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

PUBLIC REPORT

Acrylate Monomer in ECO-UV, EUV-BK

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1600	Roland Digital Group Australia Pty Ltd	Acrylate Monomer in ECO-UV, EUV-BK	Yes	< 1 tonne per annum	A component of UV-curable inks at ≤ 30%

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on analogue data, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

Xi; R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitisation by skin contact.

and

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

	<i>Hazard category</i>	<i>Hazard statement</i>
Eye irritation	2	Causes eye irritation
Skin irritation	2	Causes skin irritation
Specific Target Organ Toxicity	3	May cause respiratory irritation
Skin sensitisation	1A	May cause sensitisation by skin contact
Aquatic Environment	Acute Category 2	Toxic to aquatic life
	Chronic Category 1	Very toxic to aquatic life with long lasting effects

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 expected low aquatic exposure and 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:
 - R36/37/38: Irritating to eyes, respiratory system and skin
 - R43: May cause sensitisation by skin contact.

- The following risk phrases are recommended in the workplace on products/mixtures containing the notified chemicals:
 - Concentration $\geq 20\%$: R36/37/R38, R43
 - $\geq 1\%$ Concentration $< 20\%$: R43
- Based on ecotoxicity data, the notifier should consider their obligations under the Australian Dangerous Goods Code.

Health Surveillance

- As the notified chemical presents a skin sensitisation health hazard, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as imported at $\leq 30\%$:
 - Local exhaust ventilation where inhalation may occur.
 - Use of closed processes where possible.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as imported at $\leq 30\%$:
 - Avoid contact with eyes and skin.
 - Do not generate aerosols.
 - Clean up any spills promptly.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during handling of ink products containing the notified chemical at $\leq 30\%$, particularly during manual replacement of ink containers, cleaning of ink residuals and servicing the printing machine:
 - Gloves
 - Safety glasses
 - Protective clothing
 - Respiratory protection for any process where aerosols are generated

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

- Service personnel should wear impermeable gloves when removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 being a component of ink for industrial use, imported in closed cartridges, or is likely to change significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Roland Digital Group Australia Pty Ltd (ABN 13 007 023 690)
Allambie Grove Business Park
Unit 14, 25 Frenchs Forest Rd
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, degree of purity, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physicochemical properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

LVC/828

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

ECO-UV (product containing the notified chemical)

EUV-BK (product containing the notified chemical)

BZA

ANALYTICAL DATA

Reference MS and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point	9.32 °C	Estimated (mean of several estimate methods)
Boiling Point	233 °C (pressure unknown)	Estimated (Adapted Stein & Brown Method)
Density	1054 kg/m ³ at 25 °C	Value provided by the notifier.
Vapour Pressure	8.94 x 10 ⁻³ kPa at 25 °C	Estimated (mean of Antoine & Grain Methods)
Water Solubility	0.556×10 ⁻³ g/L	Calculated (WSKOW v1.42; US EPA, 2011)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality; however, significant hydrolysis is not expected at environmental pH (4-9) due to its expected low solubility
Partition Coefficient (n-octanol/water)	log Pow = 2.44	Calculated (KOWWIN v1.68; US EPA, 2011)
Adsorption/Desorption	log K _{oc} = 2.34, 2.21	Calculated (KOCWIN v2.00, MCI and log Kow methods, respectively; US EPA 2011)
Dissociation Constant	Not determined	No dissociable functionality
Particle Size	Not determined	Liquid
Flash Point	115.5 °C	Value provided by the notifier.
Autoignition Temperature	Does not self-ignite	Statement provided by the notifier.
Explosive Properties	Not expected to be explosive	Based on structural information and the lack of structural alerts.
Oxidising Properties	Not expected to have oxidative properties	Based on structural information and the lack of structural alerts.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal use conditions. Expected to polymerise in the presence of intense light.

Dangerous Goods classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component of UV-curable printing ink at $\leq 30\%$.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY

Sydney

IDENTITY OF RECIPIENTS

Roland Digital Group Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in 220 ml purpose-designed sealed cartridges at $\leq 30\%$. The individual cartridges will be packed in foil bag within a cardboard box.

The inks containing the notified chemical will be transported by road from the port of entry to the notifier's warehouse prior to distribution to end-users by road.

USE

The notified chemical will be used as a component of UV-curable inks. The inks will be used in the UV printers for printing on a wide variety of shrink films and plastics, including those made from PET (polyethylene terephthalate), OPS (biaxially oriented polystyrene sheet), ABS (acrylonitrile butadiene styrene), PMMA (poly(methyl methacrylate) or polycarbonate.

OPERATION DESCRIPTION

The notified chemical and imported ink product containing the notified chemical in sealed 220 ml cartridges will be stored in warehousing facilities for subsequent distribution to commercial printing houses. Distribution workers will not handle the opened packaging. Printer service technicians and operators will open the cardboard and foil packaging and insert the cartridges in 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 commercial waste. Refilling of empty cartridges is not recommended by the manufacture and the manufacture does not supply refill kits. Spent cartridges will be recycled where possible.

