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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Light Acrylate EDHG-AT

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

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

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

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Director
NICNAS

TABLE OF CONTENTS

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/1429	Sojitz Australia Limited	Light Acrylate EDHG-AT	Yes	≤ 100 tonnes per annum	Component of UV curable printing plates

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2A)	H319 – Causes serious eye irritation
Specific Organ Toxicity (Category 3)	H335 – May cause respiratory irritation
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
R36/37/38: Irritating to eyes, respiratory system and skin
R43: May cause sensitisation by skin contact

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

Hazard classification	*Hazard statement*
Acute Category 2	H401 – Toxic to aquatic life
Chronic Category 2	H411 – 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 assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment provided the notified chemical is not released to sewer or surface waters.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin Irritation (Category 2): H315 - Causes skin irritation

- Eye irritation (Category 2A): H319 – Cause serious eye irritation
- Specific Organ Toxicity (Category 3) H335 – May cause respiratory irritation
- Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

- The following should be used for products/mixtures containing the notified chemical:
  - Concentration ≥ 10%: H315 – Causes skin irritation
    H317 – May cause an allergic skin reaction
    H319 – Causes serious eye irritation
    H335 – May cause respiratory irritation
  - ≥ 1% concentration < 10%: H317 – May cause an allergic skin reaction

- Based on ecotoxicity data, the notifier should consider their obligations under the Australian Dangerous Goods Code.

Health Surveillance

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

Material Safety Data Sheet

- The MSDS provided by the notifier for the product containing the notified chemical should be amended as follows:
  - Revision to reflect the hazard classification as a skin sensitiser, as the product contains > 1% of the notified chemical.
  - Identification of the chemical name of the notified chemical in the list of ingredients, as it is a type I ingredient.

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:
  - Use closed and automated system for transfer and mixing of the notified chemical and the formulation containing the notified chemical
  - Provide adequate local exhaust ventilation

- 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:
  - Avoid direct contact with eyes and skin
  - Avoid generating vapour and aerosols
  - Clean up spills promptly
  - Avoid contact with waste materials contaminated with the notified chemical

- 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:
  - Impervious gloves
  - Chemical goggles
  - Protective clothing
  - Respiratory protection if inhalation exposure may occur

  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 for the 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.

Environment

- The following control measures should be implemented by transporters, reformulators and end-users to minimise environmental exposure during transport, reformulation and use of the notified chemical:
  - Notified chemical, reformulated mixtures or waste water containing the notified chemical is not to be released, directly or indirectly, to sewers or surface waters.

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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
  - further information becomes available on the repeated dose, reproductive or developmental effects of the notified chemical;
  - the notified chemical, reformulated mixtures or waste water associated with equipment and container cleaning operation are to be released, directly or indirectly, to sewers or to surface waters.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of UV curable printing plates or is likely to change significantly;
  - the amount of chemical being introduced has increased from 100 tonnes 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical and a product containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Sojitz Australia Limited (ABN: 000 213 132 / 16 000 213 132)
Level 13, MLC Centre
19-29 Martin Place
Sydney, NSW 2000

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, residual impurities, additives/adjuvants, use details, import volume, site of reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point/boiling point, vapour pressure, water solubility, absorption/desorption, flammability limits and autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
Light Acrylate EDHG-AT

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear pale yellow liquid with a characteristic acrylic odour.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Estimated < -30°C	MSDS
Boiling Point	Estimated > 250°C	MSDS
Specific gravity	Approximately 0.95	MSDS
Vapour Pressure	Estimated < 0.3 kPa at 20°C	MSDS
Water Solubility	0.064 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ = 116 hours at 25 °C (pH 9) > 1 year at 25 °C (pH 4 and 7)	Measured

Partition Coefficient (n-octanol/water)	log Pow = 4.30 at 20 °C	Measured
Adsorption/Desorption	log K_{oc} = 3.06 at 25 °C	Calculated (KOCWIN v2.00, USEPA, 2011)
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	151 °C (open cup)	MSDS
Flammability limits	Estimated: Upper: 7.8% Lower: 1.1%	MSDS
Autoignition Temperature	Estimated > 402°C	MSDS
Explosive Properties	Predicted not explosive	Calculated [Chemicalia (2012)]
Oxidising Properties	Predicted not oxidative	Calculated [Chemicalia (2012)]

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

Reactivity
The notified chemical is stable under normal conditions of storage and polymerises under conditions of heat and light. The notified chemical is intended to react in end-use products through UV curing.

