File No: STD/1431
STD/1432

December 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1431 Acrylate Ester 1 in HP Scitex UV Curable Inks
STD/1432 Acrylate Ester 2 in HP Scitex UV Curable Inks

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANTs	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1431 STD/1432	Hewlett Packard Australia Pty Ltd & Brenntag Australia Pty Ltd	STD/1431: Acrylate Ester 1 in HP Scitex UV Curable Inks STD/1432: Acrylate Ester 2 in HP Scitex UV Curable Inks	Yes	STD/1431: ≤ 20 tonnes per annum STD/1432: ≤ 20 tonnes per annum	Component of industrial printing inks

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemicals are 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 chemicals are 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.

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

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemicals should be classified as follows:
  - 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.

- The following should be used for products/mixtures containing the notified chemicals:
  - Conc. ≥ 10%: H315, H317, H319, H335
  - ≥ 1% Conc. < 10%: H317.

Health Surveillance

As the notified chemicals are skin sensitisers, 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.

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 chemicals:
  - Ventilation system including local exhaust ventilation
  - Use of enclosed, automated processes, where possible

- 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 chemicals:
  - Avoid contact with eyes and skin
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment promptly

- 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 chemicals:
  - impervious gloves
  - goggles
  - protective clothing
  - respiratory protection, if ventilation is inadequate

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemicals 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.

Disposal

- The notified chemicals should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemicals 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 chemicals are 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(2) of the Act; if
- the function or use of the chemicals has changed from a component of industrial printing inks, or is likely to change significantly;
- the amount of either chemical being introduced has increased from 20 tonnes per annum, or is likely to increase, significantly;
- any of the chemicals have begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemicals 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 a product containing the notified chemicals provided by the notifier was 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

APPLICANTS
Hewlett Packard Australia Pty Ltd (ABN: 74 004 394 763)
353 Burwood Highway
FOREST HILL VIC 3131

Brenntag Australia Pty Ltd (ABN: 84 117 996 595)
260-262 Highett Road
HIGHETT VIC 3190

NOTIFICATION CATEGORY
STD/1431: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that was previously assessed by NICNAS.

STD/1432: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

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, impurities, use details, import volume and analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical, toxicity and ecotoxicity endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANTS
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAMES
STD/1431: Acrylate Ester 1 in HP Scitex UV Curable Inks
STD/1432: Acrylate Ester 2 in HP Scitex UV Curable Inks

MOLECULAR WEIGHT
< 500 Da (STD/1431 & STD/1432)

ANALYTICAL DATA
Reference IR and GC/FID spectra were provided.

3. COMPOSITION
The notified chemicals are part of an inseparable reaction mixture, containing Acrylate Ester 1 (STD/1431) and Acrylate Ester 2 (STD/1432) at < 45% and < 55%, respectively.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquids.

Property	Value		Data Source/Justification
	STD/1431	STD/1432	
Melting Point	0.39 °C	22 °C	Calculated (MPBPVP v1.43; US EPA, 2009)
Boiling Point	228 °C	264 °C	Calculated (US EPA Episuite, 2009)
Density*	880 kg/m^3 at 20 °C	880 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	1.14×10^{-2} kPa at 25 °C	1.74×10^{-3} kPa at 25 °C	Calculated (MPBPVP v1.43; US EPA, 2009)
Water Solubility	1.45×10^{-2} g/L at 20 °C	1.52×10^{-3} g/L at 20 °C	Calculated (MPBPVP v1.43; US EPA, 2009)
Hydrolysis as a Function of pH	Not determined	Not determined	The notified chemicals contain hydrolysable functional groups. Hydrolysis expected to be slow at environmental pH 4-9.
Partition Coefficient (n-octanol/water)	log Pow = 4.17	log Pow = 5.15	Calculated (KOWWIN v1.67; US EPA 2009)
Adsorption/Desorption	log K_{oc} = 3.16	log K_{oc} = 3.71	Calculated (KOCWIN v2.00; US EPA 2009)
Dissociation Constant	Not determined	Not determined	The notified chemicals contain no dissociable functionality.
Particle Size	Not determined	Not determined	The notified chemicals are liquids.
Flash Point*	> 100°C	> 100°C	(M)SDS
Flammability	Not determined	Not determined	Not expected to be flammable based on flash point.
Autoignition Temperature	Not determined	Not determined	Not expected to undergo autoignition.
Explosive Properties	Not determined	Not determined	Not expected to be explosive - does not contain explosophers.
Oxidising Properties	Not determined	Not determined	Not expected to oxidise

* For mixture containing notified chemicals at < 45% (STD/1431) and < 55% (STD/1432).