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 Operators	8	260
Printer Service Technicians	4	260

EXPOSURE DETAILS

Transport and warehouse workers are not expected to be exposed to the imported notified chemical, as they will be handling closed containers. Exposure to the notified chemical is possible only in the event of an accident where the packaging is breached.

During normal use, printer operators are not expected to have high exposure to the notified chemical at $\leq 30\%$ in printing ink, as the process is mainly automated and the ink is contained in the inkjet cartridge.

Dermal exposure is possible during the replacement of ink cartridges (manual process) and during cleaning. However, operators will wear protective clothing, and impermeable gloves.

Inhalation exposure may occur but would be limited by the use of local exhaust ventilation employed in areas surrounding printing machines. After ink application to the substrate, the notified chemical will be trapped in the matrix of the ink and hence the notified chemical will be no longer bioavailable. However it may volatilise slowly from the matrix.

Service technicians will come in contact with the notified chemical during printer maintenance, where dermal or inhalation contact with residual ink is possible. Printer maintenance personnel will wear disposable cotton gloves and safety glasses.

After application to the substrate, the ink containing the notified chemical is UV cured and hence the notified chemical will not be bioavailable.

6.1.2. Public Exposure

Products containing the notified chemical will not be made available to the general public. The public may come into contact with printed substrates. However, at this stage the ink has fully cured, is strongly bound to the surface of the substrate and is not bioavailable.

6.2. Human Health Effects Assessment

No toxicity or toxicokinetic data were submitted for the notified chemical.

Toxicokinetics

The notified chemical has a low molecular weight, low estimated water solubility (0.556 mg/L) and an estimated partition coefficient ($\log PoW$) = 2.44 and is therefore considered to have the potential for absorption across biological membranes. Skin sensitisation in an analogue chemical also indicates there is potential for dermal absorption.

Irritation and sensitisation

The notified chemical contains an acrylate functional group and is a member of a chemical class which are classified as hazardous for their irritation potential, with the following risk phrases: R36/37/R38 irritating to eyes, respiratory system and skin (HSIS, 2010). In addition, an analogue chemical is classified with R43: May cause sensitisation by skin contact.

Health hazard classification

Based on analogue data, the notified chemical is classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004) with the following risk phrases:

Xi; R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitisation by skin contact.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

No toxicological data have been provided for the notified chemical, however based on analogue data it is likely to be a skin sensitiser and an irritant to eyes, the respiratory system and skin.

Service technicians handling ink products containing the notified chemical ($\leq 30\%$) may have frequent dermal exposure to the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residues and servicing the printing machine. However, the exposure is expected to be limited by the sealed cartridge packaging, the local exhaust ventilation in use in printing areas and the enclosed nature of the printing process. The use of adequate PPE (i.e., impervious gloves) is expected to further minimise exposure. Once the ink is applied to the substrate and dried, the notified chemical would not be bioavailable.

Overall the risk to workers from use in printing is not considered to be unreasonable due to the notified chemical being enclosed in a sealed ink cartridge, the enclosed nature of the printing process and the anticipated use of PPE.

6.3.2. Public Health

The inks containing the notified chemical at $\leq 30\%$ will not be sold to the public. The public may have contact with the dried printed materials, however the notified chemical will be bound in the print matrix and will not be bioavailable. Therefore, exposure of the public to the notified chemical is not expected, and the risk is not considered 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 as a component of commercial-use UV-curable printing inks in sealed 220 mL cartridges. As manufacturing and reformulation will take place overseas, no release of the notified chemical will occur in Australia from these activities. There is limited potential for release of the notified chemical from spills during transport, handling and storage due to the design and small volume of the individual cartridges. In the event of a spill, the notified chemical should be prevented from entering surface waters and sewers, collected using inert absorbent materials and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

Environmental release of the notified chemical from use in commercial printing may arise from disposal of residual ink in empty cartridges and on printing equipment. A maximum of 1% of ink is estimated to be collected from equipment cleaning and ink wastes will be disposed of by licensed waste contractors. A further 1% of ink is estimated to remain in cartridges. The ink residues will either be collected by cartridge recyclers for disposal in accordance with local regulations or will be disposed of to landfill with the spent cartridges. Release of the notified chemical to the aquatic environment is not expected from use.

The notified chemical is to be polymerised by UV-curing immediately after deposition of the ink onto the printed substrate. The resultant chemical is expected to be irreversibly bound within the inert polymeric matrix adhering to printed plastics. Release of the notified chemical into the environment is not expected during the functional life of printed films and articles.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will be used in inks for printing on plastic films and articles. The notified chemical is expected to share the fate of the printed substrates, which are likely to be disposed of to landfill. Some plastic articles printed with the ink containing the notified chemical may be recycled.

7.1.2. Environmental Fate

No environmental fate data were submitted.

The majority of the notified chemical is expected to be UV-cured to form an inert matrix adhering to plastic substrates during its normal use as an ink. The notified chemical is irreversibly bound into the matrix and, in this form, is not expected to be mobile, bioavailable or readily biodegradable. The majority of the cured notified chemical is expected to be disposed of to landfill where it will eventually degrade by biotic and abiotic processes to form water and oxides of carbon. During plastic recycling, the notified chemical or its cured form is likely to be removed during de-colouring or clarification process, collected with processing sludge, and disposed of to landfill. The majority of the cured notified chemical is anticipated to sorb to sludge and sediment in the unlikely event that it is released to sewers or surface waters.