Physical hazard classification
Based on the available physico-chemical data depicted in the above table, the notified chemical cannot be classified according to the *Globally Harmonised System for the 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 be imported as the chemical itself (100%).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical in liquid form will be imported in 180 kg steel drums by sea from the manufacturing site in Japan, stored in a warehouse in Melbourne and distributed on pallets to the reformulator's store. Reformulation will occur in Victoria. The reformulated mixtures containing 9% of the notified chemical will be packaged into 1,000 L intermediate bulk containers (IBCs) or 18 kg steel pails and supplied by road to the end users for manufacturing elastomeric printing plates.

USE
The notified chemical will be used as reformulated mixtures at a concentration of 9%. The reformulated mixtures containing the notified chemical will be used to produce UV-cured elastomeric printing plates.

OPERATION DESCRIPTION

Reformulation/Repackaging
The notified chemical will be transferred to the mixing area and then pumped into a closed mixing kettle by an operator wearing appropriate personal protective equipment (PPE) using a spear pump, with appropriate exhaust ventilation. The closed mixing kettle will contain 9% of the notified chemical and other ingredients to manufacture the reformulated mixtures in 3,000 kg batches. After five hours of mixing, small samples will be taken for quality assessment purposes by the Polymer Chemist wearing appropriate PPE for testing in a laboratory fume cupboard. When the formulated mixtures containing the notified chemical are manufactured and tested, they will be packed into 1,000 L IBCs or 18 kg pails using a pump under appropriate exhaust ventilation.

End-User Applications
Formulation mixtures containing 9% notified chemical will be supplied in 1,000 L IBCs or 18 kg pails to companies in Australia and overseas for the manufacture of elastomeric printing plates for applications such as printing designs onto cardboard cartons. The companies will transfer the formulation mixture through a closed automatic pump and pipe system to a plate making machine. The formulation mixture will then be dispensed and sandwiched between two layers of polyester sheets into trays containing positive artworks to form film. Upon exposure to UV light in an enclosed system, image areas of the film will be cured and the non-image areas containing the liquid mixture will be recycled for further use. After washing and drying, the resulting articles (printing plates) will be used in printing processes to produce positive images on cardboard cartons. Formulation mixture residues from equipment cleaning will be sent off site for waste 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)*
Transport and storage workers	1	12
Formulation mixing operators	6	120
Cleaning and maintenance workers	0.5	120
Formulation quality inspectors	0.5	120
End-user printing plate operators	0.5	60

EXPOSURE DETAILS

Transport and Storage
During transport and storage, workers are not expected to have exposure to the notified chemical under normal conditions of operation unless a spill event occurs. In the case of a spill, workers may experience dermal, ocular and inhalation exposure to the notified chemical at concentration > 90% or to the formulations containing the notified chemical up to 9%.

Reformulation
At the reformulation site, the notified chemical in liquid form will be transferred to a closed mixing kettle. Dermal, ocular and inhalation exposure to the notified chemical at > 90% may occur during the transfer, removal and testing of the chemical. Dermal, ocular and inhalation exposure to the notified chemical at concentration up to 9% may also occur during reformulation, testing, packaging and transfer of the reformulated mixtures, and during general cleaning and maintenance of the reformulation equipment. Exposure to the notified polymer would be reduced by use of the engineering controls and PPE.

End-User Application
End-users who use the reformulated mixtures (viscous liquids) in the multi-step production of elastomeric printing plates may come into contact with the notified chemical at concentration up to 9%. Dermal, ocular and inhalation exposure may occur. However, a closed automatic system will be used for transferring the reformulated mixture containing the notified chemical and, during the process, the mixture will be trapped between two layers of polyester sheets. Manual transfer of the assemblies occurs in order to recycle unused reformulated mixture and to clean and dry the plates. Under normal conditions of operation, providing that appropriate local engineering controls, safe work practices and PPE are applied, exposure to the notified chemical would be reduced.

Once the reformulated mixture is cured by UV to form elastomeric printing plates and the uncured material is removed for recycling, the notified chemical will have reacted into the matrix of the plates and will not be bioavailable for exposure.

Container Recycling
During container recycling, workers from licensed chemical waste disposal companies may come into contact

with the residues of the notified chemical at various concentrations. Exposure would be limited by use of PPE during handling.

6.1.2. Public Exposure

The notified chemical will be used for industrial print processes only and will not be available to the general public either in liquid form or as articles (print plates). Public exposure to the notified chemical is not expected except in the event of an accidental spill during transport.