DISCUSSION OF PROPERTIES
No physico-chemical data were submitted for the notified chemicals.

Reactivity
The notified chemicals are stable in the presence of an inhibitor. The notified chemicals are intended to react in end-use. High temperatures, inhibitor depletion, accidental impurities, or exposure to radiation or oxidising agents may cause spontaneous polymerisation reactions generating heat/pressure. Closed containers may rupture or explode during runaway polymerisation.

Physical hazard classification
Based on the limited submitted physico-chemical data depicted in the above table, the notified chemicals are 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 chemicals will be imported as a component (up to 10% each) of finished ink products.

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

	Year	*1*	*2*	*3*	*4*	*5*
STD/1431	*Tonnes*	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20
STD/1432	*Tonnes*	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20

PORT OF ENTRY
Sydney and Melbourne.

TRANSPORTATION AND PACKAGING
The ink products containing the notified chemicals at < 10% concentration (for each notified chemical) will be imported in 5 kg bottles (inkjet inks) or 10 kg plastic buckets (flexographic and lithographic inks) and will be transported from the port of entry to the notifiers' warehouse facilities by road.

USE
The notified chemicals will be used as a component of ultra-violet/electron beam (UV/EB) cured ink products for inkjet, flexographic and lithographic printing.

OPERATION DESCRIPTION
No reformulation or repackaging of the notified chemicals will occur in Australia.

The bottles/buckets containing the notified chemicals at < 10% concentration (for each notified chemical) will be delivered to the end-user in the same form in which they are imported. Ink bottles will be manually connected to the printing machine via an inlet and attached to a flexible tube which supplies the ink head. The ink bottles/buckets will be connected to printers by printer operators and service technicians. Printing will be largely enclosed and automated. Exhaust ventilation will be fitted to the machines to remove airborne ink components.

Residual ink containing the notified chemicals within printing equipment will be removed using cleaning cloths and solvents. Waste materials containing the notified chemicals will be disposed 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
Quality control/chemists/technical service	0.5-6	25
Printer operators	1-2	25
Service technicians	8	200
Wholesale printer supplies	8	200

EXPOSURE DETAILS
Transport and storage workers are unlikely to be exposed to either of the notified chemicals (at < 10% concentration) except in the event of an accident.

The printing process will be largely enclosed and automated; however, workers may be exposed to ink products during certain procedures.

Dermal, ocular and perhaps inhalation exposure to the notified chemicals may occur during: the replacement of ink bottles (operators); the colour matching process (operators); ink quality control operations (by chemists/technical service staff); maintenance and service tasks (service technicians).

Once the inks are cured and dried, the notified chemicals will be bound within a polymer matrix and will not be bioavailable.

Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure will be minimised by the use of local exhaust ventilation in areas around the printing machines.

6.1.2. Public Exposure
The ink products containing the notified chemicals (at < 10% concentration for each notified chemical) are intended for use in industrial situations and will not be sold to the public. The public may come into contact with the inks containing the notified chemicals after application to substrates. However, once the inks are cured and dried, the notified chemicals will be bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on analogues of the notified chemicals are summarised in the table below.