The notified chemical is predicted to be readily biodegradable (BIOWIN v4.10; US EPA, 2011) and is not expected to persist in the aquatic environment. The notified chemical has low potential for bioaccumulation based on its low predicted partition coefficient ($\log P_{ow} = 2.44$) and predicted bioconcentration factor ($BCF = 18.8$ L/kg wet-wt, BCFBAF v3.01; US EPA, 2011).

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be disposed of to the aquatic compartment in significant quantities based on the reported use and disposal pathways. Therefore, the predicted environmental concentration (PEC) could not be calculated as very limited aquatic exposure is expected for the notified chemical or its cured form.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. However, several ecotoxicological endpoints were reported for an analogue chemical which contains the same reactive functional group as the notified chemical. The endpoints for the analogue are summarised in the table below:

<i>Endpoint</i>	<i>Result</i>
Fish Toxicity (Rainbow trout)	96 h LC50 = 1.8 mg/L
Daphnia Toxicity	48 h LC50 = 1.3 mg/L
Algal Toxicity	96 h E _r C50 = 67 mg/L

The above results could not be assessed for reliability as reports were not available for the test studies.

Further, the analogue chemical nominated by the notifier has significantly different physico-chemical properties to the notified chemical, with a predicted $\log K_{ow}$ of 4.1 compared to a $\log K_{ow}$ of 2.44 for the notified chemical. Since the bioavailability and ecotoxicity of organic chemicals is known to be dependent on the $\log K_{ow}$, the ecotoxicity endpoints were calculated by a reliable QSAR method (ECOSAR v1.00; US EPA, 2011) using the class specific to the notified chemical in the absence of measured data on the notified chemical. The notified chemical was within the domain of the ECOSAR class utilised. The results are tabulated below.

<i>Endpoint</i>	<i>Result^a</i>	<i>Assessment Conclusion</i>
Acute Toxicity		
Fish	96 h LC50 = 1.8 mg/L	Toxic to fish
Daphnia	48 h EC50 = 4.5 mg/L	Toxic to aquatic invertebrates
Algal	96 h EC50 = 1.3 mg/L	Toxic to algae
Chronic Toxicity		
Fish	30 d ChV = 0.066 mg/L	Very toxic to fish with long lasting effects
Daphnia	ChV = 0.18 mg/L	At best, toxic to aquatic invertebrates with long lasting effects
Algal	ChV = 0.30 mg/L	At best, toxic to algae with long lasting effects

^a Modelled estimates (ECOSAR v1.00, class – acrylates, $\log K_{ow} = 2.44$; US EPA, 2011).

The calculated data determined for the notified chemical were considered to be more indicative of the acute toxicity of the notified chemical than the analogue data. The predicted ecotoxicological endpoints calculated by ECOSAR were utilised to determine the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) classification and derive the Predicted No-Effect Concentration (PNEC) below.

The environmental hazard classification of the notified chemical is conducted in accordance with the guidance provided in the GHS.

Under the GHS the notified chemical is considered to be acutely toxic to fish, aquatic invertebrates and algae. Based on its predicted acute toxicity to fish, aquatic invertebrates and algae the notified chemical is formally classified under the GHS as “Acute Category 2; Toxic to aquatic life”.

The GHS classifications for long-term hazard are based on NOEC (or equivalent EC_x) endpoints, whereas the available endpoints are chronic values [$\text{ChV} = (\text{LOEC} \times \text{NOEC})^{1/2}$], i.e. the geometric mean of the LOEC and NOEC. Since the LOEC is by definition greater than the NOEC it follows that, for each endpoint, the NOEC must be less than the ChV. Under the GHS the notified chemical is considered to be chronically very toxic to fish and, at best, toxic to aquatic invertebrates and algae. Therefore, based on its predicted chronic toxicity to fish (i.e. $\text{NOEC} < 0.066 \text{ mg/L}$) and lack of measured data to demonstrate rapid degradability in the aquatic environment, it is formally classified for long-term hazard under the GHS as “Chronic category 1; Very toxic to aquatic life with long lasting effects”.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the estimated chronic fish toxicity of the notified chemical and an assessment factor of 50. A conservative assessment factor is appropriate, in this case, as although chronic endpoints ($\text{ChV} = (\text{LOEC} \times \text{NOEC})^{1/2}$) for three trophic levels are available, these chronic endpoints are greater than no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (Fish, 30 d)	0.066	mg/L
Assessment Factor	50	
PNEC:	1.32	µg/L

7.3. Environmental Risk Assessment

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for the notified chemical has not been calculated as release to the aquatic environment is not expected based on its reported use pattern as a component in UV-curable inks. The majority of the notified chemical will be disposed of to landfill as cured ink where it is irreversibly bound into an inert matrix, and is unlikely to be bioavailable or mobile in this form. Therefore, based on its expected low aquatic exposure and assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

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