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April 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Acrylate SR341

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 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.

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

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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/1493	Arkema Pty Ltd Canon Australia Pty Ltd and Fujifilm Australia Pty Ltd	Acrylate SR341	Yes	≤ 20 tonnes per annum	Component of inks and overprint vanishes

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*
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
R36: Irritating to eyes
R38: Irritating to skin

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 1)	H400 – Very toxic to aquatic life
Chronic (Category 1)	H410 – Very toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended PPE is used and engineering controls are in place to limit exposure, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Eye Irritation (Category 2): H319 – Causes serious eye irritation
  - Skin Irritation (Category 2): H315 – Causes skin irritation

- Classification of products/mixtures containing the notified chemical should be considered based on the concentration of the notified chemical present.

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosed, automated processes, where possible
  - Good general ventilation
  - Local exhaust ventilation if aerosols are generated

- 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 contact with skin and eyes
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment 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 and end-users to minimise environmental exposure during transport and use of the notified chemical:
  - Notified chemical 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 and/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 carcinogenicity and sensitisation potential of the notified chemical;
- the notified chemical 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 inks and overprint vanishes, 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 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(S)
Arkema Pty Ltd (ABN: 44 000 330 772)
Suite 103
313 Canterbury Road
Canterbury VIC 3126

Canon Australia Pty Ltd (ABN: 66 005 002 951)
1 Thomas Holt Drive
North Ryde NSW 2113

Fujifilm Australia Pty Ltd (ABN: 80 000 064 433)
114 Old Pittwater Road
Brookvale NSW 2100

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, use details and import volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SR341

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow liquid (notified chemical); colourless liquid (analogue chemical)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	7.8 °C	Analogue (M)SDS
Boiling Point	Not determined	May polymerise below the boiling

		point
Density	1201.9 kg/m^3 at 20 °C	Analogue (M)SDS
Vapour Pressure	6 x 10^{-5} kPa at 20 °C	Analogue (M)SDS
Water Solubility	541 mg/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality. However, significant hydrolysis is not expected at environmental pH (4-9).
Partition Coefficient (n-octanol/water)	log Pow = 2.76	Measured
Adsorption/Desorption	log K_{oc} = 2.46	Calculated (KOCWIN v2.00; US EPA 2009).
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	> 110 °C	(M)SDS
Autoignition Temperature	235 °C	Analogue (M)SDS
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
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemical is expected to be stable under the recommended conditions of storage, in the presence of an inhibitor. It is intended to react as part of the ink curing process. The (M)SDS of the notified chemical recommends against contact with heat, sparks or flames, acids, bases, and oxidising and reducing agents.

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 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 in UV-cured inks at up to 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5-20	5-20	5-20	5-20	5-20

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Arkema Pty Ltd
Canon Australia Pty Ltd
Fujifilm Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical as a component of finished ink products (≤ 30%) will be transported in 1L sealed foil pouches.

USE
The notified chemical will be used as an ingredient in UV-cured ink and overprint varnish for large-format commercial printers using various substrates including plastic (e.g. Perspex), vinyl, cloth and paper.

OPERATION DESCRIPTION

The chemical will not be manufactured, reformulated or repackaged in Australia. The inks containing up to 30% of the notified chemical will be used in commercial printers.

The printing process will be automated. Ink pouches will be manually connected to the printing machine via ink ports and the ink is automatically pumped to the printing head. Print operators monitor the operation and attend to any substrate jams. After printing, the notified chemical will be fixed (UV-cured) with other ink ingredients onto the substrate matrix. Any residual ink within the printing equipment will be wiped clean using rags and solvents. Used rags and dirty solvents will be disposed of by the printing company through licensed waste disposal contractors.

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	4-8	50
Printer operators	8	200
Service technicians	4	200

EXPOSURE DETAILS
Dermal exposure of transport, warehousing and wholesale workers to the imported notified chemical will occur only in the event of an accident where the packaging is breached.

Dermal exposure is the most likely route of exposure in service technicians as they will come in contact with the notified chemical during maintenance. Inhalation exposure is unlikely due to the low vapour pressure of the notified chemical. Printer maintenance personnel will wear disposable gloves and safety glasses.

There is limited exposure of the notified chemical expected of printer operators because of the automated printing process. Dermal and ocular exposure may occur during operation in the event of ink leakage. Inhalation exposure will be limited due to the low vapour pressure of the notified chemical and because of good general ventilation employed in areas surrounding printing machines to remove solvents and other airborne ink components.