Endpoint	*Result and Conclusion*				
	Analogue 1	Analogue 2	Analogue 3	Analogue 4	Analogue 5
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 3000 mg/kg bw; low toxicity	LD50 > 9000 mg/kg bw; low toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 8000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 7500 mg/kg bw; low toxicity	LD50 > 1500 mg/kg bw; low toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 5000 mg/kg bw; low toxicity	LD50 > 2500 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 1.4 mg/L/8 hour;	LC50 > 10.3 mg/L/4 hour;	LC50 > 30 mg/L/4 hour;	-	-
Rabbit, skin irritation Rabbit, eye irritation	severely irritating irritating	- -	moderate irritating moderate irritating	slightly irritating slightly irritating	- -

Endpoint	*Result and Conclusion*				
	Analogue 1	Analogue 2	Analogue 3	Analogue 4	Analogue 5
Guinea pig, skin sensitisation	evidence of sensitisation	-	evidence of sensitisation	no evidence of sensitisation	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation	weak sensitiser	evidence of sensitisation	-	-
Rat, repeat dose inhalation toxicity – 90 days.	NOAEL = 23 mg/kg bw/day. LOAEL = 0.225 mg/L (68 mg/kg bw/day)	NOAEL = 84 (male) and 111 (female) mg/kg bw/day	-	-	-
Mutagenicity – bacterial reverse mutation	non mutagenic	non mutagenic	non mutagenic	non mutagenic	-
Genotoxicity – in vitro mammalian chromosomal aberration test	non genotoxic	-	-	-	-
Genotoxicity – in vivo cytogenetic assay - clastogenicity	non genotoxic	-	-	-	-
Carcinogenicity	evidence of carcinogenicity through dermal route (>21%)	no evidence of carcinogenicity	no evidence of carcinogenicity	no evidence of carcinogenicity	-

Toxicokinetics, metabolism and distribution.
Based on the calculated water solubilities (14.54×10^{-3} and 1.52×10^{-3} g/L at 20 °C), partition coefficients (log P_{ow} = 4.17 and 5.15) and the low molecular weights (< 500 Da) of the notified chemicals, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur (the expected irritant effects of the notified chemicals may increase the dermal absorption potential). The notified chemicals may also be absorbed across the respiratory tract.

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 chemicals, are rapidly metabolised and eliminated, therefore will not likely cause cumulative toxicity (Patty's Toxicology, 2012).

Acute toxicity.
Overall, the results of studies conducted on the analogue chemicals indicate that they are of low acute oral, dermal and inhalation toxicity. Therefore, based on the available information on the analogue chemicals, the notified chemicals are expected to be of low acute toxicity via the oral, dermal and inhalation routes.

Irritation and Sensitisation.
The results of studies conducted on the analogue chemicals indicate a range in the irritation potential to the skin and eyes, from slightly irritating to severely irritating. In addition, it is noted that 2/5 of the analogue chemicals are classified (HSIS) as irritating to the eyes and 5/5 are classified (HSIS) as irritating to the respiratory system and skin. Based on the available information, the notified chemicals are expected to be irritating to the skin, eyes and respiratory system.

The results of studies conducted on the analogue chemicals indicate evidence of skin sensitisation. Therefore, based on the available information, the notified chemicals have the potential to be skin sensitisers.

Repeated Dose Toxicity.
Following subchronic 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).

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. Therefore, while the notified chemicals may be genotoxic in vitro, based on the available information, they are not expected to be genotoxic in vivo.

Health hazard classification
Based on the available information, the notified chemicals are 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 chemicals are 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
Workers most at risk of exposure to products containing the notified chemicals (at < 10% concentration per chemical) include printer operators, technical staff and service technicians, when conducting manual processes (e.g. replacement of ink bottles, colour matching, quality control and servicing). Exposure is most likely to occur via the dermal route, although ocular and inhalation exposure to the notified chemicals may also occur.

Based on the available information, the notified chemicals are likely to cause skin, eye and respiratory irritation and have the potential to cause skin sensitisation. To minimise occupational exposure to the notified chemicals, PPE should be employed, including impervious gloves, goggles and protective coveralls. In addition, local exhaust ventilation should be employed in the areas surrounding the printers and enclosed/automated processes should be used (where possible), to minimise inhalation exposure of workers to the notified chemicals. Respiratory protection should be worn by workers if local exhaust ventilation cannot be employed and/or the general ventilation is inadequate.

The risk to workers is not considered to be unreasonable if such controls are in place.