6.2. Human Health Effects Assessment

The result from a skin irritation study in rabbits, conducted on the notified chemical is summarised in the following table. For details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rabbit, skin irritation	Moderately irritating

Three analogue chemicals containing acrylate groups (as does the notified chemical) are listed in the table below with their health hazard classifications under Safe Work Australia. The classifications applied to the analogues are for skin, eye and respiratory irritation, and skin sensitisation.

	HSIS Classification	*Cut-off Concentration*
Analogue 1	Xi; R37/38; R43	Conc ≥ 20%: Xi; R37/38; R43 ≥ 1% Conc < 20%: Xi; R43
Analogue 2	Xi; R36/37/38; R43	Conc ≥ 20%: Xi; R36/37/38; R43 ≥ 1% Conc < 20%: Xi; R43
Analogue 3	Xi; R36/37/38;	Conc ≥ 10%: Xi; R36/37/38

Toxicokinetics, metabolism and distribution.

Based on the measured water solubility (64 mg/L), the partition coefficient (log Pow = 4.30) and the low molecular weight (< 500 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. Dermal absorption may be reduced by the log Pow > 4 or by binding to the skin components, but may also be increased by the expected irritant properties of the notified chemical. Absorption across the respiratory tract may also occur.

The notified chemical contains the acrylate group, which is detoxified predominantly via conjugation with glutathione via the Michael addition reaction or glutathione-S-transferase. It is also likely to be hydrolysed via carboxylesterases. The lower molecular weight acrylate esters can be rapidly metabolised and eliminated, therefore, will not likely cause cumulative toxicity. The notified chemical also contains the glycol group which may be metabolised through oxidation via alcohol dehydrogenase, leading to the formation of alkoxy acids (Patty's Toxicology 2012).

Acute toxicity.

No acute toxicity data on the notified chemical were provided by the notifier. The three analogue chemicals containing the acrylate groups are, in general, of low acute toxicity. However, the effect of the glycol component in the notified chemical is not known, and an overall higher level of toxicity for the notified chemical, given the presence of both structures of concern, cannot be ruled out.

Irritation and sensitisation.

No data on eye or respiratory irritation or skin sensitisation were provided for the notified chemical. A study in rabbits using the notified chemical indicated that it is a moderate skin irritant, causing well defined erythema and slight oedema initially. However the protocol was not to OECD guidelines and observations were made for up to 72 h only, and it is unclear whether classification could be made based on the study. However, based on available data on the analogues containing acrylate groups, the notified chemical is likely to be irritating to the skin, eyes and the respiratory system.

Two of the three analogue chemicals containing acrylate groups were tested for skin sensitisation and are classified for this endpoint. It is therefore expected that the notified chemical would also have skin sensitisation potential.

Repeated Dose Toxicity.
No data on the repeat dose toxicity were provided for the notified chemical. Following sub-chronic exposures to atmospheres of excessive concentrations of acrylates and/or methacrylates, pulmonary congestion or haemorrhage and cloudy swelling and organ weight changes of the liver and kidney have been reported (Patty's Toxicology, 2012). Studies with rats on Analogue 2 revealed that, after repeated inhalation exposure, irritating effects to nasal and respiratory mucosa and the eyes were observed. In developmental toxicity studies via inhalation, the analogue chemical caused fetotoxic effects at maternally toxic concentrations. Analogue 1 produced degeneration of the olfactory epithelium after repeated inhalation exposure in rats. It induced skin tumours in a mouse dermal carcinogenicity study, assumed to be via a non-genotoxic mechanism.

Short-chain ethylene glycol ethers are known to be developmental and reproductive toxicants (US EPA 2010). As the notified chemical contains the glycol moiety (in addition to the acrylate groups) the potential for reproductive and/or developmental effects cannot be ruled out.

Mutagenicity
The results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen *et al*., 2008). In general, it was found that compounds were negative in bacterial reverse mutation assays (and other *in vitro* mammalian point mutation assays) and while positive results were noted in *in vitro* mammalian clastogenicity assays, the results in *in vivo* assays were negative. This pattern of results was supported by the data obtained in the genetic toxicity studies of Analogue 2. Therefore, while the potential for the notified chemical to be genotoxic *in vitro* cannot be ruled out, based on the available information it is not expected to be genotoxic *in vivo*.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Irritation – Category 2	H315 – Causes skin irritation
Eye Irritation – Category 2A	H319 – Causes serious eye irritation
Specific Organ Toxicity – Category 3	H335 – May cause respiratory irritation
Skin Sensitisation – Category 1	H317 – May cause an allergic skin reaction

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

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
The notified chemical has very limited available toxicological information. Based on the available data on the type of structural groups present and the analogue data, the notified chemical is expected to be a skin, eye and respiratory irritant, and a skin sensitiser. There is uncertainty about the potential chronic health effects of the notified chemical, if long term, repeated exposure occurs.