After printing and curing, the ink containing the notified chemical will be fixed (UV-cured) onto the substrate and will therefore not be bioavailable.

6.1.2. Public Exposure
The inks containing the notified chemical will not be sold for public use. After application onto the substrate and cured, the notified chemical is expected to remain bound to the cured print matrix, making it unavailable to the public.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified chemical. The results from toxicological investigations conducted on an analogue chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, combined repeat dose oral toxicity with reproductive/developmental screen – 28/52 days	NOAEL systemic toxicity = 250 mg/kg bw/day NOAEL reproductive toxicity = 750 mg/kg bw/day* NOAEL neonatal toxicity = 750 mg/kg bw/day
Rat, reproduction/developmental toxicity screening test	NOAEL = 750 mg/kg bw/day

* NOAEL for reproductive toxicity was based on the combined results of this study and the follow-up study that is also listed in the table.

Toxicokinetics.
Based on the low molecular weight (< 500 Da) and partition coefficient (log Pow = 2.76) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. The expected irritant effects of the notified chemical may increase the dermal absorption potential. Oral and respiratory absorption may occur through micellular solubilisation.

Acrylates and methacrylates are detoxified predominantly via conjugation with glutathione via the Michael addition reaction or glutathione-S-transferase. They are also likely to be hydrolysed via carboxylesterases. The lower molecular weight esters, such as the notified chemical, are expected to be rapidly metabolised and eliminated, therefore, not likely to cause cumulative toxicity (Patty's Toxicology, 2012).

Acute toxicity.
The notified chemical is expected to be of low acute toxicity *via* the oral and dermal routes based on information available for an analogue chemical (Andrews & Clary, 1986; Lewis, 1996).

Irritation and sensitisation.
The notified chemical is expected to have irritation and sensitisation potential, based on an analogue and the general characteristics of the chemical group. It contains the acrylate functional group that has been associated with irritation and skin sensitisation effects (US EPA, 2010). The analogue chemical is classified as irritating to eyes and skin (HSIS, 2014). Multifunctional acrylates (MFAs) including diacrylates were considered to be skin and eye contact hazards following single or repeated exposures (Andrews & Clary, 1986). Chronic inhalation of acrylic acid esters can lead to tissue changes or lesions due to local irritant or inflammatory reactions (Patty's Toxicology, 2012).

The analogue chemical is classified as a skin sensitiser (HSIS, 2014). The analogue chemical was found to be sensitising in older studies in guinea pigs (Parker, 1983; Bjorkner, 1984). The US EPA identified concerns for sensitization for the notified chemical, based on SAR analysis of test data on analogous acrylates (US EPA Federal Register, 2012).

Some case reports of skin sensitisation by the analogue chemical after accidental or occupational exposure have been reported (Contact Dermatitis, 1992; Australas J Dermatol, 2000). Delayed irritation from the analogue chemical, without incidences of contact sensitisation, was also reported (Contact Dermatitis; 1979).

Repeated dose toxicity
In a 28/52-day combined repeat dose and reproduction/developmental gavage study in rats for the analogue chemical, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was established as 250 mg/kg bw/day, based on reduced mean body weights and body weight gains in the 750 mg/kg bw/day group males and adverse changes in serum chemistry parameters associated with increased liver weights in the 750 mg/kg bw/day group males and females.

Patty's Toxicology (2012) states that following subchronic exposures to excessive concentrations of the analogue chemical, the reported effects from the pathology include pulmonary congestion or haemorrhage and cloudy swelling and organ weight changes of the liver and kidney.

Toxicity for Reproduction
Information on the reproductive toxicity of the notified chemical is not available. In a 28/52-day combined repeat dose and reproduction/developmental gavage study in rats using the analogue chemical, the NOAEL for neonatal toxicity was established as 750 mg/kg bw/day, the highest dose tested, based on the absence of effects on the general physical condition of the F_1 pups. The NOAEL for reproductive toxicity was established as 750 mg/kg bw/day, based on the combined results of this 28/52-day study and a follow-up study using a higher number of animals.

In older studies reported by Andrews and Clary (1986), multi-functional acrylates including the analogue chemical were screened for fetotoxic or teratogenic potential in the rat following dermal exposure. In the study, doses were selected based on a preliminary dermal maternal toxicity screen. The object of the preliminary screen was to establish a dose at which slight maternal toxicity (e.g., decreased weight gain) would be expected. In the teratology screen, 20 pregnant rats were given a single dose of test substance during day 6-15 of gestation. Maternal and fetal observations included number of implantations, number of live and dead fetuses, number of early and late sorptions, and number of copora lutea, as well as external, skeletal, and visceral evaluation of

fetuses for malformations. The analogue chemical was not fetotoxic or teratogenic at a clearly maternally toxic dose.