6.3.2. Public Health
The products containing the notified chemicals will not be sold to the public. The public may have contact with the dried printed materials. However, once cured, the notified chemicals will be bound within a polymer matrix and will not be bioavailable. Hence, public exposure to the notified chemicals is not expected, and the risk to health of the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemicals will be imported as components of industrial printing inks. As manufacturing and reformulation will take place overseas, no release of the notified chemicals will occur in Australia from these activities. Spills are expected to be collected using inert solids and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the release of the notified chemicals to the environment from use will be from ink spills, wash-downs of printing equipment and from disposal of empty containers containing residual ink. The notified chemicals will be UV-cured and the resultant chemicals are expected to be stable within an inert matrix on the printed substrates. A maximum of 3% of ink was estimated by the notifier to be released to sewer from equipment washing. Any spills of the notified chemicals are likely to polymerise on exposure to UV light.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemicals will be used in inks for printing on vinyl, canvas and plastic packaging. At the end of their useful life, these articles are expected to be disposed of to landfill. Up to 20% of the introduction volume of the notified chemicals is expected to be used for printing onto paper. It is assumed that of that 20%, half (10%) will be disposed of to landfill and half (10%) will undergo paper recycling processes. Remaining residues of the notified chemicals in empty containers are expected to account for 1% of the total import volume of the notified chemicals and are expected to be disposed of to landfill. Hence, the total import volume of the notified chemicals will predominately be disposed of to landfill with a minor amount potentially reaching the sewer.

7.1.2. Environmental Fate

Notified chemicals applied to substrates will be UV/EB cured and are not expected to be bioavailable. Environmental fate studies conducted on an analogue of the notified chemicals indicates that the analogue chemical is readily biodegradable. For the details of the environmental fate studies please refer to Appendix A. The analogue chemical is considered to be acceptable with respect to biodegradation as it has the same functional groups as the notified chemicals and only differs slightly in structure. The notified chemicals also have the potential to undergo hydrolysis in the environment. Therefore, the notified chemicals are likely to be rapidly degradable and are not expected to persist in the environment. The notified chemicals are expected to degrade to form water and oxides of carbon.

Approximately half of the paper to which the ink containing the notified chemicals is applied to will be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks from the fibres. However, the notified chemicals are UV/EB cured into the ink matrix and are unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified chemicals are anticipated to sorb to sludge and sediment where they are expected to degrade biotically and abiotically. The predicted bioconcentration factor (BCF) for the notified chemicals are 10.99 (STD/1431) and 48.88 (STD/1432) L/kg wet-wt (BCFBAF (v3.01); US EPA 2009) indicating that they are unlikely to have a potential for bioaccumulation.

Upon release of the notified chemicals to sewer during equipment cleaning, an estimated 89% of STD/1431 and 92% of STD/1432 entering the sewer is predicted to be removed during sewage treatment plant processes (SimpleTreat; European Commission, 2003). These percentages include 73% (STD/1431) and 45% (STD/1432) removal by degradation and a further 16% (STD/1431) and 47% (STD/1432) removed through partitioning to sludge, before discharge to surface waters on a nationwide basis. Therefore, an estimated 11% of STD/1431 and 8% of STD/1432 released to sewer is expected to remain in surface waters. The notified chemicals are expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The following predicted environmental concentrations (PEC) for ocean and river waters have been calculated assuming that 3% of the notified chemicals will reach the aquatic compartment due to equipment washing. The results for the SimpleTreat (European Commission, 2003) calculations indicated 89% and 92% removal of STD/1431 and STD/1432 respectively in the sewage treatment plant (STP). It was also assumed that release of the notified chemicals occurred over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment			
	STD/1431	**STD/1432**	
Total Annual Import/Manufactured Volume	20,000	20,000	kg/year
Proportion expected to be released to sewer	3%	3%	
Annual quantity of chemical released to sewer	600	600	kg/year
Days per year where release occurs	260	260	days/year
Daily chemical release:	2.31	2.31	kg/day
Water use	200.0	200.0	L/person/day
Population of Australia (Millions)	22.613	22.613	million
Removal within STP	89%	92%	
Daily effluent production:	4,523	4,523	ML
Dilution Factor - River	1	1	
Dilution Factor - Ocean	10	10	
PEC - River:	0.056	0.041	µg/L
PEC - Ocean:	0.0056	0.0041	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4.541 mg/kg and 4.694 mg/kg for STD/1431 and STD/1432 respectively (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 STD/1431 and STD/1432 may approximate 0.030 mg/kg and 0.031 mg/kg in applied soil, respectively. This assumes that degradation of the notified chemicals occurs in the soil within 1 year from application. Assuming accumulation of the notified chemicals in soil for 5 and 10 years under repeated biosolids application, the concentration of STD/1431 in the applied soil in 5 and 10 years may approximate 0.15 mg/kg and 0.30 mg/kg, respectively. The concentration of STD/1432 in the applied soil in 5 and 10 years may approximate 0.16 mg/kg and 0.31 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 chemicals in this volume are 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 0.056 µg/L (STD/1431) and 0.041 µg/L (STD/1432) may potentially result in a soil concentration of approximately 0.374 µg/kg and 0.272 µg/kg for STD/1431 and STD/1432, respectively. Assuming accumulation of the notified chemicals in soil for 5 and 10 years under repeated irrigation, the concentration of STD/1431 in the applied soil in 5 and 10 years may be approximately 1.87 µg/kg and 3.74 µg/kg, respectively. The concentration of STD/1432 in the applied soil in 5 and 10 years may be approximately 1.36 µg/kg and 2.72 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from short term ecotoxicological investigations conducted on an analogue chemical which contains the same reactive functional groups as the notified chemicals are summarised in the table below. Details of these studies can be found in Appendix A.