Workers with high potential for dermal, ocular and inhalation exposure will be those handling high concentrations (> 90%) of the notified chemical at the formulation site, particularly during the transfer and mixing processes.

Workers handling the formulated mixture at the formulation sites, and workers who use the formulated mixture to make elastomeric printing plates at the end-use sites, may also have dermal, ocular and inhalation exposure to the notified chemical at concentration up to 9%. In the plate-making process, the multiple steps involved, high viscosity of the formulated mixture and the need for manual transfer of partially completed plates increases the potential for drips and spills, contaminating the surfaces and the atmosphere with the formulated mixture containing the notified polymer at concentration up to 9%.

At both formulation and end-use sites, workers carrying out cleaning of equipment activities, are also potentially exposed.

While dermal exposure is the most likely route of exposure, incidental ocular exposure could also occur. Respiratory exposure is possible if mists or aerosols were generated, or if some volatilisation of the chemical occurred, noting that its vapour pressure is low.

The use of automated equipment, closed processes and local exhaust ventilation during mixture formulation and elastomeric printing plates manufacturing processes would reduce the risk to workers. Safe work practices such as cleaning up any spills promptly and isolation of contaminated clothing, wash water, cleaning cloths and surfaces would assist in safe handling of the notified chemical. To mitigate the risk of irritation and sensitisation, the use of impervious gloves, chemical goggles, protective clothing and, where necessary, respiratory protection would be required during processes where exposure is possible.

The risk to workers handling the final printing plates after they are cured, washed and dried is considered to be negligible as the notified chemical will be reacted and cured into the matrix of the printing plates and will not be bioavailable.

Overall the risk to the workers is not considered to be unreasonable if the above engineering and PPE controls are in place.

6.3.2. Public Health

The notified chemical, the reformulated mixture containing the notified chemical at up to 9% and the elastomeric printing plates will not be sold to the public. Therefore, 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 is not manufactured in Australia. Release of the notified chemical to the environment may occur as a result of accidental spills or leaks.

The notified chemical is reformulated at a site in Victoria. The majority of the notified chemical is expected to be incorporated into the reformulated product. Release of the notified chemical to the environment during reformulation is expected to occur as a result of equipment cleaning processes and as residues in empty import containers. The notified chemical released during equipment cleaning processes (up to 0.375% of the total annual import volume) is expected to be collected and disposed of via a licensed chemical waste disposal company. Empty import containers containing residues of the notified chemical (up to 1% of the total import volume) are expected to be sent to an off-site chemical disposal company. Therefore, the majority of the notified chemical in wastes created during reformulation is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be UV-cured (chemically reacted) to form inert elastomeric printing plates at printing sites nationwide and overseas. Only a small amount of waste is expected to be generated during this process. The majority of the waste containing the notified chemical is a result of residues in empty product containers. These containers are expected to be sent to a chemical waste disposal site for recycling.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical cured in elastomeric printing plates is expected to be disposed of to landfill at the end of its serviceable life.

7.1.2. Environmental Fate

The notified chemical will be UV-cured (chemically reacted) to form inert elastomeric printing plates and is not expected to be bioavailable. The majority of the cured notified chemical is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon. The notified chemical

is also predicted to be readily biodegradable (BIOWIN v 4.10; US EPA 2011), therefore the notified chemical is not expected to persist in the environment, supported by information available for an analogue chemical.

The notified chemical has a low predicted vapour pressure and is not expected to readily volatilise (MPBPWIN v1.43; US EPA 2011). Therefore, any of the notified chemical that enters surface waters is not expected to volatilise to the atmosphere. However, the notified chemical is expected to be efficiently removed by sorption to sediment where it will degrade by biotic and abiotic processes. The predicted bioconcentration factor (BCF) for the notified chemical is 13.5 L/kg wet-wt (BCFBAF v3.01; US EPA 2011) indicating it does not have a potential for bioaccumulation.

