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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylate Ester Sartomer CD-595

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
STD/1399	Hewlett Packard Australia Pty Ltd and International Sales & Marketing Pty Ltd	Acrylate Ester Sartomer CD-595	Yes	≤ 10 tonnes per annum	An additive in UV/EB (ultra violet)/(electron beam) cured ink products (< 30%)

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the analogue data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
Xi; R36/38: Irritating to eyes and skin.
R43: May cause sensitisation by skin contact.

and

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. The environmental classification under this system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Eye irritation	2	Causes eye irritation
Skin irritation	2	Causes skin irritation
Skin sensitisation	1A	May cause sensitisation by skin contact
Environment	Acute 1	Very toxic to aquatic life
	Chronic 1	Very toxic to aquatic life with long lasting effects

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

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

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R36/38: Irritating to eyes and skin

- R43: May cause sensitisation by skin contact.

- The following risk phrases are recommended in the workplace on products/mixtures containing the notified chemicals:
  - Concentration ≥ 20% : R36/R38, R43
  - ≥1% Concentration < 20% : R43

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

Health Surveillance

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

Material Safety Data Sheet

- The MSDS provided by the notifier should be amended as follows:
  - In section 2 of the MSDS for workers, a full chemical name and CD-595 must be included for the chemical, as well as the classification of R36/R38, R43;
  - In section 2 of the sanitised MSDS, "Acrylate Ester Sartomer CD-595" should be used as the name for the chemical.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Local exhaust ventilation should be in place during all operations involving handling of the notified chemical.
  - Use of closed processes where possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.
  - Do not generate aerosols.
  - Clean up any spills or soiled personal protective equipment promptly.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during handling of ink products containing the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residuals and servicing the printing machine:
  - Gloves
  - Safety glasses
  - Protective clothing
  - Respiratory protection for any process where aerosols are generated

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an additive in UV/EB (ultra violet)/(electron beam) cured ink products (< 30%), or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 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 MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd (ABN 74 004 394 763)
353 Burwood Highway,
Forest Hill, VIC 3131

and

International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
260-262 Highett Road
Highett, VIC 3190

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, spectral data, purity, identity and % weight of impurities and additives/adjuvants, identity of manufacturer, and details of use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
PHYSICAL CHEMICAL PROPERTIES
Melting Point, Boiling Point, Density, Vapour Pressure, Water Solubility, Partition Coefficient, Dissociation Constant, Flash Point, Autoignition Temperature and Flammability Limits.
TOXICITY
Acute Oral toxicity, Acute Dermal Toxicity, Skin Irritation, Eye Irritation, Skin Sensitisation, Repeated Dose Toxicity, Induction of Point Mutations, Induction of Germ Cell Damage and Chromosome Damage.
ECOTOXICITY
Fish, Acute Toxicity; Daphnia sp., Acute Immobilisation/Reproduction; Algal growth inhibition; Bioaccumulation and Biodegradation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sartomer CD-595 (acrylate ester)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, IR and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Melting Point	10.62°C	Estimated (mean of several estimate methods)
Boiling Point	320°C (pressure unknown)	Estimated (Adapted Stein & Brown Method)
Density	980 kg/m^3 at 20°C	MSDS
Vapour Pressure	8.9×10^{-5} kPa at 25°C	Estimated (Modified Grain Method)
Water Solubility	2.605×10^{-3} g/L	Calculated (WSKOW v1.41, US EPA 2009)
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality. However, due to the expected low solubility of the notified chemical, significant hydrolysis is not expected at environmental pH (4-9).
Partition Coefficient (n-octanol/water)	log Kow = 5.04	Calculated (KOWWIN v1.67; US EPA 2009)
Adsorption/Desorption	log K_{oc} = 3.58, 3.06	Calculated (KOCWIN v2.00; US EPA 2009). The two values were calculated by the Kow and MCI methods respectively.
Dissociation Constant	Not determined	No dissociable functionality

Particle Size	Not determined	Liquid
Flash Point	> 100ºC (Setaflash closed cup)	MSDS
Flammability Limits	-	Not tested
Autoignition Temperature	Does not self ignite	Statement provided by the notifier.
Explosive Properties	Not expected to be explosive	Based on structural information and the lack of structural alerts

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is only stable under normal conditions of storage and with use of a stabiliser.