The notified chemicals belong to a group of chemicals with demonstrated chronic aquatic toxicity. ECOSAR has been deemed reliable for providing an indication of ecotoxicity for this group of chemicals, based on experimental endpoints from several similar chemicals being consistent with calculated data. ECOSAR was used to supplement available chronic toxicity data, fill data gaps and provide a defined endpoint where values were determined to be less than the reported endpoint. The chronic 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*
Acute - Analogue data		
Fish Toxicity	LC50 (96 h) = 0.67 mg/L	Very toxic to fish
Daphnia Toxicity	EC50 (48 h) = 0.40 mg/L	Very toxic to aquatic invertebrates
Algal Toxicity	E_rC50 (96 h) = 2.13 mg/L	Toxic to algae
Chronic – Analogue data		
Daphnia Toxicity (reproduction)	LOEC (21 d) = 0.13 mg/L NOEC (21 d) < 0.13 mg/L NOEC (14 d) = 0.51 mg/L	At best, harmful to aquatic invertebrates with long lasting effects
Algal Toxicity	NOEC (96 h) = 1.70 mg/L	Not classified for long-term hazard
ECOSAR (v1.00) data for STD/1431		
Chronic		
Fish Toxicity	ChV (30 d) = 0.011 mg/L	Potentially toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 0.028 mg/L	Potentially toxic to aquatic invertebrates with long lasting effects
ECOSAR (v1.00) data for STD/1432		
Chronic		
Fish Toxicity	ChV (30 d) = 0.004 mg/L	Very toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 0.011 mg/L	Potentially toxic to aquatic invertebrates with long lasting effects

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemicals are considered to be acutely very toxic to fish and aquatic invertebrates, and toxic to algae. Based on the predicted acute toxicity to fish the notified chemicals are 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 long term 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, STD/1431 is considered to be chronically potentially toxic to fish and aquatic invertebrates and potentially harmful to algae. Therefore, based on its predicted chronic toxicity to fish (i.e. NOEC < 0.011 mg/L) and expected rapid degradability, STD/1431 is formally classified under the GHS as at best "Chronic category 2; Toxic to aquatic life with long lasting effects".