Mutagenicity/Genotoxicity.
Genotoxicity studies were not submitted for the notified chemical. The results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen, 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. The limited available information does not raise a strong suspicion of genotoxicity for the notified chemical; however, this cannot be ruled out.

Carcinogenicity
The analogue chemical showed no increase incidence of skin or visceral tumors (although acanthosis and fibrosis were frequently present) in a chronic dermal study (Andrews & Clary, 1986). However, based on SAR analysis of test data on analogous acrylates, US EPA identified concerns for carcinogenicity (US EPA, 2012a).

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*
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation

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(s):
R36: Irritating to eyes
R38: Irritating to skin

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical has not been tested for any toxicological properties, however based on analogue data it is likely to be a skin and eye irritant and a potential skin sensitiser. Long-term adverse effects from exposure cannot be ruled out.

Printer operators may be at risk of irritating and potentially sensitising effects when handling the formulated inks containing the notified chemical at up to 30% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes, good general ventilation and the use of PPE including coveralls, impervious gloves and goggles. If aerosols were generated during production or cleaning processes, exhaust ventilation or respiratory protection would be needed to avoid inhalation exposure. Provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health
The notified chemical will be used in industrial settings only and will not be sold to the public. The public may come into contact with the printed articles containing the notified chemical. However, once the notified chemical is cured, it will be bound within a solid matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of industrial printing inks. As manufacturing and reformulation will take place overseas, no release of the notified chemical is expected in Australia from these activities.

RELEASE OF CHEMICAL FROM USE

The majority of the release of the notified chemical to the environment from use will be from ink spills, cleaning of printing equipment and from disposal of empty containers containing residual ink. The notified chemical is likely to be stable within an inert matrix on printed substrate once UV-cured. A maximum of 2% of ink is estimated to be released from equipment cleaning. This material will be wiped off the equipment using cloth which is expected to be disposed of to landfill. Up to 1% of ink is estimated to be released from spills. However, spilled notified chemical is likely to polymerise on exposure to UV light.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical will be used in inks for printing on non-recyclable materials and is expected to share the fate of the printed articles which are expected to be disposed of to landfill. A minor amount of ink containing notified chemical (up to 5%) will be used for paper printing. Of the 5% notified chemical applied to paper, half of this amount is expected to be recycled. Residues in empty containers will comprise up to 1% of annual ink import volume and the containers are expected to be disposed to landfill. Formulated ink products will not be released directly to the environment. Hence, the total import volume of the notified chemical will predominately be disposed of to landfill with a minor amount potentially reaching the sewer in a cured form via the paper recycling process.

7.1.2. Environmental Fate

Notified chemical applied to substrates will be UV/EB cured (chemically reacted) 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.

A calculated ready biodegradability (BIOWIN v4.1 US EPA 2011) of the notified chemical indicated that it is readily biodegradable. Therefore the notified chemical is likely to be rapidly degradable and is not expected to persist in the environment. This is supported by biodegradation data for similar chemicals, which shows that low molecular weight chemicals, belonging to the same chemical class as the notified chemical, are expected to rapidly degrade in the environment.

Approximately half of the paper to which the ink containing the notified chemical is applied will 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. However, the notified chemical is UV/EB cured (chemically reacted) into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified chemical is anticipated to sorb to sludge and sediment where it is expected to degrade biotically and abiotically. The measured n-octanol/water partition coefficient (log Pow) for the notified chemical is 2.76 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 that 2.5% of notified chemical will reach the aquatic compartment due to paper recycling. Based on SimpleTreat (EC, 2003) calculations it was assumed that 88% of the notified chemical would be removed from effluent in sewage treatment plants (STPs) primarily due to degradation in sludge. It was also assumed that release of the notified chemical occurred over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	88%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	

Dilution Factor - Ocean	10.0	
PEC - River:	0.05	µg/L
PEC - Ocean:	0.005	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 0.149 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 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.001 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 0.005 mg/kg and 0.01 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.051 µg/L may potentially result in a soil concentration of approximately 0.34 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 1.7 µg/kg and 3.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

As the notified chemical belongs to a group of chemicals that have a demonstrated acute and chronic toxicity to aquatic organisms, endpoints were calculated by ECOSAR (v1.11, US EPA 2012) and used to provide representative endpoints in the absence of measured data on the notified chemical. The ecotoxicological endpoints calculated by ECOSAR were utilised to determine the GHS rating and derive the Predicted No-Effect Concentration (PNEC) below.