7.1.3. Predicted Environmental Concentration (PEC)

Predicted Environmental Concentrations (PECs) for ocean and river have been calculated assuming up to 0.375% of notified chemical may accidentally be released to the aquatic compartment due to equipment cleaning at the reformulation site based in Victoria. Based on SimpleTreat calculations (European Commission, 2003) it was assumed that 72% of the notified chemical would be removed from effluent in sewage treatment plants (STPs) due to partitioning to sludge (17%) and degradation (55%). It was also assumed that release of the notified chemical occurred over 260 days per annum.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	< 0.375%	
Annual quantity of chemical released to sewer	< 375	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	< 1.44	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	358	ML/day
Removal within STP	72%	
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	< 1.13	µg/L
PEC - Ocean:	< 0.113	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 6.85 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.046 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 0.23 mg/kg and 0.46 mg/kg, respectively.

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 1.13 µg/L may potentially result in a soil concentration of approximately 7.52 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 37.6 µg/kg and 75.2 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the analogue chemical, which contains the same reactive functional group as the notified chemical, are summarised in the table below. Details of the acute toxicity studies were reported in a publication by OECD.

The analogue chemical nominated by the notifier has significantly different physico-chemical properties to the notified chemical, with a log Pow of 2.38 and water solubility of 2,000 mg/L compared to a log Pow of 4.30 and water solubility of 64 mg/L measured for the notified chemical. Since the bioavailability and ecotoxicity of organic chemicals is known to be dependent on these properties, the ecotoxicity endpoints were compared with those calculated by ECOSAR v1.00 (US EPA 2011) using the class specific to the notified chemical, and are tabulated below. The notified chemical was within the domain of the ECOSAR class utilised.

The notified chemical belongs to a group of chemicals with demonstrated acute and chronic aquatic toxicity. Measured ecotoxicity endpoints from analogues have been found to be consistent with ECOSAR calculations, and hence ECOSAR is deemed reliable for providing an indication of ecotoxicity for this group of chemicals. Therefore, the calculated data determined for the notified chemical were considered to be more indicative of the acute toxicity of the notified chemical than simple read-across from measured analogue data. The measured log Pow was used in the ECOSAR calculations as it was deemed to be reliable data.

Endpoint	*Result*	*Assessment Conclusion*
Acute - Analogue Data		
Fish Toxicity	LC50 (96 h) 2.1 mg/L	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 8.2 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	E_rC50 (72 h) = 2.6 mg/L	Toxic to algae
Inhibition of Bacterial Respiration	NOEC (72 h) ≥ 150 mg/L	Not expected to be inhibitory to microbial activity
ECOSAR (v1.00) Data for the Notified Chemical		
Acute		
Fish Toxicity	LC50 (96 h) = 1.08 mg/L	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 1.88 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 1.30 mg /L	Toxic to algae
Chronic		
Fish Toxicity	ChV (30 d) = 0.014 mg/L	Potentially toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 0.036 mg/L	Potentially toxic to aquatic invertebrates with long lasting effects
Algal Toxicity	ChV = 0.216 mg/L	Potentially harmful to algae with long lasting effects

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is considered to be acutely toxic to fish, aquatic invertebrates and algae. Based on the predicted acute toxicity to fish 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 ECx) endpoints, whereas the available endpoints are chronic values [ChV = $(LOEC \times NOEC)^{½}$], 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 potentially toxic to fish and aquatic invertebrates, and potentially harmful to algae. Therefore, based on its predicted chronic toxicity fish and aquatic invertebrates (i.e. NOEC < 0.032 mg/L and NOEC < 0.085 mg/L, respectively) and expected rapid degradability, it is at best formally classified under the GHS as "Chronic category 2; 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 (ChV = $(LOEC \times NOEC)^{½}$) for three trophic levels are available, these chronic endpoints are greater than the no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (Fish, 30 d)	< 0.014	mg/L
Assessment Factor	50	
PNEC:	< 0.28	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	< 1.13	< 0.28	4.03
Q - Ocean	< 0.113	< 0.28	0.403

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be > 1 based on the above calculated

PEC and PNEC values. However, the notifier states that the notified chemical potentially released due to equipment cleaning will be collected and sent to a licensed chemical waste disposal company. Therefore, as wastes are expected to be collected and disposed of to landfill, and there is no expected aquatic exposure, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its assessed use pattern. To ensure the notified chemical does not pose an unreasonable risk to the environment, all measures should be taken to ensure the notified chemical is not released to sewers or surface waters.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.064 g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Flask Method
Test Facility Intertek (2012)

Hydrolysis as a Function of pH $t_{½}$ = 116 hours at 25 °C (pH 9)
> 1 year at 25 °C (pH 4 and 7)

