae

The notified chemical and analogue A can be considered to belong to the similar group based on their structures and functional groups. Therefore, the ecotoxicological endpoints measured for analogue A are considered acceptable for the purpose of regulatory risk assessment.

Based on the above endpoints, the notified chemical is not considered to be harmful to aquatic organisms. Therefore, based on the toxicity to aquatic biota the notified chemical is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) on acute and chronic bases.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the most sensitive species (Algae, NOEC of 53 mg/L) for the analogue. Acute ecotoxicity endpoints for aquatic species from three trophic levels are available. Therefore, an assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Alga)	53	mg/L
Assessment Factor	100	
PNEC:	530	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient values have been calculated as follows:

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	4.25	530	0.008
Q - Ocean:	0.43	530	0.001

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be << 1 for the river and ocean compartments. The notified chemical is not expected to be bioaccumulative and is expected to rapidly degrade in the environment. Based on the short half-life of the notified chemical in air, it is not expected to be persistent in the atmosphere. Based on the assumed low hazard and the assessed use pattern of the notified chemical, it is not expected to pose an unreasonable risk to the environment.

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