Endpoint	Result	Assessment Conclusion
ECOSAR (v1.11) data for the notified chemical		
Acute		
Fish Toxicity	LC50 (96 h) = 1.77 mg/L	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 2.641 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 0.406 mg /L	Very Toxic to algae
Chronic		
Fish Toxicity	ChV (30 d) = 0.004 mg/L	Very toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 0.117 mg/L	Potentially harmful to aquatic invertebrates with long lasting effects
Algal Toxicity	ChV = 0.144 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 and algae, and very toxic to aquatic invertebrates. Based on the predicted acute toxicity to fish and algae the notified chemical is formally classified under the GHS as “Acute category 1; Very 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 [ChV = (LOEC × 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 very toxic to fish, potentially harmful to aquatic invertebrates and potentially harmful to algae. Therefore, based on its predicted chronic toxicity to fish (i.e. NOEC < 0.004 mg/L) and in the absence of ready biodegradability data, it is formally classified 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 (ChV = (LOEC × NOEC)^{½}) 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)	0.004	mg/L
Assessment Factor	50	
PNEC:	0.08	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.05	0.08	0.63
Q - Ocean	0.005	0.08	0.063

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC values. The Q value of < 1 indicates the notified chemical is not expected to pose an unreasonable risk to the aquatic environment from its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 541 mg/L at 20 °C

Method OECD TG 105 Water Solubility. Slow Stir Method.

Remarks As per the above guideline, the column elution method and the flask method cover the solubility of substances below and above 10^{-2} g/L. However, the notifier has used a slow stir method which is not described in the guideline and thus no validity criteria were described. However, The concentrations measured in the two flasks did not differ by more than 15%.

Two flasks were used for the test. Pure water (650 mL) was poured into the flasks. Test substance (20 mL) was gently poured to the bottom of each flask. The mixture was stirred under a slow speed. Samples of water phase was taken from each flask over 4 days period.

Test Facility Arkema (2013a)

Partition Coefficient (n-octanol/water) log Pow = 2.76 at 55 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water). HPLC Method.
.

Remarks The test was conducted according to the guidelines above using good laboratory practice (GLP). Test substance (38.5 mg) was accurately weighed and dissolved with 20 mL of methanol. It was observed that the test substance was sufficient to ensure a total solubilisation. All the validity criteria were met.

Test Facility Arkema (2013b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Repeat dose toxicity, with reproduction/developmental toxicity screening

TEST SUBSTANCE	Analogue Chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: ≥ 28 days, up to 52 days Dose regimen: 7 days per week
Vehicle	Corn oil
Remarks - Method	Dose levels were selected based on the results of a previous repeated dose-range-finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	12 males and 12 females	0	None treatment related
low dose	12 males and 12 females	75	None treatment related
mid dose	12 males and 12 females	250	None treatment related
high dose	12 males and 12 females	750	None treatment related

Mortality and Time to Death

There were no treatment-related unscheduled deaths during the study.

Clinical Observations

Statistically significant reductions in mean body weight gain and food consumption were noted in the 750 mg/kg bw/day group males during the pre-mating period, resulting in a mean body weight that was 6.8% lower (not statistically significant) than the control group on study day 28. No other differences in mean body weights, body weight gains or food consumption at any dosage level when compared to the control group were considered indicative of parental toxicity.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no treatment-related alterations in haematological, coagulation and urinalysis parameters measured at any dosage level. Statistically significant changes in serum chemistry parameters were noted in urea nitrogen and bile acids for males and in cholesterol, calcium and phosphorus levels in females at the dosage level of 750 mg/kg bw/day. Increases (not statistically significant) at this dose level were also seen in total bilirubin in males and in urea nitrogen, alanine aminotransferase, bile acids and triglycerides in females.

Effects in Organs

Treatment-related findings included micro- to macrovesicular vacuolar change within the liver at dosage levels of 75, 250 and 750 mg/kg bw/day in a dose-related manner. This change was also present within the liver of 3 control group animals (2F and 1M). The change in all these animals was minimal to mild and there was no evidence of cellular or tissue damage; therefore, the change was not considered by the study authors to be an adverse effect.