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	25	> 1 year
7	25	> 1 year
9	25	116 hours

Remarks A preliminary test indicated < 10% degradation after 5 days for the test substance at 50 °C at pH 4 and 7. Greater than 10% degradation was observed for pH 9 under the same conditions. The test substance is therefore stable at pH 4 and 7 under these conditions. A Tier 2 test on the test substance at pH 9 resulted in a hydrolysis rate constant (k) of 0.006 h^{-1} at 25 °C. Therefore, the half-life of the test substance at pH 9 and 25 °C is 116 hours [$t_{½} = \ln 2 \div k$].
Test Facility Intertek (2012)

Partition Coefficient (n-octanol/water) log Pow = 4.302 at 20 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method
Test Facility Intertek (2012)

Dissociation Constant Not determined

Method OECD TG 112 Dissociation Constants in Water.
Remarks The conductometric method was unsuccessful. The test substance did not appear to be ionised in water. This is expected as the notified chemical does not contain ionisable functionality.
Test Facility Intertek (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: Code of Federal Regulations, Title 16, Section 1500.41
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 6
- Vehicle: None, the test substance was administrated directly.
- Observation Period: 72 hours
- Type of Dressing: Occlusive
- Remarks - Method: The test substance was administrated to both intact and abraded skin. The abraded areas were treated with the tip of a scalpel blade to make minor incisions through the stratum corneum. The test substance in the volume of 0.5 ml was applied under 25 × 25 mm^2 gauze pads to the intact and abraded skin sites on each animal and the treatment sites were covered with elastic adhesive dressing backed with waterproof strapping for 24 hours. At the end of the exposure period, the occlusive dressing and gauze pads were removed and the treatment sites were washed with water to remove any residual test substance.

  Test animals were examined in 24 and 72 hours after the exposure and local dermal irritation was assessed using the following numerical system.

  Erythema and eschar scores:

No erythema	0
Very slight erythema	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema to slight eschar	4

  Oedema scores:

No oedema	0
Very slight oedema	1
Slight oedema	2
Moderate oedema	3
Severe oedema	4

RESULTS: The test substance caused well-defined erythema with slight oedema.

Test on Intact Skin

Lesion	*Mean Score**		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	24 h	*72 h*			
Erythema/Eschar	1.83	0.5	2	> 72 h	2
Oedema	1.33	0.5	2	> 72 h	2

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Test on Abraded Skin

Lesion	*Mean Score**		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	24 h	*72 h*			
Erythema/Eschar	2	1.17	2	> 72 h	2
Oedema	1.33	1	2	> 72 h	2

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

- Remarks - Results: A single occlusive application of the notified chemical to intact and abraded rabbit skin for 24 hours elicited well-defined dermal irritation. The Primary Irritation Index (PII) was calculated to be 2.4.

CONCLUSION	The notified chemical is moderately irritating to the skin.
TEST FACILITY	Huntingdon (1998)

BIBLIOGRAPHY

Chemicalia (2012) Light Acrylate DHG-AT, Explosive Properties and Oxidising Properties (Liquids), 13 July 2012, Mount Waverley, Australia, Chemicalia Pty Ltd (Unpublished report submitted by the notifier).

European Commission (2003), Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part II. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities. <http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd>.

Huntingdon (1998) [Notified Chemical] Skin Irritation to the Rabbit (Study No. KYO 13/940499/SE, February 1998). East Millstone, New Jersey, USA, Huntingdon Life Science Ltd (Unpublished report submitted by the notifier).

Intertek (2012) Analytical Report: Analysis of Acrylate to OECD guidelines (Study No. AU720-0008985/12, June, 2012). West Footscray, Victoria, Australia, Intertek Probe (Unpublished report submitted by the notifier).

Johannsen, F. R.; Vogt, B.; Waite, M.; Deskin, R. (2008) Mutagenicity assessment of acrylate and methacrylate compounds and implications for regulatory toxicology requirements. Regulatory Toxicology and Pharmacology, 50: 322-335.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) (2007) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia.

Patty's Toxicology (2012) Bingham, E. and Cohrssen, B. (eds.) Patty's Toxicology: Volume 4 (Chapter 57). 6th ed. New York: John Wiley Sons, 1999-2012.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington. http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf, accessed 2012, December 5.

US EPA (2011) Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington DC, USA, <http://www.epa.gov/oppt/exposure/pubs/episuite.htm >. Accessed 2012, October 16.