Storing inks containing the notified chemical at high temperatures and exposure to ultraviolet radiation or oxidising/reducing agents may cause spontaneous polymerisation, generating heat/pressure.

Dangerous Goods classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical as a component of finished ink products at a concentration of up to 30% will be imported in 10 kg plastic buckets (flexographic inks) and 5 kg bottles (ink-jet inks).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1	< 7	< 8	< 10	< 10

PORT OF ENTRY

Sydney or Melbourne

TRANSPORTATION AND PACKAGING

The notified chemical as a component of finished ink products (< 30%) will be transported in 10 kg plastic buckets (flexographic inks) and 5 kg bottles (ink-jet inks) from port of entry to notifiers' warehouse facilities.

USE

The notified chemical is used as an ingredient in UV/EB (ultra violet/electron beam) cured ink products. Ink jet inks (digital printing) are used to print large format images on vinyl, canvas, paper, mesh vinyl, shade cloth and a variety of other substrates, whereas flexographic (offset printing) inks are used for a wide variety of substrates, including packaging materials, labels, envelopes and stickers, flexible films, newspapers and other publications.

OPERATION DESCRIPTION

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

The ink buckets or bottles will be manually connected to the printing machines via an inlet and attached to a flexible tube which supplies the ink head. Ink will be automatically injected into printing machines.

While printers are running, printer operators monitor the operation, keep the substrate feeders stocked, attend to substrate jams, and carry out the quality control work as required.

After printing, the notified chemical will be fixed (UV/EB-cured) with other ink ingredients into the substrate matrix.

Any residual ink within printing equipment will be wiped clean using rags and solvents. Printer operators wear gloves during these tasks. Rags and dirty solvents are normally disposed of by the printing company through

licensed waste disposal contractors.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storages	10-20	4-8	50
Quality control/chemists and technical service	6	0.5-6	25 (max)
Printer operators	> 1000	1-2	25 (max)
Service technicians	200	8	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.

The most likely route of exposure of service technicians is dermal as they will come in contact with the notified chemical during printer 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.

Printer operators will have limited exposure to the notified chemical, as the process is mainly automated. Dermal and ocular exposure is possible during the replacement of ink buckets or bottles (manual process) and cleaning residual ink from printers. Inhalation exposure will be limited due to the low vapour pressure of the notified chemical and because of local exhaust ventilation employed in areas surrounding printing machines.

After application to the substrate, the ink containing the notified chemical is UV/EB-cured (chemically reacted) and hence the notified chemical will not be bioavailable.

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

6.2. Human Health Effects Assessment

No toxicity or toxicokinetic data were submitted for the notified chemical. Toxicity information on one analogue chemical was submitted.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue chemical	LD50 = 5000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	Analogue chemical	LD50 = 3600 mg/kg bw; low toxicity

Toxicokinetics, metabolism and distribution
Measured data on water solubility and partition coefficient for the notified chemical are unavailable, however modeled estimates were obtained. Based on these estimates, the notified chemical has a reasonably high lipophilicity, and hence percutaneous absorption would be limited. In addition, the acrylate group may bind to skin components and slow the absorption. However, the irritating effects of the notified chemical may increase dermal absorption. 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 rapidly metabolised and eliminated, therefore, will not likely cause cumulative toxicity (Patty's Toxicology 2001).

Acute toxicity

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

Irritation and sensitisation
The analogue chemical is classified with risk phrases R36/R38 (irritating to eyes and skin). Multifunctional acrylates (MFAs) including diacrylates were considered to be skin and eye contact hazards following single or repeated exposures (Andrews & Clary 1986). Skin irritation results varied with MFA tested, time of observation, and also as to whether single or repeated applications were made.

The analogue chemical is classified with risk phrase R43 (may cause sensitisation by skin contact). Skin sensitisation was produced in guinea pigs with mono-, di-, and tri- acrylate compounds, including the analogue chemical (Parker and Turk 1983).

Observations on human exposure
A case of sensitisation after a single occupational exposure to the analogue chemical was reported in an employee in a plastic paint factory (Contact Dermatitis; 1992).

Two cases of workers in the printing industry who developed allergic contact dermatitis to the analogue chemical within a short period of exposure were reported (Australas J Dermatol, 2000). The first developed within weeks of exposure to a plastic sheet primed with the analogue chemical. The second developed after a single accidental exposure.