STD/1432 is considered to be chronically very toxic to fish, potentially toxic 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 expected rapid degradability, STD/1432 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 concentrations (PNEC) have been calculated from the estimated chronic fish toxicity of the notified chemicals 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			
	STD/1431	***STD/1432***	
ChV (Fish, 30 d)	0.011	0.004	mg/L
Assessment Factor	50	50	
PNEC:	0.22	0.08	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
STD/1431			
Q - River	0.056	0.22	0.255
Q - Ocean	0.0056	0.22	0.0255
STD/1432			
Q - River	0.041	0.08	0.513
Q - Ocean	0.0041	0.08	0.0513

The risk quotients (Q = PEC/PNEC) for aquatic exposure for the notified chemicals are calculated to be less than 1, based on the above calculated PEC and PNEC values. The Q values of less than 1 indicate the notified chemicals are not expected to pose an unreasonable risk to the aquatic environment from their assessed use patterns.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue Chemical 4
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Unknown
Exposure Period	28 days
Auxiliary Solvent	Unknown
Analytical Monitoring	Unknown
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	72	5	56
15	100	15	74
28	100	28	> 83

Remarks - Results	The reference substance was degraded > 60% by day 14, indicating a valid test. Since the raw data were not available, it was not possible to determine if the other validity criteria were satisfied. However, as the authors of the summary considered the study to be valid without restriction, it is considered that the test was valid.
CONCLUSION	The test substance and, by inference, the notified chemicals are considered to be readily biodegradable.
TEST FACILITY	Exempt Information

A.2. Ecotoxicological Investigations

A.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue Chemical 4
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Flow Through
Species	*Pimephales promelas* (fathead minnow)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	186-187 mg $CaCO_3$/L
Analytical Monitoring	GC/MS
Remarks – Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals. Standard protocol guidelines were followed with no significant deviations reported. The LC50 and NOEC were determined using the trimmed Spearman-Karber method and TOXSTAT, respectively.

RESULTS

Concentration mg/L			*Mortality*					
Nominal	*Mean Measured*	*Number of Fish*	*3 h*	*6h*	*24 h*	*48 h*	*72 h*	*96 h*

0	NC	20	0	0	0	0	0	0
0.35	0.09	20	0	0	0	0	0	0
0.62	0.15	20	0	0	0	0	0	0
1.12	0.34	20	0	0	0	1	1	1
2.01	0.82	20	0	0	0	7	13	13
3.45	1.75	20	0	0	1	20	20	20

NC = not calculated. All measurements of the control sample were <0.04 mg/L, which was the detection limit of the analytical method.

LC50	0.67 mg/L at 96 hours (based on mean measured test concentrations)
NOEC	0.34 mg/L at 96 hours (based on mean measured test concentrations)
Remarks – Results	All validation criteria for the study were satisfied, except that the mean measured concentrations of the test substance were 26-50% of the nominal concentrations. The measured concentrations should preferably be at least 80% of the nominal concentrations. In accordance with test guidelines, the measured concentrations were used to determine the study endpoints.

CONCLUSION The test substance and, by inference, the notified chemicals are considered to be very toxic to fish.

TEST FACILITY Exempt Information

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue Chemical 4

METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	193 - 197 mg $CaCO_3$/L
Analytical Monitoring	Conducted with an unknown method
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals. Standard protocol guidelines were followed with no significant deviations reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*[*]		*24 h*	*48 h*
0	<0.04	20	0	0
0.5	0.24	20	0	5
1.0	0.53	20	2	13
2.0	1.21	20	5	20
4.0	2.78	20	15	20
8.0	7.40	20	20	20

*Mean of the 0, 24 and 48 h concentrations

EC50	0.40 mg/L at 48 hours (based on mean of 0, 24 and 48 h concentrations)
NOEC	< 0.24 mg/L at 48 hours
Remarks - Results	All validation criteria for the study were satisfied.

CONCLUSION The test substance and, by inference, the notified chemicals are considered to be very toxic to invertebrates.

TEST FACILITY Exempt Information

A.2.3. Chronic toxicity to aquatic invertebrates (Study 1)

TEST SUBSTANCE Analogue Chemical 4

METHOD OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)

Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	127 - 170 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method and the EC50 (reproduction)*, was determined using a point estimation technique.