Treatment-related squamous epithelial hyperplasia and hyperkeratosis in the non-glandular stomach were noted to males and females at dosage levels of 250 and 750 mg/kg bw/day. This was considered to be a manifestation of local irritation rather than a systemic effect.

Reproductive/Developmental Toxicity

Mean reproductive indices were generally comparable to control group values at all dosage levels. However, the occurrence of high-dose group females with only 1 implantation site was much greater than the historical occurrence of 1 implantation site in control group females from development and reproductive toxicity studies conducted in the test facility.

The mean number of corpora lutea in the 750 mg/kg bw/day group was lower (though not statistically

significantly) compared to the control group.

In a follow-up screening study (WIL, 2012b) with larger group sizes, no differences in the mean numbers of corpora lutea or implantation sites were observed at a dosage level of 750 mg/kg bw/day. Given that the effects were not replicated, the lower numbers of corpora lutea and implantation sites in this study were not considered by the study authors to be test substance-related. The study report was revised to include this information.

Remarks – Results
Dose-related incidents of clinical findings indicative of aversion to test substance administration were noted prior to, at the time of, or approximately 1 hour following dose administration throughout the treatment period mainly at dosage levels of 250 and 750 mg/kg bw/day. However, some of these findings were attributed to the irritative properties of the test substance and were not considered adverse. Treatment-related significant changes considered to be systemically adverse are noted above.

CONCLUSION
The no-observed-adverse-effect level (NOAEL) for reproductive toxicity was established by the study authors as 750 mg/kg bw/day, based on the combined results of this study and the follow-up study (WIL, 2012b).

The NOAEL for systemic toxicity was established as 250 mg/kg bw/day, based on reduced mean body weights and body weight gains in the 750 mg/kg bw/day group males and adverse changes in serum chemistry parameters associated with increased liver weights in the 750 mg/kg bw/day group males and females.

The NOAEL for neonatal toxicity was established as 750 mg/kg bw/day, based on the absence of effects on the general physical condition of the F_1 pups.

TEST FACILITY WIL (2012a)

B.2. Reproduction/Developmental toxicity

TEST SUBSTANCE Analogue Chemical

METHOD OECD TG 421 Reproduction/Developmental Toxicity Screening Test (partial only).

Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage/diet/drinking water
Exposure Information	Exposure days: ≥ 28 days, up to 46 days
Vehicle	Corn oil
Remarks - Method	The study was designed to evaluate specific reproductive parameters. Females were euthanized before delivery, on gestation Day 20. No histopathology of reproductive or other organs was carried out. The dose level was determined based on the results of a previous combined repeated dose with reproduction/developmental toxicity screening study (WIL, 2012a). In the previous study, there was an equivocal effect on the process of implantation at 750 mg/kg bw/day. The current study was performed to obtain additional information at dosage level of 750 mg/kg bw/day, using a larger number of animals per group.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	25M, 25F	0	None
treatment	25M, 25F	750	None

Mortality and Time to Death
All animals survived to the scheduled necropsies.

Effects on Parental Animals
Treatment-related lower mean body weight gains were noted for males. Corresponding lower food consumption was noted in the treatment group following the first week of dosing but was similar to the control group

thereafter.

For females, mean body weights and body weight gains were unaffected by treatment during the pre-mating period but during gestation, treatment-related lower mean body weight gains were noted during the latter portion of the gestation. However, mean body weights in the group were similar to the control group throughout the gestation. Mean food consumption in the treatment group was unaffected by the treatment during the pre-mating and gestation periods and mean gravid uterine weight in the treatment group was similar to the control group value.

Male and female mating and fertility, male copulation and female conception indices were unaffected by the treatment. All females were found to be gravid, except one animal in the treatment group. A shorter mean pre-coital interval in the 750 mg/kg bw/day (test) group was attributed to a higher value in the control group.

A thickened portion of the non-glandular stomach was noted in males and females in the treatment group. However, this finding was considered to be of a manifestation of local irritation rather than a systemic effect. Other macroscopic changes either were present at similar incidences in control and test animals or occurred in a single animal. The latter included one animal with small testes.

Gestation data

No statistically significant changes were seen in parameters related to inter-uterine survival. Pre- and post-implantation losses were slightly higher in the test group; however, the changes were not statistically significant.

CONCLUSION

The no-observed-adverse-effect level (NOAEL) for reproductive/developmental toxicity was established as 750 mg/kg bw/day.

TEST FACILITY WIL (2012b)

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