Topical contact with the analogue chemical may cause delayed irritant dermatitis. During a 4 year observation of 20 workers, contact sensitisation did not occur (Contact Dermatitis; 1979).

Repeated dose toxicity
Detailed information is not available. A National Toxicological Program summary includes a report 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 (Patty's Toxicology 2001).

Toxicity for reproduction
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 tetratogenic at a clearly maternally toxic dose (Andrews & Clary 1986).

Mutagenicity
Multi-functional acrylates, including the analogue chemical, gave positive results in the in vitro mouse lymphoma forward mutation assay, whereas they were negative in the Ames test and yeast D_4 assay (Andrews & Clary 1986). The response in the mouse lymphoma assay for several MFAs (including the analogue chemical) was quite weak (only a doubling or tripling of background was achieved) and was only observed at relatively low cell survival rates. The limited data does not raise a strong suspicion of genotoxicity for the notified chemical, however this cannot be ruled out.

Health hazard classification
Based on the data provided for the analogue chemical, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
Xi; R36/38: Irritating to eyes 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 not been tested for any toxicological properties, however based on analogue data it is likely to be a skin and eye irritant and a skin sensitiser.

Workers most at risk will be those handling ink products containing up to 30% of the notified chemical, particularly during manual replacement of ink containers, cleaning of ink residues and servicing the printing machine.

In order to mitigate the irritation and sensitisation risk the use of impervious gloves and protective clothing would be required during any manual handling processes where dermal exposure is likely. The use of automated equipment, closed processes and local exhaust ventilation during any process that could generate aerosols would reduce the risk to workers.

The risk to workers handling printed material is considered to be negligible as the notified chemical will be reacted and cured onto the print matrix and will not be bioavailable.

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

6.3.2. Public Health

The inks containing the notified chemical at up to 30% will not be sold to the public. The public may have contact with the dried printed materials, however the notified chemical will be reacted and cured and will not be bioavailable. Therefore, exposure of the public to the notified chemical is not expected, and the risk is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of industrial printing inks. As manufacturing and reformulation will take place overseas, no release of the notified chemical will occur in Australia from these activities. The potential release of inks containing the notified chemical from transport is estimated to be ≤ 1% of total imported volume of ink. 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 chemical 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 chemical is UV-cured (chemically reacted) and the resultant chemical is expected to be stable within an inert matrix on printed substrate once it is cured. A maximum of 2% of ink was estimated by the notifier to be released to sewer from equipment washing. 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 vinyl, canvas and shade cloth 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 10%) will be used for paper printing. Of the 10% 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.

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 fate study provided for an analogue of the notified chemical indicated that the analogue is readily biodegradable. The analogue chemical is considered to be acceptable with respect to biodegradation as it has the same functional groups as the notified chemical and only differs in carbon chain length. Therefore the notified chemical is likely to be rapidly degradable and is not expected to persist in the environment.

Approximately half of the paper to which the ink containing the notified chemical is applied to 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 predicted bioconcentration factor (BCF) for the notified chemical is 41.69 L/kg wet-wt (BCFBAF (v3.00); US EPA 2009) indicating it does not have a potential for bioaccumulation.

For the details of the environmental fate study please refer to Appendix A.

7.1.3. Predicted Environmental Concentration (PEC)

Predicted Environmental Concentrations (PECs) for ocean and river have been calculated assuming that 2% of notified chemical will reach the aquatic compartment due to equipment washing. Based on Simple Treat (EC, 2003) calculations it was assumed that 82% of the notified chemical would be removed from effluent in sewage treatment plants (STPs) due to partitioning to sludge (51%) and ready biodegradation (31%). 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	10,000	kg/year
Proportion expected to be released to sewer	2%	
Annual quantity of chemical released to sewer	200	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	0.77	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	82%	
Daily effluent production	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.033	µg/L
PEC - Ocean	0.0033	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 0.927 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 0.006 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 0.03 mg/kg and 0.06 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 0.033 µg/L may potentially result in a soil concentration of approximately 0.218 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 1.09 µg/kg and 2.18 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the analogue chemical which contains the same reactive functional groups as the notified chemical are summarised in the table below. Details of the acute toxicity studies submitted by the notifier can be found in Appendix A. The chronic ecotoxicity endpoints for the analogue were obtained from the OECD Toolbox (OECD, 2011).