*50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 21			
Concentration (mg/L)		*Cumulative Percentage Immobilised* [a]	*Mean Number of Offspring Released per original female* [d]
Nominal	*Actual* [b]		
0	0	5	162.6
0.25	0.13	5	133.6
0.5	0.29	5	138.6
1	0.51	8	138.4
2	1.06	10	74.9
4	2.40	90[c]	< 1

[a] N=40
[b] Based on measured mean for Day 3, 16 and 21.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.61 mg/L [e]
EC50 (reproduction)	1.02 mg/L [e]
NOEC (immobilisation)	1.06 mg/L [e]
NOEC (reproduction)	< 0.13 mg/L [e]

[e] At 21 d, based on mean measured concentrations

Remarks - Results All validation criteria for the study were satisfied. A reproduction NOEC was not calculated. Therefore based on the LOEC of 0.13 mg/L the NOEC was determined to be < 0.13 mg/L, and hence indicates that the test substance, and by inference the notified chemicals, should be categorised as at least harmful to aquatic invertebrates with long lasting effects. Based on the NOEC result for immobilisation, the test substance, and therefore the notified chemicals, cannot be classified for long-term hazard.

CONCLUSION The test substance and, by inference, the notified chemicals are considered to be at least harmful to aquatic invertebrates with long lasting effects.

TEST FACILITY Exempt Information

A.2.4. Chronic toxicity to aquatic invertebrates (Study 2)

TEST SUBSTANCE Analogue Chemical 4

METHOD OECD TG 202 part 2 "*Daphnia sp.*, Reproduction Test" – Semi Static (1993)

Species	*Daphnia magna*
Exposure Period	14 d
Auxiliary Solvent	None

Water Hardness	128 - 169 mg $CaCO_3$ /L
Analytical Monitoring	Solid/liquid extraction GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals. The EC50 (immobilisation) was determined using the trimmed Spearman-Karber method. The EC50 (reproduction)*, was determined using a point estimation technique.

*50% inhibition of the mean number of young produced per female compared to the control organism reproduction

RESULTS

Test Day 14			
Concentration (mg/L)		*Cumulative Percentage Immobilised*[a]	*Mean Number of Live Young Released per original female*[d]
Nominal	*Actual*[b]		
0	0	3	66.9
0.25	0.11	5	43.2
0.5	0.28	8	52.6
1	0.51	0	59.3
2	1.09	3	28.0
4	2.50	68[c]	< 1

[a] N=40
[b] Mean values from Day 2 initial and Day 3 final measurements.
[c] Value significantly different from the control value at $p \leq 0.05$
[d] Calculated from N=30. First brood released on day 7.

EC50 (immobilisation)	1.99 mg/L [e]
EC50 (reproduction)	0.97 mg/L [e]
NOEC (immobilisation)	1.09 mg/L [e]
NOEC (reproduction)	0.51 mg/L [e]

[e] At 14 d, based on mean measured concentrations

Remarks - Results	All validation criteria for the study were satisfied.

CONCLUSION The test substance and, by inference, the notified chemicals are considered to be harmful to aquatic invertebrates with long lasting effects

TEST FACILITY Exempt Information

A.2.5. Algal growth inhibition test

TEST SUBSTANCE Analogue Chemical 4

METHOD OECD TG 201 Alga, Growth Inhibition Test - Static

Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 0.0, 0.7, 1.3, 2.7, 5.3 and 10.6 mg/L Actual: < 0.04, 1.13, 1.70, 2.66, 5.22 and 9.39 mg/L
Auxiliary Solvent	None
Water Hardness	Unknown
Analytical Monitoring	GC/MS
Remarks - Method	The analysis of this study is based on summary information presented in a reliable internationally peer reviewed data set for an analogue of the notified chemicals.

RESULTS

Biomass		*Growth*	
E_rC_{50} mg/L	*NOEC mg/L*	*E_rC_{50} mg/L at 96 h*	*NOEC mg/L at 96 h*
Not determined	Not determined	2.13	1.70

Remarks - Results	The increase in the mean algal biomass in the inoculum control within 72 hours was a factor of 7.4, which is less than the minimum 16 fold factor required by the test guideline. The lower than expected growth rate was thought to be due to the use of vessels which did not allow air exchange or introduction of ambient CO_2, which are both essential for algal propagation. Based on the dose response of algal growth inhibition this study was considered valid.
CONCLUSION	The test substance and, by inference, the notified chemicals are toxic to algae.
TEST FACILITY	Exempt Information

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