The analogue chemical nominated by the notifier has significantly different physico-chemical properties to the notified chemical, with a log Kow of 2.81 and water solubility of 360 mg/L compared to a log Kow of 5.04 and water solubility of 2.6 mg/L calculated 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 2009) 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 several other analogues provided by the notifier were 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.

As the notified chemical belongs to a group of chemicals that have a demonstrated chronic toxicity to aquatic organisms, endpoints were calculated by ECOSAR and used to provide representative chronic endpoints in the absence of measured data on the notified chemical. 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) 4.6 – 10 mg/L	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 2.59 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	E_rC50 (72 h) = 1.383 mg/L	Toxic to algae
Inhibition of Bacterial Respiration	EC50 (0.5 h) = 270 mg/L	Not inhibitory to bacterial respiration
Chronic – Analogue data		
Fish Toxicity	NOEC (30 d) = 0.072 mg/L	Toxic to fish with long lasting effects
Daphnia Toxicity	NOEC (21 d) = 0.14 mg/L	Harmful to invertebrates with long lasting effects
Algal Toxicity	NOEC (72 h) = 0.27 mg/L	Harmful to algae with long lasting effects
ECOSAR (v1.00) data for the notified chemical		

Acute		
Fish Toxicity	LC50 (96 h) = 0.737 mg/L	Very toxic to fish
Daphnia Toxicity	EC50 (48 h) = 1.125 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 1.106 mg /L	Toxic to algae
Chronic		
Fish Toxicity	ChV (30 d) = 0.006 mg/L	Very toxic to fish with long lasting effects
Daphnia Toxicity	ChV = 0.016 mg/L	Potentially toxic to aquatic invertebrates with long lasting effects
Algal Toxicity	ChV = 0.160 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 very toxic to fish, and toxic to aquatic invertebrates and algae. Based on the predicted acute toxicity to fish 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 = $(LOEC \times NOEC)^{½}$], 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 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 < 0.006 mg/L) and expected rapid degradability, 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 = $(LOEC \times NOEC)^{½}$) 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)	0.006	mg/L
Assessment Factor	50	
PNEC:	0.12	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.033	0.12	0.273
Q - Ocean	0.0033	0.12	0.027

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: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE: The analogue chemical (purity 93.7%)

METHOD: ISO 14593: 1999 Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium - Method by analysis of inorganic carbon in sealed vessels (CO_2 headspace test).

Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	TOC analyser
Remarks - Method	The test was conducted for 28 days in accordance with the above guidelines. The definitive test was carried out with test substance at 20 mg TOC/L. The test substance was added to a liquid medium inoculated with sewage microorganisms (4 mg/L dry substance) and aerated at approximately 22°C. CO_2 production was analysed. A reference (aniline), and toxicity control were run in parallel.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
3	3	3	39
7	45	7	57
10	57	10	67
14	69	14	76
28	69	28	80

Remarks - Results: All validity criteria were satisfied. The reference compound reached the 60% pass level by day 14 indicating the suitability of the inoculum. The toxicity control attained 76% degradation after 14 days indicating the notified chemical is not toxic to the inoculum. Since biodegradation reached the pass level of > 60% CO_2 production within the 10 day window, it can be classed as readily biodegradable.

CONCLUSION: The test substance is readily biodegradable

TEST FACILITY: BASF (2004)

A.2.1. Acute toxicity to fish

TEST SUBSTANCE: The analogue chemical (purity > 85%)

METHOD: DIN 38 412 (1982) – Static

Species	*Leuciscus idus* (golden orfe)
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	2.5 mmol/L
Analytical Monitoring	None reported
Remarks – Method	Only a summary report was provided.

Test water was prepared from fully demineralised tap water with the following salts added; $CaCl.2H_2O$ (294.0 mg/L), $MgSO_4.7H_2O$ (123.3

mg/L), $NaHCO_3$ (63.0 mg/L) and KCl (5.5 mg/L). The water was continuously aerated with oil free air. The loading was 2.7 g fish/L.

Following two range finding tests, a definitive test was conducted at with concentrations 0.464 – 21.50 mg/L under static conditions for a period of 96 h. Test conditions were: 20-21°C, pH 7.3 – 7.7, 8.0 – 8.7 O_2 mg/L, 8 hours dark and 16 hours light period. The LC50 was calculated using probit analysis.

RESULTS

		Mortality					
Nominal Concentration mg/L	*Number of Fish*	*1 h*	*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0	0
0.464	10	0	0	0	0	0	0
1.000	10	0	0	0	0	0	0
2.150	10	0	0	0	0	0	0
4.640	10	0	0	0	0	0	0
10.00	10	0	0	10	10	10	10
21.50	10	0	0	10	10	10	10

LC50	4.6 – 10 mg/L at 96 hours (based on nominal concentrations)
NOEC	4.64 mg/L at 96 hours (based on nominal concentrations)
Remarks – Results	No undissolved test substance was observed and no abnormalities were observed in live fish.

CONCLUSION The test substance is toxic to fish

TEST FACILITY BASF (1989)

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE The analogue chemical (purity ca. 90%)

METHOD Guideline for testing of chemicals EG-1 of Jan 1982 (EPA Office of Toxic Substances) - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	dimethylsulfoxide
Water Hardness	2.6 mmol/L
Analytical Monitoring	None reported
Remarks - Method	Only a summary report was provided.

The test substance and dimethylsulfoxide (dispersing agent) were added to the dilution water at 50 and 100 mg/L respectively. The stock suspension was stirred for 17 hours at 25°C. Serial dilution was used to prepare the test solutions.

A definitive test was conducted with test substance concentration 0.098 – 3.13 mg/L. Test conditions were: 19.8°C, pH 7.9–8.2, 7.5–9.0 mg O_2/L, 8 hours dark and 16 hours light period. The EC50 after 48 hours was determined by the Spearman-Karber method.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Number Immobilised* 3 h	6 h	24 h	48 h
Control	4 × 5	0	0	0	0
0.098	4 × 5	0	0	0	0
0.39	4 × 5	0	0	0	0
0.78	4 × 5	0	0	0	0
1.56	4 × 5	0	0	0	3
3.13	4 × 5	0	0	3	14
6.25	4 × 5	0	0	4	19
12.5	4 × 5	0	0	18	20
25	4 × 5	0	0	20	20
50	4 × 5	3	9	20	20

EC50 2.59 mg/L at 48 hours (95% CI = 2.13 – 3.14 mg/L; based on nominal concentrations)

EC0 0.78 mg/L at 48 hours (based on nominal concentrations)

Remarks - Results No remarks. Only a summary report was provided.

CONCLUSION The test substance is toxic to aquatic invertebrates

TEST FACILITY BASF (1988)

A.2.3. Algal growth inhibition test

TEST SUBSTANCE The analogue chemical

METHOD Inhibition of the algae cell multiplication according to DIN 38412 L9 understood to be equivalent to OECD TG 201

Species *Scenedesmus subspicatus*

Exposure Period 96 hours

Concentration Range Nominal: 0.0, 0.5, 1.0, 2.5, 10 and 25 mg/L
Actual: Not reported

Auxiliary Solvent None

Water Hardness Unknown

Analytical Monitoring None reported

Remarks - Method Only a translated summary report was provided. Following a range finding test, a definitive test at 0.5 - 25 mg/L was conducted in accordance with the guidelines above. A solvent control and toxicity control (potassium dichromate) were run in parallel.

RESULTS

E_rC_{50} *mg/L at 96 h*	E_rC_0 *mg/L at 96 h*	E_bC_{50} *mg/L at 96 h*	E_bC_0 *mg/L at 96 h*
1.383	< 0.50	0.829	< 0.50

Remarks - Results No remarks. Only a translated summary report was provided.

CONCLUSION The test substance is toxic to algae.

TEST FACILITY Dr. U. Noack-Laboratorium (1989)

A.2.4. Inhibition of microbial activity

TEST SUBSTANCE The analogue chemical (purity 95%)

METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sewage sludge
Exposure Period	30 minutes
Concentration Range	Nominal: 16 - 1000 mg/L
Remarks – Method	No deviations to the test protocol were reported.
RESULTS	
IC50	270 mg/L
NOEC	Not reported
Remarks – Results	A definitive test was conducted according to the guidelines above at test substance concentrations of 16 - 1000 mg/L. A blank control and reference (3,5-dichlorophenol) control were run in parallel. The rate of respiration was determined after 0.5 h contact time and compared to the results from the control and reference material. Test conditions: approximately 20°C, pH 6.5-6.7.
CONCLUSION	The test substance is not expected to inhibit microbial respiration.
TEST FACILITY	BASF (1998)

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